

Official Journal of the European Union

L 162



English edition

Legislation

Volume 66

28 June 2023

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1308

of 21 June 2023

entering a name in the register of protected designations of origin and protected geographical indications ('Novigradska dagnja' (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Croatia's application to register the name 'Novigradska dagnja' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Novigradska dagnja' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Novigradska dagnja' (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.

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 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 80, 3.3.2023, p. 84.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

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

Done at Brussels, 21 June 2023.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

COMMISSION DELEGATED REGULATION (EU) 2023/1309**of 26 April 2023****amending Delegated Regulation (EU) 2022/127 as regards transitional rules and correcting that Regulation as regards certain provisions for the EAGF and the EAFRD**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/2116 of the European Parliament and of the Council of 2 December 2021 on the financing, management and monitoring of the common agricultural policy and repealing Regulation (EU) No 1306/2013 ⁽¹⁾, and in particular Article 38(2), Article 47(1), Article 55(6), Article 76(2), Article 94(5) and (6) and Article 105 thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2022/127 ⁽²⁾ supplements Regulation (EU) 2021/2116 with rules on paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro.
- (2) Title IV, Chapter III, of Regulation (EU) 2021/2116 provides for the scrutiny of the transactions of those entities receiving or making payments relating directly or indirectly to the system of financing by the European Agricultural Guarantee Fund (EAGF), in order to ascertain whether transactions forming part of the system of financing by the EAGF have actually been carried out and have been executed correctly. Measures that are by their nature unsuited to *ex post* control by way of scrutiny checks of commercial documents, as well as measures that are concerned with payments that are either area-related or unrelated to commercial documents that can be subject to scrutiny should be excluded from the scope of scrutiny of transactions. Pursuant to Article 46 of Commission Implementing Regulation (EU) 2022/128 ⁽³⁾, which lays down that the scrutiny of transactions covers the EAGF financial year preceding the beginning of the period of scrutiny, which runs each year from 1 July to 30 June of the following year, the scrutiny of transactions covers transactions from before the entry into application of Regulation (EU) 2021/2116. In order to ensure a smooth transition from the arrangements provided for in Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽⁴⁾, it is appropriate to provide for transitional rules excluding from the scope of scrutiny of transactions those measures previously exempted by Commission Delegated Regulation (EU) No 907/2014 ⁽⁵⁾. Since those measures have never been suited for scrutiny of transactions control, this amendment should apply retroactively from 1 January 2023, the date of application of Delegated Regulation (EU) 2022/127.
- (3) Delegated Regulation (EU) 2022/127 repealed Delegated Regulation (EU) No 907/2014 with effect from 1 January 2023. However, Article 40, second paragraph, of Delegated Regulation (EU) 2022/127 which lists the provisions of Delegated Regulation (EU) No 907/2014 which continue to apply, did not take into account that certain provisions need to continue to apply in relation to the expenditure incurred and payments made for support schemes under

⁽¹⁾ OJ L 435, 6.12.2021, p. 187.

⁽²⁾ Commission Delegated Regulation (EU) 2022/127 of 7 December 2021 supplementing Regulation (EU) 2021/2116 of the European Parliament and of the Council with rules on paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro (OJ L 20, 31.1.2022, p. 95).

⁽³⁾ Commission Implementing Regulation (EU) 2022/128 of 21 December 2021 laying down rules for the application of Regulation (EU) 2021/2116 of the European Parliament and of the Council on paying agencies and other bodies, financial management, clearance of accounts, checks, securities and transparency (OJ L 20, 31.1.2022, p. 131).

⁽⁴⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

⁽⁵⁾ Commission Delegated Regulation (EU) No 907/2014 of 11 March 2014 supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro (OJ L 255, 28.8.2014, p. 18).

Regulation (EU) No 1307/2013 of the European Parliament and of the Council ⁽⁶⁾ up to and including the calendar year 2022, to measures implemented under Regulations of the European Parliament and of the Council (EU) No 228/2013 ⁽⁷⁾, (EU) No 229/2013 ⁽⁸⁾, (EU) No 1308/2013 ⁽⁹⁾ and (EU) No 1144/2014 ⁽¹⁰⁾ until 31 December 2022, in relation to expenditure incurred and payments made for operations implemented pursuant to Regulation (EU) No 1308/2013 after 31 December 2022 and until the end of those aid schemes, and as regards the implementation of rural development programmes pursuant to Regulation (EU) No 1305/2013 of the European Parliament and of the Council ⁽¹¹⁾. This created a legal gap. Article 40, second paragraph, of Delegated Regulation (EU) 2022/127 should therefore be corrected by adding the provisions concerned to the list. This correction should apply retroactively from 1 January 2023, the date of application of Delegated Regulation (EU) 2022/127.

- (4) Delegated Regulation (EU) 2022/127 should therefore be amended and corrected accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Delegated Regulation (EU) 2022/127

Article 39 of Delegated Regulation (EU) 2022/127 is replaced by the following:

'Article 39

Transitional provisions

1. Where a paying agency, accredited in accordance with Regulation (EU) No 1306/2013, assumes responsibility for expenditure for which it was not previously responsible, it shall be accredited with the new responsibilities before 1 January 2023.
2. The measures listed in Annex VI to Delegated Regulation (EU) No 907/2014 shall not be subject to the system of scrutiny established by Title IV, Chapter III, of Regulation (EU) 2021/2116¹.

Article 2

Correction to Delegated Regulation (EU) 2022/127

In Article 40, second paragraph, of Delegated Regulation (EU) 2022/127, point (a) is replaced by the following:

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- ⁽⁶⁾ Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).
- ⁽⁷⁾ Regulation (EU) No 228/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 (OJ L 78, 20.3.2013, p. 23).
- ⁽⁸⁾ Regulation (EU) No 229/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in favour of the smaller Aegean islands and repealing Council Regulation (EC) No 1405/2006 (OJ L 78, 20.3.2013, p. 41).
- ⁽⁹⁾ 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).
- ⁽¹⁰⁾ Regulation (EU) No 1144/2014 of the European Parliament and of the Council of 22 October 2014 on information provision and promotion measures concerning agricultural products implemented in the internal market and in third countries and repealing Council Regulation (EC) No 3/2008 (OJ L 317, 4.11.2014, p. 56).
- ⁽¹¹⁾ Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

- (a) Article 5, 5a, Article 7(3) and (4), Article 10, Article 11(1), second subparagraph, Article 11(2), Article 12, Article 13 and Article 41(5) of that Delegated Regulation shall continue to apply:
- (i) in relation to expenditure incurred and payments made for support schemes under Regulation (EU) No 1307/2013 of the European Parliament and of the Council (*) in respect of the calendar year 2022 and before;
 - (ii) for measures implemented until 31 December 2022 under Regulations (EU) No 228/2013, (EU) No 229/2013, (EU) No 1308/2013 and (EU) No 1144/2014;
 - (iii) for the aid schemes referred to in Article 5(6), first subparagraph, point (c), and Article 5(7) of Regulation (EU) 2021/2117 of the European Parliament and of the Council (**) in relation to expenditure incurred and payments made for operations implemented pursuant to Regulation (EU) No 1308/2013 after 31 December 2022 and until the end of those aid schemes; and
 - (iv) as regards the EAFRD, in relation to expenditure incurred by the beneficiaries and payments made by the paying agency in the framework of the implementation of rural development programmes pursuant to Regulation (EU) No 1305/2013.

(*) Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

(**) Regulation (EU) 2021/2117 of the European Parliament and of the Council of 2 December 2021 amending Regulations (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products, (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, (EU) No 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union (OJ L 435, 6.12.2021, p. 262).

Article 3

Entry into force and application

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

It shall apply from 1 January 2023.

