

Official Journal of the European Union

L 5



English edition

Legislation

Volume 66

6 January 2023

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2023/56 of 19 July 2022 amending Regulation (EU) 2019/1241 of the European Parliament and of the Council as regards specific technical measures for red seabream (*Pagellus bogaraveo*) in ICES subareas 6 to 8** 1
- ★ **Commission Delegated Regulation (EU) 2023/57 of 31 October 2022 amending and correcting Delegated Regulation (EU) 2022/127 supplementing Regulation (EU) 2021/2116 of the European Parliament and of the Council** 7
- ★ **Commission Implementing Regulation (EU) 2023/58 of 5 January 2023 authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470 ⁽¹⁾** 10
- ★ **Commission Implementing Regulation (EU) 2023/59 of 5 January 2023 concerning the authorisation of a preparation of *Pediococcus pentosaceus* DSM 32292 as a feed additive for all animal species ⁽¹⁾** 16
- ★ **Commission Implementing Regulation (EU) 2023/60 of 5 January 2023 concerning the authorisation of conjugated linoleic acid (t10, c12)-methyl ester as a feed additive for pigs for fattening and dairy cows (holder of authorisation: BASF SE) ⁽¹⁾** 19
- ★ **Commission Implementing Regulation (EU) 2023/61 of 5 January 2023 concerning the authorisation of a preparation of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, a preparation of endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, a preparation of endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and a preparation of endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 as feed additives for all animal species ⁽¹⁾** 24

⁽¹⁾ Text with EEA relevance.

EN

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

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

★ Commission Implementing Regulation (EU) 2023/62 of 5 January 2023 correcting the Polish language version of Regulation (EU) No 1300/2014 on the technical specifications for interoperability relating to accessibility of the Union's rail system for persons with disabilities and persons with reduced mobility ⁽¹⁾	31
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DECISIONS

★ Decision No 1/2022 of the Joint Committee on Agriculture of 17 November 2022 amending Annexes 1 and 2 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products [2023/63]	32
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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/56

of 19 July 2022

amending Regulation (EU) 2019/1241 of the European Parliament and of the Council as regards specific technical measures for red seabream (*Pagellus bogaraveo*) in ICES subareas 6 to 8

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1241 of the European Parliament and of the Council of 20 June 2019 on the conservation of fisheries resources and the protection of marine ecosystems through technical measures, amending Council Regulations (EC) No 1967/2006, (EC) No 1224/2009 and Regulations (EU) No 1380/2013, (EU) No 2016/1139, (EU) 2018/973, (EU) 2019/472 and (EU) 2019/1022 of the European Parliament and of the Council, and repealing Council Regulations (EC) No 894/97, (EC) No 850/98, (EC) No 2549/2000, (EC) No 254/2002, (EC) No 812/2004 and (EC) No 2187/2005 ⁽¹⁾, and in particular Article 2(2) and Article 15(2) thereof,

Whereas:

- (1) Regulation (EU) 2019/1241 (the 'Technical Measures Regulation') on the conservation measures of fisheries resources and the protection of marine ecosystems through technical measures entered into force on 14 August 2019. Annex VI and VII of that Regulation lay down specific regional technical measures for the North Western Waters and the South Western Waters of Union waters.
- (2) Belgium, Spain, France, Ireland and the Netherlands (the 'North Western Waters Member States') have a direct fisheries management interest in the North Western Waters; Belgium, Spain, France, the Netherlands and Portugal (the 'South Western Waters Member States') have a direct fisheries management interest in the South Western Waters. On 5 March 2021, the two regional groups submitted two joint recommendations proposing measures to improve the conservation status of red seabream (*Pagellus bogaraveo*) that the International Council for the Exploration of the Sea (ICES) assessed with a zero-catch advice in ICES subareas 6 to 8 for the period 2021-2022 ⁽²⁾. In March 2022, Member States submitted updated versions of these joint recommendations suggesting an extension of the proposed end date of certain measures.
- (3) The North Western Waters Advisory Council and the South Western Waters Advisory Council were consulted on these joint recommendations in March 2021 and in February 2021, respectively.

⁽¹⁾ OJ L 198, 25.7.2019, p. 105.

⁽²⁾ <https://www.ices.dk/sites/pub/Publication%20Reports/Advice/2020/2020/sbr.27.6-8.pdf>

- (4) The Scientific, Technical and Economic Committee for Fisheries (STECF) assessed the joint recommendations and the evidence provided by the North Western Waters Member States and the South Western Waters Member States in the Plenary of May 2021 ⁽³⁾. These joint recommendations propose to extend the type of the technical measures that were previously taken by France and Spain at national level, and were assessed by the STECF in the Plenaries of April 2019 ⁽⁴⁾ and June 2019 ⁽⁵⁾ to make them applicable in the NWW and SWW sea basins.
- (5) The Fisheries and Aquaculture Expert Group (EGFA) was consulted on the joint recommendations by written procedure in May 2022.
- (6) The North Western Waters Member States' joint recommendation proposes a spatio-temporal closure for vessels flying the French flag to fish for red seabream in ICES subareas 6 and 7. The STECF ⁽⁶⁾ concluded that the management measure has the potential to reduce catches of red seabream and that the spatio-temporal closure for commercial fisheries coincides with the spawning period for this species. The proposed measure should therefore be included in Regulation (EU) 2019/1241.
- (7) The South Western Waters Member States' joint recommendation proposes a seasonal spatio-temporal closure for commercial fisheries and a year-round closure for recreational fisheries in several areas. The joint recommendation also includes an additional seasonal closure for vessels flying the French flag to fish for red seabream in ICES subarea 8. The STECF ⁽⁷⁾ concluded that the closures for commercial fisheries are in the area where spawning is likely to take place and that the closure for recreational fisheries appears to be in areas where juvenile red seabream aggregate. The proposed measures should therefore be included in Regulation (EU) 2019/1241.
- (8) Both joint recommendations propose in addition setting minimum conservation reference sizes (MCRS) of 36 cm and 40 cm for the catches of red seabream in commercial and recreational fisheries, respectively. In the North Western Waters, this Regulation proposes amending Annex VI to increase the Minimum Conservation Reference Sizes (MCRS) to 36 cm for commercial fisheries and to 40 cm for recreational fisheries. In the South Western Waters, this Regulation proposes amending Annex VII to include the MCRS of 36 cm for commercial fisheries. The MCRS of 40 cm for recreational fisheries is already a legal obligation in accordance with Commission Delegated Regulation (EU) 2020/2013 ⁽⁸⁾.
- (9) The STECF ⁽⁹⁾ concluded that the joint recommendation contains positive elements that will improve the management of the stocks, but due to lack of supporting data it is not possible to fully assess the impact of these measures on the respective stocks. Member States will review these measures by 31 December 2023 in light of the ongoing scientific studies and pending the new advice on red seabream to be released by ICES in 2023. Given that both commercial and recreational fisheries contribute to the overall fishing mortality of a stock for which data is scarce and with a zero-catch advice, the proposed MCRS should be included in Annexes VI and VII of Regulation (EU) 2019/1241, except for recreational fisheries in Annex VII, which is already a legal obligation.
- (10) Overall, although the STECF ⁽¹⁰⁾ cannot assess whether the catches of red seabream will be reduced, these management measures represent an improvement as compared to those presented in 2019 and have the potential to reduce catches of red seabream as compared to the baseline measures provided in Regulation (EU) 2019/1241. Therefore, Annexes VI and VII of Regulation (EU) 2019/1241 should be amended to include these measures.

⁽³⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2874177/STECF+21-05+-+Eval+JRs+LO+and+TM+Reg.pdf>

⁽⁴⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2485362/STECF+PLEN+19-01.pdf>

⁽⁵⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2620849/STECF+PLEN+19-03.pdf>

⁽⁶⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2874177/STECF+21-05+-+Eval+JRs+LO+and+TM+Reg.pdf>

⁽⁷⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2874177/STECF+21-05+-+Eval+JRs+LO+and+TM+Reg.pdf>

⁽⁸⁾ Commission Delegated Regulation (EU) 2020/2013 of 21 August 2020 amending Regulation (EU) 2019/1241 of the European Parliament and of the Council as regards technical measures for certain demersal and pelagic fisheries in the North Sea and in the South Western Waters (OJ L 415, 10.12.2020, p. 3).

⁽⁹⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2874177/STECF+21-05+-+Eval+JRs+LO+and+TM+Reg.pdf>

⁽¹⁰⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2874177/STECF+21-05+-+Eval+JRs+LO+and+TM+Reg.pdf>

- (11) As the measures provided for in this Regulation have a direct impact on the planning of the fishing season of Union vessels and on related economic activities, this Regulation should enter into force on the day following that of its publication.
- (12) The measures in this Regulation applicable to Union waters are in pursuit of the objectives set out in Article 494(1) and (2) of the Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part ⁽¹⁾, and have regard to the principles referred to in Article 494(3) of that agreement. They are without prejudice to any measures applicable in waters of the United Kingdom of Great Britain and Northern Ireland,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VI and VII to Regulation (EU) 2019/1241 are amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply until 31 December 2023.

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹⁾ OJ L 149, 30.4.2021, p. 10.

ANNEX

Annexes VI and VII to Regulation (EU) 2019/1241 are amended as follows:

(1) In Annex VI, Part A is amended as follows:

(a) The nineteenth entry of table is replaced as follows:

Red seabream (<i>Pagellus bogaraveo</i>)	36 cm ⁽¹⁾ ⁽²⁾ ⁽³⁾
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⁽¹⁾ This minimum conservation reference size shall apply until 31 December 2023.

⁽²⁾ In ICES sub-areas 6 and 7 a minimum conservation reference size of 40 cm shall apply for the catches of red sea-bream in recreational fisheries.

⁽³⁾ In the absence of new rules adopted before 31 December 2023, as of 1 January 2024 the applicable MCRS shall be 33 cm.'

(b) The text in point 1 below the table is replaced as follows:

'1. The minimum conservation reference sizes specified in this Part for cod (*Gadus morhua*), haddock (*Melanogrammus aeglefinus*), saithe (*Pollachius virens*), pollack (*Pollachius pollachius*), hake (*Merluccius merluccius*), megrim (*Lepidorhombus* spp.), sole (*Solea* spp.), plaice (*Pleuronectes platessa*), whiting (*Merlangius merlangus*), ling (*Molva molva*), blue ling (*Molva dypterygia*), mackerel (*Scomber* spp.), herring (*Clupea harengus*), horse mackerel (*Trachurus* spp.), anchovy (*Engraulis encrasicolus*), bass (*Dicentrarchus labrax*) and sardine (*Sardina pilchardus*) shall apply to recreational fisheries in the North Western Waters, except for red seabream (*Pagellus bogaraveo*), for which a minimum conservation reference size (MCRS) of 40 cm shall apply in ICES sub-areas 6 and 7 until 31 December 2023⁽¹⁾.

⁽¹⁾ In the absence of new rules adopted before 31 December 2023, as of 1 January 2024 the applicable MCRS for red seabream shall be 33 cm.'

(2) In Annex VI, the following point is added to Part C:

'11. Closed areas for the conservation of red seabream in ICES sub-areas 6 and 7

11.1. From 1 January to 30 June 2023, all fishing for red seabream in ICES sub-areas 6 and 7 shall be prohibited to vessels flying the French flag.'

(3) In Annex VII, Part A, the twentieth entry of the table is replaced as follows:

Red sea-bream (<i>Pagellus bogaraveo</i>)	36 cm ⁽¹⁾ ⁽²⁾
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⁽¹⁾ This minimum conservation reference size shall apply until 31 December 2023.

⁽²⁾ In the absence of new rules adopted before 31 December 2023, as of 1 January 2024 the applicable MCRS shall be 33 cm.'

(4) In Annex VII, the following point is added to Part C:

'5. Closed areas for the conservation of red seabream in ICES sub-area 8

5.1. From 1 February to 30 September each year, fishing with bottom set longlines (LLS) and bottom trawls (OTB) in the western area of the Cantabrian Sea, opposite to Asturias and Galicia, shall be prohibited within the geographical areas enclosed by sequentially joining with rhumb lines the following coordinates, which shall be measured according to the WGS84 system:

— 43°47'00" N, 005°15'00" W

— 43°47'00" N, 005°12'00" W

— 43°43'00" N, 005°12'00" W

— 43°43'00" N, 005°15'00" W

— 43°55'00" N, 006°46'00" W

— 43°55'00" N, 006°37'00" W

— 43°53'00" N, 006°46'00" W

— 43°53'00" N, 006°37'00" W

- 44°00'49" N, 007°01'12" W
- 44°00'49" N, 006°57'26" W
- 43°58'32" N, 006°57'26" W
- 43°58'32" N, 007°01'12" W
- 44°02'48" N, 007°13'49" W
- 44°00'15" N, 007°10'03" W
- 44°00'15" N, 007°10'03" W
- 44°00'15" N, 007°13'49" W
- 44°10'00" N, 008°18'00" W
- 44°10'00" N, 008°14'00" W
- 44°07'00" N, 008°14'00" W
- 44°07'00" N, 008°18'00" W
- 43°34'00" N, 004°44'00" W
- 43°34'00" N, 004°39'00" W
- 43°32'00" N, 004°39'00" W
- 43°32'00" N, 004°44'00" W
- 44°07'00" N, 007°50'00" W
- 44°07'00" N, 007°45'00" W
- 44°05'00" N, 007°45'00" W
- 44°05'00" N, 007°50'00" W

5.2. From 1 January to 30 June each year, fishing for red seabream in ICES subarea 8 shall be prohibited to vessels flying the French flag.

5.3. For recreational fisheries, fishing for red seabream shall be prohibited within the geographical areas enclosed by sequentially joining with rhumb lines the following coordinates, which shall be measured according to the WGS84 system:

Area RF 1 (Cariño/Celeiro)

- 43°46'23" N, 007°52'04" W
- 43°48'30" N, 007°52'04" W
- 43°49'26" N, 007°41'17" W
- 43°45'44" N, 007°33'21" W
- 43°43'49" N, 007°33'21" W

Area RF 2 (Ribadeo)

- 43°33'26" N, 007°02'58" W
- 43°35'27" N, 007°02'58" W
- 43°35'29" N, 007°01'20" W
- 43°33'33" N, 007°01'20" W

Area RF 3 (Navia):

- 43°33'51" N, 006°44'02" W
- 43°35'52" N, 006°44'02" W
- 43°35'52" N, 006°42'32" W
- 43°33'52" N, 006°42'32" W

Area RF 4 (Ensenada Canero)

- 43°33'10" N, 006°28'55" W
- 43°34'53" N, 006°30'17" W

— 43°36'14" N, 006°28'13" W

— 43°34'18" N, 006°28'13" W

Area RF 5 (Ensenada de Cabrera/Ría San Martín de la Arena)

— 43°26'18" N, 004°04'51" W

— 43°28'22" N, 004°04'51" W

— 43°28'55" N, 004°01'17" W

— 43°26'56" N, 004°01'17" W

Area RF 6 (Ría de Treto)

— 43°27'49" N, 003°25'58" W

— 43°28'59" N, 003°23'36" W

— 43°26'16" N, 003°22'27" W

— 43°25'09" N, 003°24'41" W

Area RF 7 (Bilbao/Plentzia)

— 43°21'18" N, 003°07'47" W

— 43°23'18" N, 003°07'47" W

— 43°28'13" N, 002°56'42" W

— 43°26'08" N, 002°56'42" W

Area RF 8 (Bermeo/Mundaka)