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

Done at Brussels, 26 April 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1310**of 27 June 2023****establishing a derogation from Implementing Regulation (EU) 2019/2072 concerning the introduction into the Union territory of naturally or artificially dwarfed plants for planting of *Chamaecyparis* Spach, *Juniperus* L. and certain species of *Pinus* L., originating in the Republic of Korea**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ⁽¹⁾, and in particular Articles 40(2) and 41(2) thereof,

Whereas:

- (1) Commission Decision 2002/499/EC ⁽²⁾ authorised the Member States to provide for derogations from Article 4(1) of Council Directive 2000/29/EC ⁽³⁾, with regard to the prohibitions referred to in point 1 of Part A of Annex III to that Directive, for introduction into the Union territory of naturally or artificially dwarfed plants of *Chamaecyparis* Spach, *Juniperus* L. and *Pinus* L., other than fruit and seeds, originating in the Republic of Korea.
- (2) On 17 January 2019, the Republic of Korea submitted a request for extension of the period of application of Decision 2002/499/EC, but that extension was not granted before the expiry of that Decision on 31 December 2020.
- (3) Regulation (EU) 2016/2031 has replaced Directive 2000/29/EC, while Commission Implementing Regulation (EU) 2019/2072 ⁽⁴⁾ has replaced Annexes I to V to that Directive.
- (4) Implementing Regulation (EU) 2019/2072 establishes a list of plants, plant products and other objects whose introduction into the Union territory from certain third countries is prohibited. In accordance with point 1 of Annex VI to that Regulation, the introduction into the Union territory of plants for planting of *Chamaecyparis* Spach, *Juniperus* L. and *Pinus* L., other than fruit and seeds is prohibited.
- (5) Until 31 December 2020, the introduction of the specified plants into the Union, subject to the requirements of Decision 2002/499/EC, as effectively applied by the Republic of Korea, has presented no phytosanitary risk for the Union territory. Moreover, since the date of application of that Decision, no scientific or technical evidence has indicated the emergence of any new risk with regard to those plants. Therefore that derogation should be granted again.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ Commission Decision 2002/499/EC of 26 June 2002 authorising derogations from certain provisions of Council Directive 2000/29/EC in respect of naturally or artificially dwarfed plants of *Chamaecyparis* Spach, *Juniperus* L. and *Pinus* L., originating in the Republic of Korea (OJ L 168, 27.6.2002, p. 53).

⁽³⁾ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

- (6) The derogation should be subject to the same requirements as those that were set out in Decision 2002/499/EC. Those requirements should apply without prejudice to point 30 of Annex VII to Implementing Regulation (EU) 2019/2072, concerning the introduction into the Union territory of naturally or artificially dwarfed plants for planting other than seeds.
- (7) At the same time, the list of the pests of concern should be updated in relation to the corresponding list of Decision 2002/499/EC in order to reflect recent new scientific information.
- (8) Several of the pests hosted by the specified plants, and in particular the pests *Coleosporium paederiae* Dietel ex Hirats. f., *Crisicoccus pini* (Kuwana), *Dendrolimus spectabilis* (Butler), *Dendrolimus superans* Butler, and *Thecodiplosis japonensis* Uchida & Inouye are not yet listed as Union quarantine pests, because their phytosanitary risk has not been fully assessed. Therefore, as this Regulation addresses a particular phytosanitary risk, which is not yet fully assessed, the requirements it provides are to have a temporary character pursuant to Article 7 of Implementing Regulation (EU) 2019/2072.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'specified plants' means naturally or artificially dwarfed plants for planting, originating in the Republic of Korea, of the following species:
 - (a) *Chamaecyparis* sp. Spach;
 - (b) *Juniperus* sp. L.;
 - (c) *Pinus parviflora* Sieb. & Zucc. (*Pinus pentaphylla* Mayr);
 - (d) *Pinus parviflora* Sieb. & Zucc., grafted on a rootstock of another *Pinus* species, originating in the Republic of Korea;
- (2) 'pest of concern' means:
 - (a) for all specified plants: any Union quarantine pest, protected zone quarantine pest or pest subject to the measures referred to in Article 30 of Regulation (EU) 2016/2031 which is not known to occur in the Union;
 - (b) for *Pinus parviflora* Sieb. & Zucc. (*Pinus pentaphylla* Mayr) plants, the pests referred to in point (a) and any of the following pests:
 - (i) *Coleosporium paederiae* Dietel ex Hirats. f.;
 - (ii) *Crisicoccus pini* (Kuwana);
 - (iii) *Dendrolimus spectabilis* (Butler);
 - (iv) *Dendrolimus superans* Butler;
 - (v) *Thecodiplosis japonensis* Uchida & Inouye.

*Article 2***Derogation from the prohibition to introduce the specified plants into the Union territory**

1. By way of derogation from point 1 of Annex VI to Implementing Regulation (EU) 2019/2072, the introduction into the Union territory of the specified plants shall be allowed subject to compliance with the requirements set out in the Annex to this Regulation.
2. Paragraph 1 shall apply to the specified plants introduced into the Union territory in the following periods:
 - (a) for *Chamaecyparis*: from 1 July 2023 to 31 December 2028;
 - (b) for *Juniperus*: from 1 November to 31 March of each year until 31 December 2028;
 - (c) for *Pinus parviflora* Sieb. & Zucc. (*Pinus pentaphylla* Mayr) and *Pinus parviflora* Sieb. & Zucc., grafted on a rootstock of another *Pinus* species, originating in the Republic of Korea: from 1 July 2023 to 31 December 2028.

*Article 3***Confirmed presence of a pest of concern during or following the post-entry detention period**

Member States shall notify the Commission and the other Member States of any pest of concern, the presence of which has been confirmed during or following the post-entry detention period referred to in point 9 of the Annex.

In such case, all specified plants originating from the nursery from which the infected/infested specified plant originated shall not be allowed to be introduced into the Union territory, until the renewal of nursery registration referred to in point 11 of the Annex.

*Article 4***Entry into force and period of application**

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

It shall apply until 31 December 2028.

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

Done at Brussels, 27 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Requirements for the introduction into the Union territory of the specified plants as referred to in Article 2

1. In the case where the specified plants are *Pinus parviflora* Sieb. & Zucc., grafted on a rootstock of another *Pinus* species, the rootstock shall not bear any shoots.
2. The total number of the specified plants imported shall not exceed the quantities that have been determined for each year and notified to the Commission and the other Member States by the importing Member State, having regard to the available confinement facilities or quarantine stations.
3. Prior to export to the Union, the specified plants shall have been grown, held and trained for at least two consecutive years in authorised nurseries, which are subject to a control regime by the National Plant Protection Organisation of the Republic of Korea ('NPPO') and specifically authorised for the purpose of export to the Union. The annual lists of the officially authorised nurseries shall be made available to the Commission, by 30 September of each year. Those lists shall include the number of plants grown in each of these nurseries, as far as they are deemed suitable for introduction into the Union territory
4. In the case of *Juniperus* plants, the plants of the genera *Chaenomeles* Lindl., *Crataegus* L., *Cydonia* Mill., *Juniperus* L., *Malus* Mill., *Photinia* Ldl. and *Pyrus* L., which have been grown in the two last years prior to import in the authorised nurseries mentioned in point 3 and in their immediate vicinity, shall have been officially inspected at least six times a year at appropriate intervals for the presence of the pests of concern for the respective plants. In the case of *Chamaecyparis* and *Pinus* plants, the plants of the genus *Chamaecyparis* Spach and of the genus *Pinus* L., which have been grown in those naturally or artificially dwarfed plants nurseries and in their immediate vicinity, shall have been officially inspected at least six times a year at appropriate intervals, for the presence of the respective pests of concern.
5. The specified plants shall have been found free, in those inspections, from the pests of concern.

Infested plants shall be removed by the NPPO, or the competent national bodies or professional operators under the official supervision of the NPPO. The remaining specified plants shall be effectively treated and held for an appropriate period and inspected to ensure freedom from those pests.

Any detection of pests of concern, during the inspections carried out pursuant to point 4, shall be officially recorded, and the records shall be made available to the Commission, upon request.

Any detection of any of those pests of concern shall disqualify the nursery from the list of authorised nurseries. The NPPO of the Republic of Korea shall inform immediately the Commission thereof and remove the nursery from the list of authorised nurseries, as referred to in point 3. The NPPO may only renew the registration of that nursery at the earliest in the following year.

6. The specified plants intended for export to the Union, shall at least during the period of two consecutive years referred to in point 3:
 - (a) be potted in pots which are placed either on shelves at least 50 cm above ground, or onto concrete flooring, impenetrable for nematodes, which is well maintained and free from debris;
 - (b) be found free, in the inspections referred to in point 4, from the pests of concern;
 - (c) be made recognisable with a marking or a traceability code, exclusive for each individual plant and notified to the NPPO, enabling the identification of the officially authorised nursery and the year of potting; and
 - (d) if they belong to the genus *Pinus* L. and in the case of grafting on a rootstock of a *Pinus* species other than *Pinus parviflora* Sieb. & Zucc., have a rootstock derived from sources officially approved as healthy material.