— 43°25'36" N, 002°43'23" W

— 43°27'35" N, 002°43'23" W

— 43°26'57" N, 002°38'45" W

— 43°24'57" N, 002°38'45" W

5.4. The measures listed in points 5.1 to 5.3 shall apply until 31 December 2023.'

COMMISSION DELEGATED REGULATION (EU) 2023/57
of 31 October 2022
amending and correcting Delegated Regulation (EU) 2022/127 supplementing Regulation (EU) 2021/2116 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 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 44(5), Article 64(3), point (d), and Article 94(5) 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) In accordance with Article 44(3a) of Regulation (EU) 2021/2116, Member States may decide to pay advances to beneficiaries as regards the interventions referred to in Title III, Chapter III, of Regulation (EU) 2021/2115 of the European Parliament and of the Council ⁽³⁾ and as regards measures regulating or supporting agricultural markets. In order to ensure a coherent and non-discriminatory payment of advances and to guarantee the protection of Union funds, it is appropriate to set out specific conditions for the payment of advances in the form of maximum percentages of forecast expenditure and the requirement for beneficiaries to lodge a security.
- (3) In addition, the provisions on securities laid down in Chapter IV of Delegated Regulation (EU) 2022/127 should be adapted to take into account those specific conditions.
- (4) In Article 24(4) of Delegated Regulation (EU) 2022/127, the reference to Article 27 is incorrect and should be replaced by a reference to Article 26 of that Regulation.
- (5) For aid payments under apiculture programmes made pursuant to Article 55 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽⁴⁾, it is appropriate to ensure continuity by maintaining the currently applicable operative event for the exchange rate.
- (6) Delegated Regulation (EU) 2022/127 should therefore be amended and corrected accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) 2022/127

Delegated Regulation (EU) 2022/127 is amended as follows:

⁽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⁾ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

⁽⁴⁾ 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).

(1) the following Chapter IIIa is inserted:

‘CHAPTER IIIa

Specific conditions for the payment of advances

Article 15a

Specific conditions for the payment of advances referred to in Article 44(3a) of Regulation (EU) 2021/2116

1. The payment of advances referred to in Article 44(3a) of Regulation (EU) 2021/2116 shall not exceed 80 % of the forecasted expenditure of the approved operational programme or, where relevant, of the interventions referred to in Articles 55 and 58 of Regulation (EU) 2021/2115.

2. The payment of advances referred to in paragraph 1 shall be subject to the lodging of a security at least equivalent to the amount of the advance.’;

(2) Article 27 is replaced by the following:

Article 27

Scope

This Section shall apply in cases where specific Union rules provide that a sum may be advanced before the obligation established to obtain any aid or advantage has been met.’;

(3) in Article 28, the following paragraph 1a is inserted:

‘1a. Applications for the release of the security relating to advance payments shall be accompanied by supporting documents proving final entitlement to the sum granted or that the sum granted, plus any addition provided for in the specific Union rules, has been repaid.’;

(4) the following Article 31a is inserted:

Article 31a

Apiculture programmes

For amounts paid as aid under apiculture programmes pursuant to Article 55 of Regulation (EU) No 1308/2013, the operative event for the exchange rate shall be 1 January of the year when the payment is made.’.

Article 2

Correction to Delegated Regulation (EU) 2022/127

In Article 24 of Delegated Regulation (EU) 2022/127, the first subparagraph of paragraph 4 is replaced by the following:

‘4. If an obligation is fulfilled timely, and the presentation of the proof of fulfilment is subject to a fixed time limit, the security covering that obligation shall be forfeited for each calendar day exceeding that time limit according to the formula $0,2/\text{time limit in days set and taking account of Article 26}$.’.

Article 3

Entry into force

This Regulation shall enter into force on the seventh 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, 31 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/58

of 5 January 2023

authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ has established a Union list of novel foods.
- (3) On 7 January 2018, the company Ynsect NL B.V. (formerly known as Proti-Farm Holding NV) ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) on the Union market as a novel food. The applicant requested for *Alphitobius diaperinus* larvae in frozen, paste (ground), dried, and powder (ground) forms to be used as a food ingredient in a number of food products for the general population, and in powder form in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ for the adult population.
- (4) The applicant also made a request to the Commission for the protection of proprietary scientific data for a number of studies submitted in support of the application, namely analytical data on the composition of the novel food ⁽⁴⁾, the stability studies on the novel food ⁽⁵⁾, an *in vitro* protein digestibility study ⁽⁶⁾, and a sub-chronic 90-day toxicity study ⁽⁷⁾.
- (5) On 17 July 2018, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of frozen and freeze-dried forms of the *Alphitobius diaperinus* larvae as a novel food.
- (6) On 26 April 2022, the Authority adopted its scientific opinion on the 'Safety of frozen and freeze-dried formulations of the lesser mealworm (*Alphitobius diaperinus* larvae) as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁸⁾ in accordance with Article 11 of Regulation (EU) 2015/2283.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁴⁾ Ynsect NL B.V. 2018, 2019, 2020 and 2021 (unpublished).

⁽⁵⁾ Ynsect NL B.V. 2019 and 2020 (unpublished).

⁽⁶⁾ Ynsect NL B.V. 2018 and 2019 (unpublished).

⁽⁷⁾ Ynsect NL B.V. 2021 (unpublished).

⁽⁸⁾ EFSA Journal 2022; 20(7):7325.

- (7) In its scientific opinion, the Authority concluded that the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae are safe under the proposed conditions of use at the proposed use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae under the assessed conditions of use fulfil the conditions for their placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In that scientific opinion, the Authority also concluded, based on limited published evidence on food allergy related to insects, that the consumption of the novel food may induce primary sensitisation and allergic reactions to lesser mealworm proteins. The Authority recommended carrying out further research on the allergenicity of *Alphitobius diaperinus* larvae.
- (9) In order to address the Authority's recommendation, the Commission is currently exploring the ways to carry out the necessary research on the allergenicity of *Alphitobius diaperinus* larvae. Until the data generated by the research is assessed by the Authority, and considering that, to date, evidence directly linking the consumption of *Alphitobius diaperinus* larvae to cases of primary sensitisation and allergies is inconclusive, the Commission considers that no specific labelling requirements concerning the potential of *Alphitobius diaperinus* larvae to cause primary sensitization should be included in the Union list of authorised novel foods.
- (10) In its scientific opinion, the Authority also considered that the consumption of *Alphitobius diaperinus* larvae may cause allergic reactions in persons that are allergic to crustaceans and dust mites. Furthermore, the Authority noted that additional allergens may end up in the novel food, if these allergens are present in the substrate fed to insects. Therefore, it is appropriate that frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae as such and foods containing them are appropriately labelled in accordance with Article 9 of Regulation (EU) 2015/2283.
- (11) Food supplements containing the powder form of *Alphitobius diaperinus* larvae should not be consumed by persons under 18 years of age and therefore, a labelling requirement should be provided in order to properly inform the consumers about that.
- (12) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on the analytical data on the composition of the novel food, the stability studies on the novel food, the *in vitro* protein digestibility study, and the sub-chronic 90-day toxicity study submitted by the applicant, without which it could not have assessed the novel food and reached its conclusion.
- (13) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (14) The applicant declared that they held proprietary and exclusive right of reference to the scientific data from those studies at the time they submitted the application.
- (15) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific data on the composition of the novel food, the stability studies on the novel food, the *in vitro* protein digestibility study, and the sub-chronic 90-day toxicity study should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae on the market within the Union during a period of 5 years from the entry into force of this Regulation.
- (16) However, restricting the authorisation of frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae and the reference to the scientific data contained in the applicant's file to the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food, provided that their application is based on legally obtained information supporting such authorisation.

- (17) It is appropriate that the inclusion of frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (18) Frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (19) 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

1. The frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) are authorised to be placed on the market within the Union.

The frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Ynsect NL B.V. (*) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from the date of entry into force of this Regulation, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Ynsect NL B.V.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of Ynsect NL B.V.

Article 4

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, 5 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

(*) Address: Harderwijkerweg 141B, 3852 AB Ermelo, the Netherlands.