7. The specified plants shall be traceable from the time of their removal from the nursery until the time of loading for export, through sealing of transport vehicles or appropriate alternatives.
8. The specified plants and the adhering or associated growing medium ('the material') shall be accompanied by a phytosanitary certificate, issued by the NPPO, attesting compliance with the requirements specified in points 1 to 7 of this Annex, and in point 30 of Annex VII to Regulation (EU) 2019/2072.

The certificate shall indicate:

- (a) the name or the names of the authorised nursery or authorised nurseries;
 - (b) the markings or traceability codes referred to in point 6(c), as far as they enable identification of the authorised nursery and the year of potting;
 - (c) the specification of the last treatment applied, prior to dispatch;
 - (d) under 'Additional Declaration', the statement 'This consignment meets the requirements laid down in Regulation (EU) 2023/1310'.
9. Before the specified plants are released, they shall be subject to official post-entry detention in a confinement facility or quarantine station for a period of not less than three months of active growth.

In the case of *Juniperus* plants, the detention period shall cover the period from 1 April until 30 June.

The material shall also be found free, during and following that detention period, from any pests of concern. Particular attention shall be given by the competent authority or the professional operators to preserve the marking or traceability code, referred to in point 6(c) for each plant.

10. Any lot containing material which has not been found free from the pests of concern, during the post-entry detention period referred to in point 9, shall be immediately destroyed by the competent authority or the professional operator under the official supervision of the competent authority.
11. In such case, the relevant nursery in the Republic of Korea shall be removed by the NPPO from the list of the authorised nurseries, as referred to in point 3.

The NPPO may then only renew the registration of that nursery at the earliest in the following year.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1311**of 27 June 2023****granting a Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L (+) Lactic Acid' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 24 April 2019, CVAS Development GmbH submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for a Union authorisation of a biocidal product family named 'CVAS Biocidal Product Family based on L (+) Lactic Acid' of product-types 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Slovenia had agreed to evaluate the application. The application was recorded under case number BC-XR051157-11 in the Register for Biocidal Products.
- (2) 'CVAS Biocidal Product Family based on L (+) Lactic Acid' contains L-(+)-lactic acid as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 3 and 4.
- (3) On 7 January 2022, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 5 July 2022, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics ('SPC') of 'CVAS Biocidal Product Family based on L (+) Lactic Acid' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'CVAS Biocidal Product Family based on L (+) Lactic Acid' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 20 July 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'CVAS Biocidal Product Family based on L (+) Lactic Acid'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 15 June 2022 on the Union authorisation of 'CVAS Biocidal Product Family based on L (+) Lactic Acid' (ECHA/BPC/345/2022), <https://echa.europa.eu/opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0028957-0000 is hereby granted to CVAS Development GmbH for the making available on the market and use of the biocidal product family 'CVAS Biocidal Product Family based on L (+) Lactic Acid' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 18 July 2023 to 30 June 2033.

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, 27 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

CVAS Biocidal Product Family based on L(+) Lactic Acid

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0028957-0000

R4BP asset number: EU-0028957-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	CVAS Biocidal Product Family based on L(+) Lactic Acid
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1.2. Product type(s)

Product type(s)	PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	CVAS Development GmbH
	Address	Am Hafen 16, 68526 Ladenburg Germany
Authorisation number	EU-0028957-0000	
R4BP asset number	EU-0028957-0000	
Date of the authorisation	18.7.2023	
Expiry date of the authorisation	30.6.2033	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Am Hafen 16, 68526 Ladenburg Germany
Location of manufacturing sites	Am Hafen 16, 68526 Ladenburg Germany

Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstraße 1, 83115 Neubeuern Germany
Location of manufacturing sites	Pfaffensteinstraße 1, 83115 Neubeuern Germany

1.5. Manufacturer(s) of the active substance(s)

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkelsedijk 46, 4206AC Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46, 4206AC Gorinchem Netherlands

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	17,6
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	0,0	10,5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	18,75
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	0,0	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	0,0	2,5

2.2. Type(s) of formulation

Formulation(s)	AL - Any other liquid SL - Soluble concentrate
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PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	mSPC1
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1.2. **Suffix to the authorisation number**

Number	1-1
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1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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2. **META SPC 1 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	1,96

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation(s)	AL - Any other liquid
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	
Precautionary statements	

4. **AUTHORISED USE(S) OF THE META SPC 1**4.1. **Use description**

Table 1

Use # 1 – Use # 1.1 - Teat-disinfection post-milking by manual or automated dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data

Field(s) of use	Indoor Teat-disinfection post-milking
Application method(s)	Method: Dipping Detailed description: Teat-disinfection post-milking Manual dipping using a dip cup Automated dipping by robot
Application rate(s) and frequency	Application Rate: Ready-To-Use (RTU) product, 1,92-1,96% L-(+)-lactic acid Dilution (%): - Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	High density polyethylene (HDPE) jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE Intermediate Bulk Container (IBC): 600-1 000 kg

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1**

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

Apply the product by manual or automated dipping. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

5.2. Risk mitigation measures

None

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: if symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF SWALLOWED: if symptoms occur call a POISON CENTRE or a doctor.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like

sawdust. Dispose of the material collected in accordance with local regulations.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip Amadine Film		Market area: EU		
	AGRIMARKT MILCHSÄUREMANTEL		Market area: EU		
	IWETEC MILCHSÄURE DIPP		Market area: EU		
Authorisation number	EU-0028957-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es lac DL		Market area: EU		
	Traylac O-F		Market area: EU		
	Baktostop Lactic		Market area: EU		
	Lacti-Bac Dip		Market area: EU		
	DS 1.0 F		Market area: EU		
Authorisation number	EU-0028957-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip Blue Kamille Film		Market area: EU		
Authorisation number	EU-0028957-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es protect DL		Market area: EU		
	BaktoStop lactic H		Market area: EU		
	Dip Agro Protect		Market area: EU		
	Kuhmilin Dip Top M		Market area: EU		
	Lacti-Protect Dip		Market area: EU		
	DSR 1.5 F		Market area: EU		
	ProfiMix inSilk		Market area: EU		
Authorisation number	EU-0028957-0004 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	mSPC2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8	6,8

2.2. Type(s) of formulation of the meta SPC 2

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves. Wear eye protection. IF ON SKIN:Wash with plenty of water. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 2

Use # 1 – Use # 2.1 - Teat-disinfection post-milking by manual or automated dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	Indoor Teat-disinfection post-milking
Application method(s)	Method: Dipping Detailed description: Teat-disinfection post-milking Manual dipping using a dip cup Automated dipping by robot

Application rate(s) and frequency	Application Rate: RTU product, 6,80% L-(+)-lactic acid Dilution (%): - Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 2**

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. **Risk mitigation measures**

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent. See section 6 for the full titles of the EN standards.

Goggles, gloves and coverall material to be specified by the authorisation holder within the product information.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to this act.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected in accordance with local regulations.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

The full titles of EN standards mentioned in the section 5.2 'Risk mitigation measures' are:

EN ISO 16321– Eye and face protection for occupational users.

EN ISO 374 – Protective gloves against dangerous chemicals and micro-organisms.

The full reference of the legal act mentioned in the section 5.2 'Risk mitigation measures' is:

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip Amadine forte Film		Market area: EU		
Authorisation number	EU-0028957-0005 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es lac DLX		Market area: EU		
Authorisation number	EU-0028957-0006 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip Blue Kamille forte Film		Market area: EU		
Authorisation number	EU-0028957-0007 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es protect DLX	Market area: EU
Authorisation number	EU-0028957-0008 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

META SPC 3**1. META SPC 3 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 3 identifier**

Identifier	mSPC3
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. Product type(s)

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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2. META SPC 3 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	1,96

2.2. Type(s) of formulation of the meta SPC 3

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 3

Use # 1 – Use # 3.1 – Teat-disinfection post-milking by manual or automated dipping or spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	Indoor Teat-disinfection post-milking
Application method(s)	Method: Dipping Detailed description: Teat-disinfection post-milking Manual dipping using a dip cup Automated dipping by robot Method: Spraying Detailed description: Teat-disinfection post-milking Manual spraying using a trigger sprayer Manual spraying using an electronic sprayer Automated spraying by robot
Application rate(s) and frequency	Application Rate: RTU product, 1,92-1,96% L-(+)-lactic acid Dilution (%): - Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 3**

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

5.2. **Risk mitigation measures**

None

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

First aid instructions

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: if symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF SWALLOWED: if symptoms occur call a POISON CENTRE or a doctor.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected in accordance with local regulations.