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Frozen, paste, dried and powder forms of <i>Alphitobius diaperinus</i> larvae (lesser mealworm)	Specified food category	Maximum levels (g/100g)	<ol style="list-style-type: none"> The designation of the novel food on the labelling of the foodstuffs containing it shall be “Frozen/paste <i>Alphitobius diaperinus</i> larvae (lesser mealworm)” or “Dried/powder <i>Alphitobius diaperinus</i> larvae (lesser mealworm)” depending on the form used. The labelling of food supplements containing the novel food shall bear a statement that those food supplements should not be consumed by persons under 18 years of age. The labelling of the foodstuffs containing frozen, paste, dried or powder forms of <i>Alphitobius diaperinus</i> larvae (lesser mealworm) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, and products thereof, and to dust mites. <p>This statement shall appear in close proximity to the list of ingredients.</p>		<p>Authorised on 26.1.2023. This inclusion is based on proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Ynsect NL B.V, Harderwijkerweg 141B, 3852 AB Ermelo, the Netherlands.</p> <p>During the period of data protection, the novel food is authorised for placing on the market within the Union only by Ynsect NL B.V., unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283, or with the agreement of Ynsect NL B.V.</p> <p>End date of the data protection: 26.1.2028.’</p>
	Cereal bars	25 (Dried form) 25 (Powder form)			
	Bread and rolls	20 (Powder form)			
	Processed and breakfast cereals	10 (Dried form) 10 (Powder form)			
	Porridge	15 (Powder form)			
	Pre-mixes (dry) for baked products	10 (Powder form)			
	Dried pasta-based products	10 (Powder form)			
	Stuffed pasta-based products	28 (Frozen or paste form) 10 (Powder form)			
	Whey powder	35 (Powder form)			
	Soups	15 (Powder form)			
	Cereal-, pasta-based dishes	5 (Powder form)			
	Pizza-based dishes	5 (Dried form) 5 (Powder form)			
	Noodles	10 (Powder form)			
Snacks other than chips	10 (Dried form) 10 (Powder form)				

Chips/crisps	10 (Powder form)			
Crackers and bread sticks	10 (Powder form)			
Peanut butter	15 (Powder form)			
Ready-to-eat savoury based sandwich	20 (Powder form)			
Meat preparations	14 (Frozen or paste form) 5 (Powder form)			
Meat analogues	40 (Frozen or paste form) 15 (Powder form)			
Milk and dairy analogues	10 (Powder form)			
Chocolate confectionary	5 (Powder form)			
Food supplements as defined in Directive 2002/46/EC for the adult population	4 g/day (Powder form)			

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised novel food	Specification
Frozen, paste, dried and powder forms of <i>Alphitobius diaperinus</i> larvae (lesser mealworm)	<p>Description/Definition: The novel food consists of the frozen, paste, dried, and powder forms of the whole lesser mealworm. The term “lesser mealworm” refers to the larval form of <i>Alphitobius diaperinus</i>, an insect species that belongs to the family of <i>Tenebrionidae</i> (darkling beetles). The entire lesser mealworms are meant for human consumption, no parts are removed. The novel food is intended to be marketed in 4 different forms, namely: (i) whole blanched and frozen <i>A. diaperinus</i> larvae (ADL frozen), (ii) paste from whole blanched, ground, and frozen <i>A. diaperinus</i> larvae (ADL paste), (iii) whole blanched, and freeze-dried <i>A. diaperinus</i> larvae (ADL dried), and (iv) powder from whole blanched, freeze-dried and ground <i>A. diaperinus</i> larvae (ADL powder). A minimum 24 hours fasting period is required to allow the larvae to discard their bowel content before killing the insects by a thermal treatment.</p>

Characteristics/Composition (ADL frozen or paste):	Characteristics/Composition (ADL dried or powder):
<p>Ash (% w/w): ≤ 1,5</p> <p>Moisture (% w/w): 65-80</p> <p>Crude protein (N × 6,25) (% w/w): 12-25</p> <p>Digestible Carbohydrates (% w/w): 0,4-2</p> <p>Fat (% w/w): 5-12</p> <p>Peroxide value (Meq O₂/kg fat): ≤ 0,2</p> <p>Dietary fibre (% w/w): 1-4</p> <p>(*)Chitin (% w/w): 1,0-2,6</p> <p>Heavy metals:</p> <p>Lead: ≤ 0,1 mg/kg</p> <p>Cadmium: ≤ 0,05 mg/kg</p> <p>Mycotoxins:</p> <p>Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg</p> <p>Aflatoxin B1 (µg/kg): ≤ 2</p> <p>Deoxynivalenol: ≤ 200 µg/kg</p> <p>Ochratoxin A: ≤ 1 µg/kg</p> <p>Microbiological criteria:</p> <p>Total aerobic colony count: ≤ 10⁵ (**)CFU/g</p> <p>Yeasts and moulds: ≤ 100 CFU/g</p> <p><i>Escherichia coli</i>: ≤ 50 CFU/g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p><i>Listeria monocytogenes</i>: Absence in 25 g</p> <p>Sulphite-reducing Anaerobes: ≤ 30 CFU/g</p> <p><i>Bacillus cereus</i>: ≤ 100 CFU/g</p> <p>Enterobacteriaceae: ≤ 100 CFU/g</p> <p>Coagulase-positive <i>staphylococci</i>: ≤ 100 CFU/g</p>	<p>Ash (% w/w): ≤ 5</p> <p>Moisture (% w/w): 1-5</p> <p>Crude protein (N × 6,25) (% w/w): 50-70</p> <p>Digestible Carbohydrates (% w/w): 1,5-3,5</p> <p>Fat (% w/w): 20-35</p> <p>Peroxide value (Meq O₂/kg fat): ≤ 5</p> <p>Dietary fibre (% w/w): 3-6</p> <p>(*)Chitin (% w/w): 3,0-9,1</p> <p>Heavy metals:</p> <p>Lead: ≤ 0,1 mg/kg</p> <p>Cadmium: ≤ 0,05 mg/kg</p> <p>Mycotoxins:</p> <p>Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg</p> <p>Aflatoxin B1 (µg/kg): ≤ 2</p> <p>Deoxynivalenol: ≤ 200 µg/kg</p> <p>Ochratoxin A: ≤ 1 µg/kg</p> <p>Microbiological criteria:</p> <p>Total aerobic colony count: ≤ 10⁵ CFU/g</p> <p>Yeasts and moulds: ≤ 100 CFU/g</p> <p><i>Escherichia coli</i>: ≤ 50 CFU/g</p> <p><i>Salmonella</i> spp.: Absence in 25 g</p> <p><i>Listeria monocytogenes</i>: Absence in 25 g</p> <p>Sulfite-reducing Anaerobes: ≤ 30 CFU/g</p> <p><i>Bacillus cereus</i>: ≤ 100 CFU/g</p> <p>Enterobacteriaceae: ≤ 100 CFU/g</p> <p>Coagulase-positive <i>staphylococci</i>: ≤ 100 CFU/g</p>
<p>(*) Chitin calculated as Acid Detergent Fibre.</p> <p>(**) CFU: Colony Forming Units.</p>	

COMMISSION IMPLEMENTING REGULATION (EU) 2023/59

of 5 January 2023

concerning the authorisation of a preparation of *Pediococcus pentosaceus* DSM 32292 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.
- (2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Pediococcus pentosaceus* DSM 32292. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of *Pediococcus pentosaceus* DSM 32292 as a feed additive for all animal species, to be classified in the additive category 'technological additives' and in the functional group 'silage additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Pediococcus pentosaceus* DSM 32292 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that it should be considered a respiratory sensitiser and noted that no conclusions could be drawn on its eye and skin irritancy or skin sensitisation potential. The Authority further concluded that the additive, at the proposed concentration, has the potential to improve the preservation of nutrients in silage prepared with moderately difficult to ensile material. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of *Pediococcus pentosaceus* DSM 32292 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the preparation should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) 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

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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2022;20(7):7426.

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, 5 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
1k1018	<i>Pediococcus pentosaceus</i> DSM 32292	<p><i>Additive composition:</i></p> <p>Preparation of <i>Pediococcus pentosaceus</i> DSM 32292 containing a minimum of 1×10^{10} CFU/g additive</p> <p><i>Characterisation of the active substance:</i></p> <p>Viable cells of <i>Pediococcus pentosaceus</i> DSM 32292</p> <p><i>Analytical method</i> ⁽¹⁾:</p> <p>Enumeration in the feed additive: Spread plate method on MRS agar (EN 15786)</p> <p>Identification: Pulsed-Field Gel Electrophoresis (PFGE) or DNA sequencing methods</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 5×10^7 CFU/kg of easy and moderately difficult to ensile fresh material ⁽²⁾. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection. 	26.1.2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁽²⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in the fresh material, in accordance with Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2023/60**of 5 January 2023****concerning the authorisation of conjugated linoleic acid (t10, c12)-methylester as a feed additive for pigs for fattening and dairy cows (holder of authorisation: BASF SE)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.
- (2) The substance conjugated linoleic acid (t10, c12)-methylester was authorised without a time limit in accordance with Council Directive 70/524/EEC ⁽²⁾ as a feed additive for all animal species, and was included in the category 'nutritional additives' and functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. That substance was subsequently entered into the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) The inclusion of conjugated linoleic acid (t10, c12)-methylester in the group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect' was based on a report of 18 March 1994 of the Scientific Committee for Animal Nutrition on the classification of vitamins in the Annex to Directive 70/524/EEC. This report considered that this substance had a similar effect to that of a vitamin.
- (4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted on 13 October 2010 for the authorisation of conjugated linoleic acid (t10, c12)-methylester as a feed additive for pigs for fattening and dairy cows. The applicant requested the additive to be classified in the additive category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 December 2015 ⁽³⁾ that, under the proposed conditions of use, conjugated linoleic acid (t10, c12)-methylester used in the nutrition of pigs for fattening and dairy cows does not have adverse effects on animal health, consumer safety or the environment. Concerning pigs for fattening, the Authority concluded that conjugated linoleic acid (t10, c12)-methylester might have a potential for an improvement of the feed to gain ratio. It effectively increases fat firmness due to an increased amount of saturated fatty acids in the subcutaneous fat. There is also an increase in intramuscular fat, its degree of saturation and in marbling score. Conjugated linoleic acid (t10, c12)-methylester might also have a potential to improve the proportion of lean meat to subcutaneous fat in the carcass. For dairy cows, the Authority concluded that conjugated linoleic acid (t10, c12)-methylester reduces milk fat content and has the potential to reduce milk fat

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2016;14(1):4348.

yield and milk energy output. In a further opinion of 24 January 2019 ⁽⁴⁾, the Authority stated that the allocation of this additive to the category 'nutritional additives' did not seem to be justified. The Commission, taking into account the considerations from the Authority and the effects of the additive on the zootechnical performance of pigs for fattening and dairy cows, has decided to classify this additive under the category 'zootechnical additives' and under the functional group 'other zootechnical additives'.

- (6) The Authority concluded that the exposure of users by inhalation of the solid product is likely to be minimal. As regards the liquid product, no data on potential mist formation were provided. A beadlet formulation of the liquid product elicited mild but persistent dermal irritation, whereas it was not an eye irritant. The skin sensitisation potential was masked by the effect of the placebo. Neither the liquid nor the solid product was tested as such for skin and eye irritation and skin sensitisation. The Authority further concluded that the additive was effective. The Authority does not consider that there is a need for specific requirements of post-market monitoring. The initial method of analysis provided by the applicant was validated by the Reference Laboratory set up by Regulation (EC) No 1831/2003 and verified by EFSA. Due to the fact that maximum/minimum contents are established in the EFSA opinion, the first method of analysis was not considered sufficient for the purpose of Regulation (EC) No 1831/2003 as the method applied only to feed additives but not to premixtures and feedingstuffs and did not quantify the level of incorporation of the additive in those premixtures and feedingstuffs. The applicant submitted a second method for the quantification in premixtures and feedingstuffs that was validated by the Reference Laboratory.
- (7) The assessment of conjugated linoleic acid (t10, c12)-methyl ester shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of conjugated linoleic acid (t10, c12)-methyl ester to the use of that substance in the nutrition of pigs for fattening and dairy cows, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

The substance specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as a feed additive for fattening pigs and dairy cows, in accordance with the conditions laid down in that Annex.

Article 2

1. The substance specified in the Annex and premixtures containing that substance, which are intended for pigs for fattening and dairy cows and are produced and labelled before 26 July 2023 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

⁽⁴⁾ EFSA Journal 2019;17(3):5614.

2. Feed materials and compound feed containing the substance specified in the Annex, which are intended for pigs for fattening and dairy cows and are produced and labelled before 26 January 2024 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 5 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of Zootechnical additives. Functional group: Other zootechnical additives (improvement of zootechnical parameters/performance)									
4d895	BASF SE	Conjugated linoleic acid (t10, c12)-methylester	<p><i>Additive composition:</i> Preparation of omega-6-fatty acid as t10,c12-octadecadienoic acid (conjugated linoleic acid)-methylester (CLA(t10,c12)-ME).</p> <p><i>Liquid formulation:</i> CLA (t10,c12)-ME ≥ 28 % CLA (c9,t11)-ME ≥ 28 % CLA (t10,c12) < 2 % CLA (c9,t11) < 2 % Fatty acids of sunflower oil: 38-42 % free or as methylesters and less than 1 % as trans trans isomers.</p> <p><i>Solid formulation:</i> CLA (t10,c12)-ME: ≥ 9 % CLA (c9,t11)-ME: ≥ 9 % CLA (t10,c12): < 1 % CLA (c9,t11): < 1 % Fatty acids of sunflower oil: 13-15 % (free or as methylesters). Vegetable oils (hydrogenated triglycerides, predominantly stearic acid and to a minor extent palmitic acid): 44,5 %. Colloidal silica: 15 %. Calcium sulphate: 5 %.</p>	Pigs for fattening	-	400	5 000	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. For dairy cows, the level of CLA (t10,c12)-ME in the daily ration shall not exceed 10 g/head/day. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential health risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and skin protection. 	26.1.2033
				Dairy cows	-	175	350		

		<p><i>Characterisation of the active substance:</i> Conjugated linoleic acid (t10,c12)-methylester. Chemical formula: C₁₉ H₃₄O₂ CAS number: 21870-97-3</p> <p><i>Analytical method : ⁽¹⁾</i></p> <ul style="list-style-type: none"> — For the determination of Omega-6-fatty acid as octadecadienoic acid (trans-10, cis-12- isomer) in feed additive: gas Chromatography coupled to Flame Ionization Detector (GC-FID) — For the quantification of CLA (t10,c12)-methylester in premixtures and feedingstuffs: <ul style="list-style-type: none"> — high performance liquid chromatography coupled to spectrophotometric detection (HPLC-UV) 						
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/61

of 5 January 2023

concerning the authorisation of a preparation of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, a preparation of endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, a preparation of endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and a preparation of endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 as feed additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾. Article 10(7) of Regulation (EC) No 1831/2003 sets out specific provisions for the placing on the market and use of products used in the Union as silage additives.
- (2) The preparations of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 were entered in the Register of feed additives as existing products ⁽³⁾ for all animal species belonging to the functional group of silage additives, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(2) and Article 7 thereof, an application was submitted for the authorisation of the preparations of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 as feed additives for all animal species. The applicant requested the preparations to be classified in the additive category 'technological additives' and the functional group 'silage additives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 7 March 2018 ⁽⁴⁾ and 29 June 2022 ⁽⁵⁾, that, under the proposed conditions of use, the preparations concerned do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that in the absence of data, no conclusion could be drawn on the skin and eye irritancy of the additives and on their skin sensitisation potential. Owing to the proteinaceous nature of the active substances, these preparations should be considered to be potential

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ In the Register of feed additives: endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604 was identified as cellulase from *Aspergillus niger* CBS 120604; endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199 was identified as beta-glucanase from *Aspergillus niger* MUCL 39199 or *Aspergillus tubingensis* MUCL 39199; endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 was identified as xylanase from *Trichoderma longibrachiatum* MUCL 39203 or *Trichoderma koningii* MUCL 39203; endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 was identified as xylanase from *Trichoderma longibrachiatum* CBS 614.94.