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	calgodip Amadine Spray		Market area: EU		
	AGRIMARKT MILCHSÄURENEBEL		Market area: EU		
	IWETEC MILCHSÄURE SPRAY		Market area: EU		
Authorisation number	EU-0028957-0009 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es lac DL Spray		Market area: EU		
	Traylac O-S		Market area: EU		
	Lacti-Bac Spray		Market area: EU		
	DS 1.0 S		Market area: EU		
Authorisation number	EU-0028957-0010 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip Blue Kamille Spray		Market area: EU		
Authorisation number	EU-0028957-0011 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es protect DL Spray		Market area: EU		
	Dip Agro Protect SP		Market area: EU		
	Kuhmilin Sprüh Top M		Market area: EU		
	Lacti-Protect Spray		Market area: EU		
	DSR 1.5 S		Market area: EU		
Authorisation number	EU-0028957-0012 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

META SPC 4**1. META SPC 4 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 4 identifier**

Identifier	mSPC4
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1.2. Suffix to the authorisation number

Number	1-4
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1.3. Product type(s)

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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2. META SPC 4 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8	6,8

2.2. Type(s) of formulation of the meta SPC 4

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves. Wear eye protection. IF ON SKIN:Wash with plenty of water. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. Use description

Table 4

Use # 1 – Use # 4.1 - Teat-disinfection post-milking by manual or automated dipping or spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data

Field(s) of use	Indoor Teat-disinfection post-milking
Application method(s)	Method: Dipping Detailed description: Teat-disinfection post-milking Manual dipping using a dip cup Automated dipping by robot Method: Spraying Detailed description: Teat-disinfection post-milking Manual spraying using a trigger sprayer Manual spraying using an electronic sprayer Automated spraying by robot
Application rate(s) and frequency	Application Rate: RTU product, 6,80% L-(+)-lactic acid Dilution (%): - Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 4

5.1. Instructions for use

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Goggles, gloves and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like

sawdust. Dispose of the material collected in accordance with local regulations.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	calgodip Amadine forte Spray		Market area: EU		
Authorisation number	EU-0028957-0013 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es lac DLX Spray		Market area: EU		
Authorisation number	EU-0028957-0014 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

7.3. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip Blue Kamille forte Spray		Market area: EU		
Authorisation number	EU-0028957-0015 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8
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7.4. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es protect DLX Spray		Market area: EU		
Authorisation number	EU-0028957-0016 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	mSPC5
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1.2. Suffix to the authorisation number

Number	1-5
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1.3. Product type(s)

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	1,96

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation(s)	AL - Any other liquid
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5**

Hazard statements	Causes skin irritation. Causes serious eye irritation.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves. Wear eye protection. IF ON SKIN:Wash with plenty of water. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists:Get medical advice. If eye irritation persists:Get medical attention. Dispose of container in accordance with local regulations. Dispose of contents in accordance with local regulations.

4. **AUTHORISED USE(S) OF THE META SPC 5**4.1. **Use description**

Table 5

Use # 1 – Use # 5.1 – Teat-disinfection post-milking by manual or automated dipping or spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	Indoor Teat-disinfection post-milking
Application method(s)	Method: Dipping Detailed description: Teat-disinfection post-milking Manual dipping using a dip cup Automated dipping by robot

	Method: Spraying Detailed description: Teat-disinfection post-milking Manual spraying using a trigger sprayer Manual spraying using an electronic sprayer Automated spraying by robot
Application rate(s) and frequency	Application Rate: RTU product, 1,92-1,96% L-(+)-lactic acid Dilution (%): - Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 5**

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Goggles, gloves and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

Emergency measure to protect the environment

Environmental precautions: no special environmental measures are necessary. Clean contaminated articles and floor in accordance with the environmental legislation.

Methods and material for containment: absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

5.4. Instructions for safe disposal of the product and its packaging

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

Avoid release to an individual waste water treatment plant.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5**7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Dip es poly-film Spray		Market area: EU		
	Lacti-Shield Spray		Market area: EU		
	DS 2.0 SP		Market area: EU		
Authorisation number	EU-0028957-0017 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

META SPC 61. **META SPC 6 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 6 identifier**

Identifier	mSPC6
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1.2. **Suffix to the authorisation number**

Number	1-6
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1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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2. **META SPC 6 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8	6,8

2.2. **Type(s) of formulation of the meta SPC 6**

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves. Wear eye protection. IF ON SKIN:Wash with plenty of water. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. Use description

Table 6

Use # 1 – Use # 6.1 - Teat-disinfection post-milking by manual or automated dipping or spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	Indoor Teat-disinfection post-milking
Application method(s)	Method: Dipping Detailed description: Teat-disinfection post-milking Manual dipping using a dip cup Automated dipping by robot Method: Spraying Detailed description: Teat-disinfection post-milking

	Manual spraying using a trigger sprayer Manual spraying using an electronic sprayer Automated spraying by robot
Application rate(s) and frequency	Application Rate: RTU product, 6,80% L-(+)-lactic acid Dilution (%): - Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽⁹⁾ OF THE META SPC 6**

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

⁽⁹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Goggles, gloves and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: no special environmental measures are necessary. Clean contaminated articles and floor in accordance with the environmental legislation.

Methods and material for containment: absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

5.4. Instructions for safe disposal of the product and its packaging

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6**7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Dip es poly-spray DLX		Market area: EU		
Authorisation number	EU-0028957-0018 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

META SPC 71. **META SPC 7 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 7 identifier**

Identifier	mSPC7
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1.2. **Suffix to the authorisation number**

Number	1-7
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1.3. **Product type(s)**

Product type(s)	PT04 - Food and feed area (Disinfectants)
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2. **META SPC 7 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0	17,6
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	6,3	7,0

2.2. **Type(s) of formulation of the meta SPC 7**

Formulation(s)	SL - Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe spray. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. Immediately call a POISON CENTER. Store in corrosion resistant container with a resistant inner liner. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 7

4.1. Use description

Table 7

Use # 1 – Use # 7.1 – Hard surface disinfection by manual or automated foaming

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	Indoor Hard surface disinfection
Application method(s)	Method: Foaming Detailed description: Hard surface disinfection Manual foaming using a foam lance Automated foaming with fixed installed foaming nozzles Foaming equipment

	Satellite stations: fixed installations connected to jerrycans, drums or IBCs and mobile trolleys equipped with 20 litres container of concentrated product
Application rate(s) and frequency	Application Rate: Concentrated product, 16,0-17,6% L-(+)-lactic acid Dilution (%): Bactericidal claim: 5,0% (w/w) dilution of the product, 0,80-0,88% L-(+)-lactic acid Yeasticidal claim: 5,0% (w/w) dilution of the product, 0,80-0,88% L-(+)-lactic acid Number and timing of application: once a day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽⁷⁾ OF THE META SPC 7**

5.1. **Instructions for use**

For fixed installations, connect the jerrycan, drum or IBC containing the product with the dosing unit of the satellite station. For mobile versions, place a 20 litres container of the neat product on the trolley and put the suction hose in. Connect water supply to the dosing unit. Dilution is performed automatically via the dosing unit of the fixed or mobile station and monitored by conductivity measurements.

Before disinfection remove loose dirt, any further precleaning is not necessary.

Apply the foam to the hard surfaces. Application volume is 350 ml of diluted product/m². Make sure that surfaces are well covered with the disinfectant.

Minimum contact time is 5 minutes for bacteria and 15 minutes for yeasts.

⁽⁷⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

After application, rinse treated surfaces and flush foaming equipment thoroughly with clean water. For flushing of mobile systems, put the suction hose into a container with clean water.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Goggles, gloves and coverall material to be specified by the authorisation holder within the product information.