⁽⁴⁾ EFSA Journal 2018;16(4):5224.

⁽⁵⁾ EFSA Journal 2022;20(7):7425.

respiratory sensitisers. The Authority further concluded in its opinion of 29 June 2022 that the preparations concerned have the potential to improve the production of silage from easy, moderate and difficult to ensile forage materials. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of the preparations of endo-1,4-beta-glucanase from *Aspergillus niger* CBS 120604, endo-1,3(4)-beta-glucanase from *Aspergillus neoniger* MUCL 39199, endo-1,4-beta-xylanase from *Trichoderma citrinoviride* MUCL 39203 and endo-1,4-beta-xylanase from *Trichoderma citrinoviride* CBS 614.94 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparations concerned, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) 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

Authorisation

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

Article 2

Transitional measures

1. The preparations specified in the Annex and premixtures containing these preparations, which are produced and labelled before 26 July 2023 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparations specified in the Annex which are produced and labelled before 26 January 2024 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the preparations specified in the Annex which are produced and labelled before 26 January 2025 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

Entry into force

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, 5 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity of additive/kg of fresh material			
Category: technological additives. Functional group: silage additives.								
1k105	Endo-1,4-beta-glucanase (EC 3.2.1.4)	<p><i>Additive composition</i> Preparation of endo-1,4-beta-glucanase produced by: <i>Aspergillus niger</i> CBS 120604, having a minimum activity of 25 650 DNS ⁽¹⁾/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-glucanase (EC 3.2.1.4) produced by <i>Aspergillus niger</i> CBS 120604</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For the determination of endo-1,4-beta-glucanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the carboxymethyl cellulose (CMC) at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 3 DNS/kg of fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye, and breathing protection. 	26 January 2033

⁽¹⁾ 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as glucose equivalents in µmol per g per min at pH 4,5 and 37 °C from starch.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity of additive/kg of fresh material			
Category: technological additives. Functional group: silage additives.								
1k106	Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,3(4)-β-glucanase produced by:</p> <p><i>Aspergillus neoniger</i> MUCL 39199, having a minimum activity of 10 000 DNS ⁽¹⁾/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by <i>Aspergillus neoniger</i> MUCL 39199</p> <p><i>Analytical method ⁽²⁾</i></p> <p>For the determination of endo-1,3(4)-beta-glucanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the carboxymethyl cellulose (CMC) at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 3,4 DNS/kg of fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection. 	26 January 2033

⁽¹⁾ 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as glucose equivalents in μmol per g per min at pH 4,5 and 37 °C from starch.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity of additive/kg of fresh material			
Category: technological additives. Functional group: silage additives.								
1k107	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase produced by:</p> <p><i>Trichoderma citrinoviride</i> MUCL 39203, having a minimum activity of 51 600 DNS ⁽¹⁾/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma citrinoviride</i> MUCL 39203</p> <p><i>Analytical method ⁽²⁾</i></p> <p>For the determination of endo-1,4-beta-xylanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the xylan at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 3,2 DNS/kg of fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection. 	26 January 2033

⁽¹⁾ 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as xylose equivalents in µmol per g per min at pH 4,5 and 37 °C from birchwood xylan.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity of additive/kg of fresh material			

Category: technological additives. Functional group: silage additives.

1k108	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase produced by:</p> <p><i>Trichoderma citrinoviride</i> CBS 614.94, having a minimum activity of 70 000 DNS ⁽¹⁾/g additive</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma citrinoviride</i> CBS 614.94</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For the determination of endo-1,4-beta-xylanase in the feed additive:</p> <p>— colorimetric (DNS) method based on the enzymatic hydrolysis of the xylan at pH 4,5 and 37 °C</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other enzymes or micro-organisms as silage additives: 15 DNS/kg of fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection. 	26 January 2033
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⁽¹⁾ 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as xylose equivalents in µmol per g per min at pH 4,5 and 37 °C from birchwood xylan.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

COMMISSION IMPLEMENTING REGULATION (EU) 2023/62**of 5 January 2023****correcting the Polish language version of Regulation (EU) No 1300/2014 on the technical specifications for interoperability relating to accessibility of the Union's rail system for persons with disabilities and persons with reduced mobility****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union ⁽¹⁾, and in particular Article 5(11) thereof,

Whereas:

- (1) The Polish language version of the Annex to Commission Regulation (EU) No 1300/2014 ⁽²⁾ contains an error in point 4.2.1.4 subpoint (2) that broadens the scope of the requirement set out in that provision.
- (2) The Polish language version of the Annex to Regulation (EU) No 1300/2014 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 51(1) of Directive (EU) 2016/797, delivered on 30 January 2014,

HAS ADOPTED THIS REGULATION:

*Article 1**(does not concern the English language)**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, 5 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹⁾ OJ L 138, 26.5.2016, p. 44.

⁽²⁾ Commission Regulation (EU) No 1300/2014 of 18 November 2014 on the technical specifications for interoperability relating to accessibility of the Union's rail system for persons with disabilities and persons with reduced mobility (OJ L 356, 12.12.2014, p. 110).

DECISIONS

DECISION No 1/2022 OF THE JOINT COMMITTEE ON AGRICULTURE

of 17 November 2022

amending Annexes 1 and 2 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products [2023/63]

THE JOINT COMMITTEE ON AGRICULTURE,

Having regard to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products, and in particular Article 11 thereof,

Whereas:

- (1) The Agreement between the European Community and the Swiss Confederation on trade in agricultural products ('the Agreement') entered into force on 1 June 2002.
- (2) Annexes 1 and 2 to the Agreement list the tariff concessions granted by the Swiss Confederation and the European Union ('the Parties'), respectively.
- (3) The Parties have agreed to amend Annexes 1 and 2 to the Agreement following the latest review of the Harmonised System and an error made in the latest adaptation of Annex 1 concerning the tariff concession for boneless hams. It has also been decided to incorporate into Annex 1 to the Agreement the tariff concessions granted by Switzerland in 1996 for dog and cat food intended for sale,

HAS DECIDED AS FOLLOWS:

Article 1

Annexes 1 and 2 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products are replaced, respectively, by the texts contained in the annexes to this Decision.

Article 2

This Decision shall enter into force on 1 January 2023.

Done at Brussels, 17 November 2022.

For the Joint Committee on Agriculture

*The Chair, and the Head of the
European Union Delegation*
Frank BOLLEN

The Head of the Swiss Delegation
Michèle DRÄPPEN

The Committee Secretary
Luis QUEVEDO LEY

—

ANNEX 1

CONCESSIONS GRANTED BY SWITZERLAND

The tariff concessions set out below are granted by Switzerland for the following products originating in the European Union and are, where applicable, subject to an annual quantity:

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
0101 2991	Live horses (excluding pure-bred horses for breeding and horses for slaughter) (in number of head)	0.00	100 head
0204.5010	Goat meat, fresh, chilled or frozen	40.00	100
0207.1481	Breasts of fowls of domestic species, frozen	15.00	2 100
0207.1491	Cuts and edible offal of fowls of domestic species, including livers (excluding breasts), frozen	15.00	1 200
0207.2781	Breasts of turkeys of domestic species, frozen	15.00	800
0207.2791	Cuts and edible offal of turkeys of domestic species, including livers (excluding breasts), frozen	15.00	600
0207.4210	Ducks of domestic species, not cut in pieces, frozen	15.00	700
	Fatty livers of ducks or geese of domestic species, fresh or chilled		
0207.4300	— of ducks		
0207.5300	— of geese	9.50	20
	Cuts and edible offal of ducks, geese or guinea fowls of domestic species, frozen (excluding fatty livers)		
0207.4591	— of ducks		
0207.5591	— of geese		
0207.6091	— of guinea fowls	15.00	100
0208.1000	Fresh, chilled or frozen meat and edible offal of rabbits or hares	11.00	1 700
0208.9010	Meat and edible offal of game, fresh, chilled or frozen (other than of hares or wild boar)	0.00	100
ex 0210 1191	Hams and cuts thereof, with bone in, of swine (other than wild boar), salted or in brine, dried or smoked		
ex 0210 1991	Hams and cuts thereof, boneless, of swine (other than wild boar), salted or in brine, dried or smoked	0.00	1 000 ⁽¹⁾
0210.2010	Dried meat of bovine animals	0.00	200 ⁽²⁾
	Edible birds' eggs, in shell		
ex 0407 2110	— of fowls of the species <i>Gallus domesticus</i> , fresh		

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
ex 0407 2910	— other, fresh		
ex 0407 9010	— other, preserved or cooked	47.00	150
ex 0409 0000	Natural acacia honey	8.00	200
ex 0409 0000	Natural honey, other (excluding acacia)	26.00	50
0602.1000	Unrooted cuttings and slips	0.00	unlimited
	Plants in the form of pomaceous fruit rootstock (of seedling origin or produced by vegetative propagation):		
0602.2011	— grafted, bare-rooted		
0602.2019	— grafted, with root ball		
0602.2021	— not grafted, bare-rooted		
0602.2029	— not grafted, with root ball	0.00	(³)
	Plants in the form of stone fruit rootstock (of seedling origin or produced by vegetative propagation):		
0602.2031	— grafted, bare-rooted		
0602.2039	— grafted, with root ball		
0602.2041	— not grafted, bare-rooted		
0602.2049	— not grafted, with root ball	0.00	(³)
	Plants other than in the form of pomaceous or stone fruit rootstock (of seedling origin or produced by vegetative propagation), of kinds which bear edible fruit:		
0602.2051	— with bare roots		
0602.2059	— other than bare-rooted	0.00	unlimited
	Trees, shrubs and bushes, of kinds which bear edible fruit, bare-rooted:		
0602.2071	— of kinds which bear pomaceous fruit		
0602.2072	— of kinds which bear stone fruit	0.00	(³)
0602.2079	— other than of kinds which bear pomaceous or stone fruit	0.00	unlimited
	Trees, shrubs and bushes, of kinds which bear edible fruit, with root ball:		
0602.2081	— of kinds which bear pomaceous fruit		
0602.2082	— of kinds which bear stone fruit	0.00	(³)
0602.2089	— other than of kinds which bear pomaceous or stone fruit	0.00	unlimited
0602.3000	Rhododendrons and azaleas, grafted or not	0.00	unlimited
	Roses, grafted or not:		

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
0602.4010	— wild roses and wild rose stems		
	— other than wild roses or wild rose stems:		
0602.4091	— with bare roots		
0602.4099	— other than bare-rooted, with root ball	0.00	unlimited
	Plants (of seedling origin or produced by vegetative propagation), of useful species; mushroom spawn:		
0602.9011	— seedling vegetables and turf rolls		
0602.9012	— mushroom spawn		
0602.9019	— other than seedling vegetables, turf rolls or mushroom spawn	0.00	unlimited
	Other live plants (including their roots):		
0602.9091	— with bare roots		
0602.9099	— other than bare-rooted, with root ball	0.00	unlimited
0603.1110	Cut roses of a kind suitable for bouquets or for ornamental purposes, fresh, from 1 May to 25 October		
0603.1210	Cut carnations of a kind suitable for bouquets or for ornamental purposes, fresh, from 1 May to 25 October		
0603.1310	Cut orchids of a kind suitable for bouquets or for ornamental purposes, fresh, from 1 May to 25 October		
0603.1410	Cut chrysanthemums of a kind suitable for bouquets or for ornamental purposes, fresh, from 1 May to 25 October		
0603.1510	Cut lilies (<i>Lilium</i> spp.) of a kind suitable for bouquets or for ornamental purposes, fresh, from 1 May to 25 October		
	Other cut flowers and flower buds, of a kind suitable for bouquets or for ornamental purposes, fresh, from 1 May to 25 October:		
0603.1911	— woody		
0603.1918	— other than woody	0.00	1 000
0603.1230	Cut carnations of a kind suitable for bouquets or for ornamental purposes, fresh, from 26 October to 30 April	0.00	unlimited
0603.1330	Cut orchids of a kind suitable for bouquets or for ornamental purposes, fresh, from 26 October to 30 April		
0603.1430	Cut chrysanthemums of a kind suitable for bouquets or for ornamental purposes, fresh, from 26 October to 30 April		

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
0603.1530	Cut lilies (<i>Lilium</i> spp.) of a kind suitable for bouquets or for ornamental purposes, fresh, from 26 October to 30 April		
0603.1930	Cut tulips of a kind suitable for bouquets or for ornamental purposes, fresh, from 26 October to 30 April		
	Other cut flowers and flower buds, of a kind suitable for bouquets or for ornamental purposes, fresh, from 26 October to 30 April:		
0603.1931	— woody		
0603.1938	— other than woody	0.00	unlimited
	Tomatoes, fresh or chilled:		
0702.0010	cherry tomatoes: — from 21 October to 30 April		
0702.0020	Peretti tomatoes (elongated): — from 21 October to 30 April		
0702.0030	— other tomatoes, of a diameter of 80 mm or more (beef tomatoes): — from 21 October to 30 April		
0702.0090	— other: — from 21 October to 30 April	0.00	10 000
	Iceberg lettuce, without outer leaf:		
0705.1111	— from 1 January to the end of February	0.00	2 000
	Witloof chicory, fresh or chilled:		
0705.2110	— from 21 May to 30 September	0.00	2 000
0707.0010	Cucumbers for salad, 21 October to 14 April	5.00	200
0707.0030	Pickling cucumbers, > 6 cm but ≤ 12 cm in length, fresh or chilled, from 21 October to 14 April	5.00	100
0707.0031	Pickling cucumbers, > 6 cm but ≤ 12 cm in length, fresh or chilled, from 15 April to 20 October	5.00	2 100
0707.0050	Gherkins, fresh or chilled	3.50	800
	Aubergines (eggplants), fresh or chilled:		
0709.3010	— from 16 October to 31 May	0.00	1 000
0709.5100 0709.5900	Mushrooms, fresh or chilled, of the genus <i>Agaricus</i> or other, with the exception of truffles	0.00	unlimited
	Sweet peppers, fresh or chilled:		
0709.6011	— from 1 November to 31 March	2.50	unlimited
0709.6012	Sweet peppers, fresh or chilled, from 1 April to 31 October	5.00	1 300
	Courgettes (including courgette flowers), fresh or chilled:		