Wear respiratory protection when handling the concentrated product. Respiratory protection to be specified by the authorisation holder within the product information. Avoid standing in areas with aerosol formation.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF INHALED: move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: call 112 or an ambulance for medical assistance.

If no symptoms: call a POISON CENTRE or a doctor.

IF ON SKIN: immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected in accordance with local regulations. Ensure adequate ventilation.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer depending on local requirements.

Avoid release to an individual waste water treatment plant.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Ensure good ventilation or exhaustion.

Do not store together with alkalis (caustic solutions).

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgonit DS 633		Market area: EU		
Authorisation number	EU-0028957-0019 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	7,0

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 8 identifier

Identifier	mSPC8
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1.2. Suffix to the authorisation number

Number	1-8
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1.3. Product type(s)

Product type(s)	PT04 - Food and feed area (Disinfectants)
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2. META SPC 8 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0	17,6

Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	0,0	10,5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	18,75
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	4,5	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	2,25	2,5

2.2. Type(s) of formulation of the meta SPC 8

Formulation(s)	SL - Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe spray. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Store in corrosion resistant container with a resistant inner liner. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. Use description

Table 8

Use # 1 – Use # 8.1 – Hard surface disinfection by automated spraying in closed cleaning in place (CIP) system

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	Indoor Hard surface disinfection
Application method(s)	Method: Spraying Detailed description: Hard surface disinfection Automated dosing and spraying in closed CIP system CIP system: pipe work, fermentation and storage tanks
Application rate(s) and frequency	Application Rate: Concentrated product, 16,0-17,6% L-(+)-lactic acid Dilution (%): Bactericidal claim: 2,5% (w/w) dilution of the product, 0,40-0,44% L-(+)-lactic acid Yeastocidal claim: 2% (w/w) dilution of the product, 0,32-0,35% L-(+)-lactic acid Number and timing of application: once a day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1 000 kg

4.1.1. Use-specific instructions for use

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽⁸⁾ OF THE META SPC 8

5.1. Instructions for use

Connect the jerrycan, drum or IBC containing the product with the dosing unit of the CIP system. Dosing and dilution are performed automatically via the dosing unit of the CIP system and monitored by conductivity measurements.

Avoid contact with aluminium, non-ferrous metals and galvanised materials.

Precleaning is not necessary.

Minimum contact time is 5 minutes for bacteria and 15 minutes for yeasts.

After application, rinse the treated system thoroughly with clean water.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Goggles, gloves and coverall material to be specified by the authorisation holder within the product information.

Wear respiratory protection when handling the concentrated product. Respiratory protection to be specified by the authorisation holder within the product information. Avoid standing in areas with aerosol formation.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF INHALED: move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: call 112 or an ambulance for medical assistance.

If no symptoms: call a POISON CENTRE or a doctor.

IF ON SKIN: immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected in accordance with local regulations.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer depending on local requirements.

⁽⁸⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Ensure good ventilation or exhaustion.

Do not store together with alkalis (caustic solutions).

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgonit Duocip		Market area: EU		
Authorisation number	EU-0028957-0020 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	10,5
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	2,5

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgonit Duocip P		Market area: EU		
Authorisation number	EU-0028957-0021 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0

Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	18,75
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	2,5

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1312**of 27 June 2023****establishing a derogation from Implementing Regulation (EU) 2019/2072 as regards the requirements for the introduction into the Union territory of oak logs with bark originating in the United States**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ⁽¹⁾, and in particular Article 41(2) thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC ⁽²⁾, and in particular Article 52 thereof,

Whereas:

- (1) In order to prevent the introduction into the Union territory of *Bretziella fagacearum* (Bretz) Z.W. de Beer, Marincowitz, T.A. Duong & M.J. Wingfield, comb. nov., the pathogen causing oak wilt ('the specified pest'), logs of oak (*Quercus* L.) wood, originating in the United States ('the specified wood'), may only be introduced into the Union territory if they fulfil the special requirements of point 90 of Annex VII to Commission Implementing Regulation (EU) 2019/2072 ⁽³⁾.
- (2) The same requirements for the introduction of oak logs with bark from the United States were established in Part A, Section 1, point 3, of Annex IV to Council Directive 2000/29/EC ⁽⁴⁾, which was repealed by Regulation (EU) 2016/2031. Commission Decision 2005/359/EC ⁽⁵⁾ authorised Member States to provide for derogations from those requirements for the specified wood under specific conditions, before it expired on 31 December 2020.
- (3) The conditions set out in Decision 2005/359/EC included a fumigation of the specified wood with the substance bromomethane (also called 'methyl bromide'), the use of which is restricted under the Montreal Protocol on Substances that Deplete the Ozone Layer ⁽⁶⁾ of which the Union is a party. Therefore, it was decided not to extend the derogation laid down in that Decision.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

⁽⁴⁾ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

⁽⁵⁾ Commission Decision 2005/359/EC of 29 April 2005 providing for a derogation from certain provisions of Council Directive 2000/29/EC as regards oak (*Quercus* L.) logs with bark attached, originating in the United States of America (OJ L 114, 4.5.2005, p. 14).

⁽⁶⁾ OJ L 297, 31.10.1988, p. 21.

- (4) In March 2020, the United States submitted a dossier containing technical and scientific information about an alternative treatment consisting of a systems approach, which does not include fumigation with bromomethane.
- (5) The systems approach includes harvesting the specified wood under selective conditions and under supervision of a certified forester, transporting it in closed containers from the export log yard to the place of fumigation, and fumigating it with sulfuryl fluoride by licensed operators.
- (6) Furthermore, that systems approach also includes specific conditions for the safe unloading and processing of the specified wood after introduction into the Union, in order to ensure the highest possible level of phytosanitary protection of the Union territory from the specified pest.
- (7) With a view to ensuring an efficient performance of the official controls and a proper control of risks, it is necessary to carry out the official controls completely or partly at the place of storage instead of a border control post.
- (8) In order to ensure its appropriate supervision, the specified wood is stored in places which have been designated by the competent authority of the Member State concerned as control points in accordance with Commission Delegated Regulation (EU) 2019/2123 ⁽⁷⁾ and which dispose of appropriate wet storage facilities. In order to prevent the spread of the specified pest after unloading the specified wood from the containers at the designated control point, the specified wood is immediately either processed or placed in continuous wet storage until processing.
- (9) The United States claim that the measures described in their dossier provide for the same level of protection for the Union territory against the introduction of quarantine pests as the specific requirements of point 90 of Annex VII to Implementing Regulation (EU) 2019/2072 for the introduction of oak logs originating from the United States into the Union territory.
- (10) The dossier was evaluated by the European Food Safety Authority and discussed by experts from Member States. It was concluded ⁽⁸⁾ that, despite the indicated uncertainties about the efficacy of sulfuryl fluoride as regards the specified pest, a systems approach can be established, which can effectively eliminate the risk of introduction of the specified pest into the Union territory.
- (11) In order to ensure the timely control of the specified wood by the competent authorities, the importer should, prior to importation, notify each consignment of the specified wood sufficiently in advance to the competent authority of the Member State of the envisaged first place of storage, in the format laid down in Article 40(1), point (c), of Commission Implementing Regulation (EU) 2019/1715 ⁽⁹⁾.
- (12) Taking into account that a systems approach can be established, which can effectively eliminate the risk of introduction of the specified pest into the Union territory, the specified wood should be allowed to be introduced into the Union territory, under certain requirements. As this Regulation addresses a particular phytosanitary risk which is not yet fully assessed, its requirements are to have a temporary character, in accordance with Article 8 of Implementing Regulation (EU) 2019/2072. Therefore, this Regulation should apply until 30 September 2026.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁷⁾ Commission Delegated Regulation (EU) 2019/2123 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for the cases where and the conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts (OJ L 321, 12.12.2019, p. 64).

⁽⁸⁾ Commodity risk assessment of oak logs with bark from the US for the oak wilt pathogen *Bretziella fagacearum* under an integrated systems approach. EFSA Journal 2020;18(12):6352. <https://doi.org/10.2903/j.efsa.2020.6352>.

⁽⁹⁾ Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation) (OJ L 261, 14.10.2019, p. 37).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation sets out specific measures for the introduction into the Union territory of oak (*Quercus* L.) wood, which has kept its natural round surface with bark attached, originating in the United States of America.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'the specified wood' means oak (*Quercus* L.) wood, which has kept its natural round surface with bark attached, intended for the production of veneer and originating in the United States of America;
- (2) 'the specified pest' means the pathogen *Bretziella fagacearum* (Bretz) Z.W. de Beer, Marincowitz, T.A. Duong & M.J. Wingfield, comb. nov.

Article 3

Derogation from Regulation (EU) 2019/2072

By way of derogation from the requirements set out under 'Special requirements' in point 90 of Annex VII to Implementing Regulation (EU) 2019/2072, the specified wood may be introduced into the Union territory if the requirements laid down in Articles 4 and 5 of this Regulation, and the Annex thereto have been fulfilled.

Article 4

Shipment to, and introduction into, the Union territory of the specified wood

1. The specified wood may only be shipped:
 - (a) from the United States; and
 - (b) in the period between 15 October and 10 April of the next year.
2. The specified wood may only be introduced into the Union territory:
 - (a) during the year of the shipment or by 30 April of the following year, if the ship date occurs between 15 October and 31 December, or
 - (b) by 30 April of the year of the shipment, if the ship date occurs between 1 January and 10 April.

Article 5

Phytosanitary certificate

The specified wood shall be accompanied by a phytosanitary certificate indicating the following:

- (a) under the rubric 'Place of origin', the name and location of the place of harvest of the specified wood;
- (b) under the heading 'Additional declaration', the following statement: 'This consignment complies with the European Union requirements laid down in Commission Implementing Regulation (EU) 2023/1312';
- (c) the fumigation batch identification mark referred to in point 7 of the Annex;

- (d) the log number(s) corresponding to each exported log of the specified wood;
- (e) the name of the licensed fumigation operative and the name and location of the fumigation site.

Article 6

Documentary, identity and physical checks

1. Documentary checks of the specified wood shall only be carried out at a border control post or at a control point other than a border control post designated for the category of goods in the consignment in accordance with Article 7 of Delegated Regulation (EU) 2019/2123.

Physical and identity checks of the specified wood shall be carried out either at the border control posts where the documentary check took place or at a control point other than a border control post designated for the category of goods in the consignment in accordance with Delegated Regulation (EU) 2019/2123 and where appropriate wet storage facilities are available.

2. The official controls shall include at least the following:
- (a) an examination of each phytosanitary certificate; and
 - (b) an identity check consisting of comparing the marking on each log and the number of logs with the information given in the respective phytosanitary certificate.
3. Where identity or physical checks as mentioned in paragraph 1 are not carried out at the border control post of the port of arrival of the specified wood in the Union territory, the logs of the specified wood shall remain in the shipping containers and the containers shall remain closed and under customs supervision until those checks are carried out.

Article 7

Storage

1. After unloading, the logs of the specified wood may only be stored at border control points or in places which have been designated as control points in accordance with Delegated Regulation (EU) 2019/2123, where appropriate wet storage facilities are available and which have been approved for that purpose by the relevant competent authority, until processing takes place.

2. After unloading from the containers at the places referred to in paragraph 1, the logs of the specified wood shall immediately be processed or placed in continuous wet storage until the processing.

3. The competent authority shall perform physical checks in order to verify that the conditions for storage are in compliance with this Article.

Article 8

Processing

1. The logs of the specified wood shall only be processed in places authorised for that purpose by the competent authorities, which can be:

- (a) the first place of storage, immediately after their arrival in the Union; or
- (b) other facilities at a later point.

2. Before further processing, the logs of the specified wood shall be subject to a hot water treatment, under the conditions suitable for wood intended for the production of veneer.

3. Any bark and other waste arising from unloading and processing of the logs of the specified wood shall immediately be destroyed by incineration *in situ*.

4. The competent authority shall perform physical checks in order to verify that the conditions for processing, and treatment of waste of the specified wood are in compliance with this Article.

5. The competent authority shall at appropriate intervals inspect any oak stands neighbouring the place of storage and processing for symptoms of the specified pest.

If any symptoms, which may have been caused by the specified pest, are found, further official testing shall be carried out in accordance with appropriate methods to confirm whether the specified pest is present.

Article 9

Notification of consignments

1. Prior to importation, the importer shall notify each consignment of the specified wood sufficiently in advance to the competent authority of the Member State of the first place of storage after arrival to the Union territory in the format laid down in Article 40(1), point (c), of Implementing Regulation (EU) 2019/1715.

2. The importer shall provide in the notification of the intended import for each consignment the following information:

- (a) quantity of logs;
- (b) port of shipment;
- (c) port or ports of unloading;
- (d) place or places of storage;
- (e) place or places where processing will be carried out.

3. Where an importer notifies the intended import of a consignment as referred to in paragraphs 1 and 2, the competent authority, prior to import, shall inform the importer of the requirements provided for in Articles 3 to 9.

Article 10

Entry into force and period of application

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

It shall apply until 30 September 2026.

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

Done at Brussels, 27 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Conditions with respect to fumigation and related identification of the specified wood in the United States as referred to in Article 3

The specified wood may only be introduced into the Union territory, after the competent authorities have confirmed on the phytosanitary certificate issued in accordance with Article 5 that it has complied with all of the following conditions concerning its harvest, fumigation, and identification in the United States:

- (1) The specified wood has been harvested in places of production where the specified pest is not known to occur, and the selection and harvest of the plants of the specified wood has been supervised by a forester certified by the Association of American Foresters.
- (2) All logs of the consignment have been subject to visual examination and found free from symptoms of the specified pest. After harvest and transport to an export log yard, the specified wood has been placed in shipping containers, where it has remained during the subsequent steps of transport, storage, fumigation, and shipment.
- (3) The logs have been placed in the containers, in such a way and to such a density in the container as to ensure effective gas dispersal through the logs.
- (4) For the fumigation, the containers have been piled on an impervious surface under a gasproof cover.
- (5) The logs have undergone fumigation with sulfuryl fluoride which is carried out at an average rate of 240 g/m³ of total volume in the containers, for 72 hours and at a minimum temperature of the logs of 15,6 °C. To this end, sulfuryl fluoride has been brought in the containers at a dosage of 240 g/m³ at the beginning of the treatment.

At 30 minutes and at 2, 24, 48 and 72 hours after the start of the treatment respectively, sulfuryl fluoride has been added to raise the concentration to 280 g/m³. After 72 hours, the treatment has been continued for at least 24 hours, allowing the sulfuryl fluoride to level off to a minimum of 200 g/m³ at the end of the treatment.

The fumigation resulted in an accumulated dose of sulfuryl fluoride of at least 22 500 g*h/m³.

- (6) The fumigation procedures, as described in points 3, 4 and 5, have been carried out by officially licensed fumigation operatives, using proper fumigation facilities and by qualified staff to requisite standards and taking due account of all pertinent factors, such as density and moisture of the wood, or density of the load in the container.

The list of licensed fumigation operatives and their changes has been notified to the Commission and the Commission has not objected to the fumigation operative being involved.

- (7) A fumigation batch identification mark (digits and/or letters) has been placed in a non-removable manner on the base end of each log of the pile undergoing fumigation. The fumigation batch identification mark has been reserved to the shipper. It has not been used for logs of other batches. Records of the identification marks have been kept by the licensed fumigation operatives.
 - (8) The individual fumigation procedure, including the marking referred to in point 7, has been systematically supervised at the fumigation sites, directly by officials of the official plant protection organisation concerned or by a delegated competent authority in such a way as to guarantee compliance with points 3, 4, 5, 6 and 7.
 - (9) After fumigation, the logs of the specified wood have been transported and stored in closed containers.
 - (10) Information is available ensuring the traceability in relation to the places of production referred to in point (1) and the officially licensed fumigation operatives referred to in point (6).
-

DECISIONS

COMMISSION DECISION (EU) 2023/1313

of 22 June 2023

approving, on behalf of the European Union, the amendments to Annex 14-B of the Agreement between the European Union and Japan for an Economic Partnership

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision (EU) 2018/1907 of 20 December 2018 on the conclusion of the Agreement between the European Union and Japan for an Economic Partnership ⁽¹⁾, and in particular Article 4 thereof,

Whereas:

- (1) The Agreement between the European Union and Japan for an Economic Partnership (hereinafter referred to as “the Agreement”) entered into force on 1 February 2019.
- (2) Within the framework of the Committee on Intellectual Property, the European Union and Japan (hereinafter referred to as “the Parties”) confirmed that every year, starting from 2020 and until 2022, the Joint Committee will consider up to 28 names from the European Union and from Japan respectively to be protected as geographical indications (hereinafter referred to as “GIs”) and added in Annex 14-B of the Agreement, provided that those names are protected as GIs domestically. In accordance with Article 14.30 of the Agreement, 28 GIs of the European Union and 28 GIs of Japan have been added in Annex 14-B of the Agreement on 1 February 2021 ⁽²⁾ and on 1 February 2022 ⁽³⁾, respectively. As for the third addition of GIs to Annex 14-B, the Parties confirmed that it will take place in 2023 instead of 2022 and that the said addition will be made in two separate occasions in 2023: One for both 28 GIs of the European Union and 14 GIs for Japan and the other for the rest of the Japanese agricultural GIs. Article 14.30 of the Agreement provides for the possibility to add new geographical indications to Annex 14-B to the Agreement to be adopted after the completion of the opposition procedure and after having examined the geographical indications as set out in paragraph 4 of Article 14.25 thereof to the satisfaction of the both Parties.
- (3) Following the request of the Parties and pursuant to paragraph 1 of Article 14.30, the Union has completed the opposition procedure and the examination of 14 additional geographical indications of Japan and Japan has completed the opposition procedure and the examination of 28 additional geographical indications of the Union. These geographical indications should be added under the corresponding list of geographical indications of the respective Member State of the Union and to the list of geographical indications of Japan.
- (4) Article 14.53(3) of the Agreement provides that the Committee on Intellectual Property, established pursuant to Article 22.3 of the Agreement, should make recommendations to the Joint Committee established pursuant to Article 22.1 of the Agreement on amendments to Annex 14-B on request of a Party.
- (5) Pursuant to paragraph 5 of Article 22.1 of the Agreement, the Joint Committee may adopt decisions to amend the Agreement in specific instances, including the amendment of Annex 14-B, in accordance with the respective domestic legal procedures of the Parties.

⁽¹⁾ OJ L 330, 27.12.2018, p. 1.

⁽²⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A20201D0109&qid=1635340796840> <https://www.mofa.go.jp/mofaj/files/100141732.pdf>

⁽³⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A20202D0138&qid=1675141114801> <https://www.mofa.go.jp/mofaj/files/100293455.pdf>

- (6) On 12 June 2023, the Committee on Intellectual Property recommended to the Joint Committee to amend Annex 14-B to the Agreement accordingly.
- (7) Annex 14-B to the Agreement should therefore be amended accordingly and the amendments should be approved on behalf of the Union,

HAS DECIDED AS FOLLOWS:

Article 1

The amendments to Annex 14-B to the Agreement set out in the draft Decision of the Joint Committee, are hereby approved on behalf of the European Union.

The text of the amending Agreement, in the form of a draft Decision of the Joint Committee, is attached to this Decision.

Article 2

The representative of the European Union in the Joint Committee is authorised to approve the adoption of the Decision of the Joint Committee on behalf of the European Union.

Article 3

This Decision shall be published in the *Official Journal of the European Union*.

The amending Agreement in the Annex, in the form of the Decision of the Joint Committee, shall be published in the *Official Journal of the European Union* after its adoption by the Joint Committee.

Done at Brussels, 22 June 2023.

For the Commission
Janusz WOJCIECHOWSKI
Member of the Commission

ANNEX

**DECISION No X/2023 OF THE JOINT COMMITTEE UNDER THE AGREEMENT BETWEEN THE
EUROPEAN UNION AND JAPAN FOR AN ECONOMIC PARTNERSHIP****of [date]****on the amendments to Annex 14-B on geographical indications**

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Union and Japan for an Economic Partnership (hereinafter referred to as the "Agreement"), and in particular Articles 14.30 and 22.2 thereof,

Whereas:

- (1) The Agreement entered into force on 1 February 2019.
- (2) Within the framework of the Committee on Intellectual Property, the European Union and Japan (hereinafter referred to as "the Parties") confirmed that every year, starting from 2020 and until 2022, the Joint Committee will consider up to 28 names from the European Union and from Japan respectively to be protected as geographical indications (hereinafter referred to as "GIs") and added in Annex 14-B of the Agreement, provided that those names are protected as GIs domestically. In accordance with Article 14.30 of the Agreement, 28 GIs of the European Union and 28 GIs of Japan have been added in Annex 14-B of the Agreement on 1 February 2021 ⁽¹⁾ and on 1 February 2022 ⁽²⁾, respectively. As for the third addition of GIs to Annex 14-B, the Parties confirmed that it will take place in 2023 instead of 2022 and that the said addition will be made in two separate occasions in 2023: One for both 28 GIs of the European Union and 14 GIs for Japan and the other for the rest of the Japanese agricultural GIs.
- (3) Following the request of the Parties and pursuant to paragraph 1 of Article 14.30, the European Union has completed the opposition procedure and the examination of 14 additional GIs of Japan and Japan has completed the opposition procedure and the examination of 28 additional GIs of the European Union.
- (4) On 12 June 2023, in accordance with paragraph 3 of Article 14.53 of the Agreement, the Committee on Intellectual Property recommended to the Joint Committee to amend Annex 14-B to the Agreement accordingly.
- (5) The Parties completed their internal procedures necessary for adoption of the Decision by the Joint Committee under the Agreement, and endeavour to exchange the diplomatic notes confirming the amendments to the Agreement not more than ten working days after the Decision is adopted.
- (6) Consequently, Annex 14-B to the Agreement should be amended, in accordance with paragraph 3 and subparagraph 4(g) of Article 23.2 of the Agreement.
- (7) The Parties confirmed that both sides will continue to work closely to add further GIs to be protected from the European Union and Japan to Annex 14-B in view of each side's interests with the aim to add further GIs of the European Union and of Japan as from 1 January 2025.

⁽¹⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A20201D0109&qid=1635340796840>
<https://www.mofa.go.jp/mofaj/files/100141732.pdf>

⁽²⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A2022D0138&qid=1675141114801>
<https://www.mofa.go.jp/mofaj/files/100293455.pdf>

HAS ADOPTED THIS DECISION:

Article 1

- a) In Section A of Part 1 of Annex 14-B to the Agreement, the GIs listed in Annex 1 to this Decision shall be added under the corresponding list of GIs of the respective Member State of the European Union.
- b) In Section B of Part 1 of Annex 14-B to the Agreement, the GIs listed in Annex 2 to this Decision shall be added to the list of GIs of Japan.
- c) In Section A of Part 2 of Annex 14-B to the Agreement, the GIs listed in Annex 3 to this Decision shall be added under the corresponding list of GIs of the respective Member State of the European Union
- d) In Section B of Part 2 of Annex 14-B to the Agreement, the GIs listed in Annex 4 to this Decision shall be added to the list of GIs of Japan.

Article 2

- a) The Joint Committee will decide on the further addition to Annex 14-B of the Agreement of a number of up to 6 names from Japan, to be protected as GIs under the Agreement by the end of this year (2023), provided that those names are GIs protected in the territory of Japan in accordance with its laws and regulations.
- b) In 2025, the Joint Committee will decide on a further addition to Annex 14-B of the Agreement of a sufficient number of GIs from the European Union and Japan to be protected as GIs under the Agreement, in a manner satisfactory to both Parties, reflecting the level of implementation of GI policies in their respective territories, provided that those names are GIs protected in the territory of the Party in accordance with its laws and regulations.

Article 3

This Decision is drawn up in duplicate. Article 1 and Annexes to this Decision are drawn up in duplicate in the authentic languages of the Agreement provided for in paragraph 1 of Article 23.8 of the Agreement, all texts being equally authentic.

Article 4

This Decision shall be implemented by the Parties as referred to in paragraph 1 of Article 22.2 of the Agreement. The amendments to the Agreement adopted through this Decision shall be confirmed by and enter into force upon the exchange of diplomatic notes in accordance with paragraph 3 of Article 23.2 of the Agreement.

For the Joint Committee,
Co-Chair [for Japan]

Co-Chair [for EU]

ANNEX 1

CROATIA

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Korčulansko maslinovo ulje	コルチュランスコ・マスリノ ヴォ・ウリエ	Oils and fats (butter, margarine, oil, etc.) [olive oil]

FRANCE

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Époisses	エボワス	Cheese
Mont d'Or/Vacherin du Haut-Doubs	モン・ドール/ヴァシュラン・ デュ・オー・ドゥー	Cheese
Raclette de Savoie	ラクレット・ド・サヴォワ	Cheese

GREECE

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Λακωνία (Transliteration into Latin alphabet: Lakonia)	ラコニア	Oils and fats (butter, margarine, oil, etc.) [olive oil]

ITALY

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Cotechino Modena	コテキーノ・モデナ	Meat products (cooked, salted, smoked, etc.) [pork sausage]
Finocchiona	フィノッキオーナ	Meat products (cooked, salted, smoked, etc.) [pork ham]
Limone di Siracusa	リモーネ・ディ・シラクーザ	Fruit, vegetables and cereals fresh or processed [citrus]

SPAIN

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Ajo Morado de Las Pedroñeras	アホ・モラド・デ・ラス・ペド ロニエラス	Fruit, vegetables and cereals fresh or processed [garlic]

Arzúa-Ulloa	アルスア・ウジョア	Cheese
Melocotón de Calanda	メロコトン・デ・カランダ	Fruit, vegetables and cereals fresh or processed [peach]
Queso de Valdeón	ケソ・デ・バルデオン	Cheese
Queso de Murcia al vino	ケソ・デ・ムルシア・アル・ビノ	Cheese
San Simón da Costa	サン・シモン・ダ・コスタ	Cheese
Vinagre de Jerez	ビナグレ・デ・ヘレス	Other products of Annex I to the TFEU (spices etc.) [vinegar]

ANNEX 2

Name to be protected	Transcription into Latin alphabet (for information purposes)	Category of good and short description [in square brackets, for information purpose]
大口れんこん/Okuchi Renkon	Okuchi Renkon	Agricultural product [lotus root]
氷見稲積梅/Himi Inazumiume	Himi Inazumiume	Agricultural product [Ume (Japanese apricot)]
種子島安納いも/TANEGASHIMA ANNOU SWEETPOTATO/ Tanegashima Annou Imo	Tanegashima Annou Imo	Agricultural product [sweet potato]
飛驒牛/Hidagyu/Hida Beef	Hida Gyu	Fresh Meat [beef]
伊達のあんぽ柿/DATE NO ANPO GAKI/DATE NO ANPO KAKI	Date no Anpo Gaki/Date no Anpo Kaki	Processed agricultural product [Dried Japanese persimmon]
サヌキ白みそ/Sanuki shiro miso	Sanuki Shiro Miso	Seasonings and Soups [miso paste]
たむらのエゴマ油/Tamura no egoma oil/Tamura no egoma abura	Tamura no Egoma Abura	Oils and fats [perilla oil]

ANNEX 3

AUSTRIA

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Pálinka ⁽¹⁾ (Translation into Japanese: パーリンカ)	パーリンカ	Spirits

⁽¹⁾ Product of Austria or Hungary.

BULGARIA

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Карнобатска гроздова ракия/Гроздова ракия от Карнобат/Karnobatska grozdova rakya/Grozdova rakya ot Karnobat	カルノバトスカ・グロズドヴァ・ラキヤ/グロズドヴァ・ラキヤ・オト・カルノバト	Spirits

FRANCE

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Bourg/Côtes de Bourg/Bourgeais	ブル/コート・ドゥ・ブル/ブルジェ	Wine
Cassis	カシー	Wine
Cassis de Bourgogne	カシス・ドゥ・ブルゴーニュ	Spirits

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Entre-deux-Mers	アントル・ドゥー・メール	Wine
Fronsac	フロンサック	Wine
Lustrac-Médoc	リストラック・メドック	Wine
Moulis/Moulis-en-Médoc	ムーリ/ムーリ・ザン・メドック	Wine

HUNGARY

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Pálinka ⁽¹⁾ (Translation into Japanese: パーリンカ)	パーリンカ	Spirits

⁽¹⁾ Product of Austria or Hungary.

ROMANIA

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Pălincă (Translation into Japanese: パリンカ)	パリンカ	Spirits

SLOVENIA

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Kras	クラス	Wine

SPAIN

Name to be protected	Transcription into Japanese (for information purposes)	Category of good and short description [in square brackets, for information purpose]
Montsant	モンサン	Wine
Ribeiro	リベイロ	Wine

ANNEX 4

Name to be protected	Transcription into Latin alphabet (for information purposes)	Category of good and short description [in square brackets, for information purpose]
佐賀	Saga	Seishu (Sake)
大阪	Osaka	Wine
長野	Nagano	Wine
長野	Nagano	Seishu (Sake)
山形	Yamagata	Wine
新潟	Niigata	Seishu (Sake)
滋賀	Shiga	Seishu (Sake)

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2023 OF THE EU-SWITZERLAND JOINT COMMITTEE of 12 June 2023

amending Tables III and IV of Protocol 2 to the Agreement between the European Economic Community and the Swiss Confederation of 22 July 1972, as amended (2023/1314)

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Economic Community and the Swiss Confederation of 22 July 1972 ⁽¹⁾, as amended by the Agreement between the European Community and the Swiss Confederation of 26 October 2004 amending the Agreement between the European Economic Community and the Swiss Confederation of 22 July 1972 as regards the provisions applicable to processed agricultural products ⁽²⁾ ('Agreement'), and in particular Article 7 of its Protocol 2,

Whereas:

- (1) In accordance with Article 5(2) of Protocol 2 to the Agreement, the Union and the Swiss Confederation, as Contracting Parties, provided to the Joint Committee the domestic reference prices, for the 12-month reference period from September 2021 to August 2022, of all raw materials for which price compensation measures are applied. It follows from those prices that the actual price situation regarding those raw materials in the territory of the Contracting Parties has changed.
- (2) It is therefore necessary to update the domestic reference prices and the price differences for agricultural raw materials listed in Table III of Protocol 2 to the Agreement, as well as to adapt the basic amounts of the agricultural raw materials listed in Table IV of that Protocol,

HAS ADOPTED THIS DECISION:

Article 1

Protocol 2 to the Agreement is amended as follows:

- (a) Table III is replaced by the text set out in Annex I to this Decision;
- (b) in Table IV, point (b) is replaced by the text set out in Annex II to this Decision.

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 300, 31.12.1972, p. 189.

⁽²⁾ OJ L 23, 26.1.2005, p. 19.

Article 3

This Decision shall enter into force on 1 July 2023.

Done at Brussels, 12 June 2023.

For the Joint Committee

The Chairman

Marco DUEERKOP

ANNEX I

TABLE III

EU and Swiss domestic reference prices

Agricultural raw material	Swiss domestic reference price CHF per 100 kg net	EU domestic reference price CHF per 100 kg net	Article 4(1) Applied on Swiss side Difference Swiss/EU reference price CHF per 100 kg net	Article 3(3) Applied on EU side Difference Swiss/EU reference price EUR per 100 kg net
Common wheat	55,03	34,01	21,00	0,00
Durum wheat	-	-	1,20	0,00
Rye	45,00	30,60	14,40	0,00
Barley	-	-	-	-
Maize	-	-	-	-
Common wheat flour	95,24	60,71	34,55	0,00
Whole-milk powder	652,27	463,32	188,95	0,00
Skimmed-milk powder	437,33	372,75	64,60	0,00
Butter	1 168,37	648,74	519,65	0,00
White sugar	-	-	-	-
Eggs	-	-	38,00	0,00
Fresh potatoes	40,06	15,77	24,30	0,00
Vegetable fat	-	-	170,00	0,00'

ANNEX II

‘(b) Basic amounts for agricultural raw materials taken into account for the calculation of the agricultural components:

Agricultural raw material	Applied basic amount on the Swiss side Art 3(2)	Applied basic amount on the EU side Art 4(2)
	CHF per 100 kg net	EUR per 100 kg net
Common wheat	17,10	0,00
Durum wheat	1,00	0,00
Rye	11,05	0,00
Barley	-	-
Maize	-	-
Common wheat flour	28,15	0,00
Whole-milk powder	154,00	0,00
Skimmed-milk powder	52,65	0,00
Butter	423,50	0,00
White sugar	-	-
Eggs	30,95	0,00
Fresh potatoes	18,55	0,00
Vegetable fat	138,55	0,00’

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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