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
0709.9950	— from 31 October to 19 April	0.00	2 000
ex 0710 8090	Mushrooms (uncooked or cooked by steaming or boiling in water), frozen	0.00	unlimited
0711.9090	Vegetables and mixtures of vegetables, provisionally preserved (for example, by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions), but unsuitable in that state for immediate consumption	0.00	150
0712.2000	Dried onions, whole, cut, sliced, broken or in powder, but not further prepared:	0.00	100
0713.1011	Peas (<i>Pisum sativum</i>), dried, shelled, whole, unprocessed, for use as animal feed	Rebate of CHF 0.90 on the duty applied	1 000
0713.1019	Peas (<i>Pisum sativum</i>), dried, shelled, whole, unprocessed (excluding those for use as animal feed, for technical purposes or for brewing)	0.00	1 000
	Hazelnuts or filberts (<i>Corylus</i> spp.), fresh or dried:		
0802.2190	— in shell, other than for use as animal feed or for oil extraction		
0802.2290	— shelled, other than for use as animal feed or for oil extraction	0.00	unlimited
0802.3290	Tree nuts	0.00	100
ex 0802 9090	Pine nuts, fresh or dried	0.00	unlimited
0805.1000	Fresh or dried oranges	0.00	unlimited
	Mandarins (including tangerines and satsumas); clementines, wilkings and similar citrus hybrids, fresh or dried		
0805.2100	mandarins (including tangerines and satsumas)	0.00	unlimited
0805.2200	clementines	0.00	unlimited
0805.2900	other	0.00	unlimited
0807.1100	Watermelons, fresh	0.00	unlimited
0807.1900	Melons, fresh, other than watermelons	0.00	unlimited
	Apricots, fresh, in open packings:		
0809.1011	— from 1 September to 30 June		
0809.1091	in other packings: — from 1 September to 30 June	0.00	2 100
0809.4013	Fresh plums, in open packings, from 1 July to 30 September	0.00	600
0810.1010	Strawberries, fresh, from 1 September to 14 May	0.00	10 000

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
0810.1011	Strawberries, fresh, from 15 May to 31 August	0.00	200
0810.2011	Raspberries, fresh, from 1 June to 14 September	0.00	250
0810.5000	Fresh kiwi fruit	0.00	unlimited
ex 0811 1000	Strawberries, uncooked or cooked by steaming or boiling in water, frozen, not containing added sugar or other sweetening matter, not put up in packings for retail sale, intended for industrial use	10.00	1 000
ex 0811 2090	Raspberries, blackberries, mulberries, loganberries and black, white or red currants, gooseberries, uncooked or cooked by steaming or boiling in water, frozen, not containing added sugar or other sweetening matter, not put up in packings for retail sale, intended for industrial use	10.00	1 200
0811.9010	Bilberries, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter	0.00	200
0811.9090	Edible fruit, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter (excluding strawberries, raspberries, blackberries, mulberries, loganberries and black, white or red currants, gooseberries, bilberries and tropical fruit)	0.00	1 000
0904.2200	Fruits of genus <i>Capsicum</i> or <i>Pimenta</i> , dried, crushed or ground	0.00	150
0910.2000	Saffron	0.00	unlimited
	Wheat and meslin (except durum wheat), for use as animal feed		
1001.9931	— containing other cereals of Chapter 10		
1001.9939	— other	Rebate of CHF 0.60 on the duty applied	50 000
	Maize (corn) for use as animal feed		
1005.9031	— containing other cereals of Chapter 10		
1005.9039	— other	Rebate of CHF 0.50 on the duty applied	13 000
	Virgin olive oil, other than for use as animal feed:		
1509.1091	— in glass containers holding 2 litres or less	60.60 (*)	unlimited
1509.1099	— in glass containers holding more than 2 litres or in other containers	86.70 (*)	unlimited
	Olive oil and its fractions, whether or not refined, but not chemically modified, other than for use as animal feed:		

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
1509.9091	— in glass containers holding 2 litres or less	60.60 (*)	unlimited
1509.9099	— in glass containers holding more than 2 litres or in other containers	86.70 (*)	unlimited
ex 0210 1991	Hams, in brine, boneless, enclosed in a bladder or in an artificial gut (<i>jambon en vessie</i>)		
ex 0210 1991	Piece of boneless chop, smoked (<i>jambon saumoné</i>)		
ex 0210 1991 ex 1602 4910	Pork neck, dried in air, seasoned or not, whole, in pieces or thinly sliced (<i>Coppa</i>)		
1601.0011 1601.0021	Sausages and similar products, of meat, meat offal or blood; food preparations based on these products of animals of headings 0101 to 0104, excluding wild boar	0.00	3 715
	Tomatoes, whole or in pieces, prepared or preserved other than by vinegar or acetic acid:		
2002.1010 2002.1020	— in containers holding more than 5 kg — in containers holding 5 kg or less	2.50 4.50	unlimited
	Tomatoes, prepared or preserved other than by vinegar or acetic acid, other than whole or in pieces:		
2002.9010	— in containers holding more than 5 kg	0.00	unlimited
2002.9021	Tomato pulp, puree and concentrate, in hermetically sealed containers, with a dry matter content of 25 % or more by weight, consisting of tomatoes and water and possibly salt or other seasoning, in containers holding 5 kg or less	0.00	unlimited
2002.9029	Tomatoes, prepared or preserved other than by vinegar or acetic acid, other than whole or in pieces, and other than tomato pulp, puree or concentrate:		
	— in containers holding 5 kg or less	0.00	unlimited
2003.1000	Mushrooms of the genus <i>Agaricus</i> prepared or preserved other than by vinegar or acetic acid	0.00	1 700
	Artichokes, prepared or preserved other than by vinegar or acetic acid, frozen, other than products of heading No 2006:		
ex 2004 9018	— in containers holding more than 5 kg	17.50	unlimited
ex 2004 9049	— in containers holding 5 kg or less	24.50	unlimited
	Asparagus, prepared or preserved other than by vinegar or acetic acid, not frozen, other than products of heading No 2006:		
2005.6010	— in containers holding more than 5 kg		
2005.6090	— in containers holding 5 kg or less	0.00	unlimited

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
	Olives, prepared or preserved other than by vinegar or acetic acid, not frozen, other than products of heading No 2006:		
2005.7010	— in containers holding more than 5 kg		
2005.7090	— in containers holding 5 kg or less	0.00	unlimited
	Capers and artichokes, prepared or preserved other than by vinegar or acetic acid, not frozen, other than products of heading No 2006:		
ex 2005 9911	— in containers holding more than 5 kg	17.50	unlimited
ex 2005 9941	— in containers holding 5 kg or less	24.50	unlimited
2008.3090	Citrus fruit, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included	0.00	unlimited
2008.5010	Apricot pulp, otherwise prepared or preserved, not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included	10.00	unlimited
2008.5090	Apricots, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included	15.00	unlimited
2008.7010	Peach pulp, otherwise prepared or preserved, not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included	0.00	unlimited
2008.7090	Peaches, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included	0.00	unlimited
	Juice of any single citrus fruit other than orange, grapefruit or pomelo, unfermented, not containing added spirit:		
ex 2009 3919	— not containing added sugar or other sweetening matter, concentrated	6.00	unlimited
ex 2009 3920	— containing added sugar or other sweetening matter, concentrated	14.00	unlimited
	Dessert wines, specialities and mistelles in containers:		
2204.2150	— holding 2 litres or less ⁽⁵⁾	8.50	unlimited
2204.2250	— holding more than 2 litres but not more than 10 litres ⁽⁵⁾	8.50	unlimited
2204.2960	— holding more than 10 litres ⁽⁵⁾	8.50	unlimited
ex 2204 2150	Port, in containers holding 2 litres or less, as described ⁽⁶⁾	0.00	1 000 hl

Swiss tariff heading	Description	Customs duty applicable (CHF/100 kg gross weight)	Annual quantity (tonnes net weight)
	Retsina (a Greek white wine), as described ⁽⁷⁾		
ex 2204 2121	— in containers holding 2 litres or less		
	— in containers holding more than 2 litres but not more than 10 litres, of a total alcoholic strength by volume:		
ex 2204 2221	— of more than 13 % vol.		
ex 2204 2222	— of 13 % vol. or less		
	— in containers holding more than 10 litres, of a total alcoholic strength by volume:		
ex 2204 2923	— of more than 13 % vol.		
ex 2204 2924	— of 13 % vol. or less	0.00	500 hl
	Dog and cat food intended for retail sale in hermetically sealed containers;		
2309.1021	— containing milk powder or whey		
2309.1029	— other	0.00	6 000 ⁽⁸⁾

⁽¹⁾ Including 480 tonnes of Parma and San Daniele ham under the terms of the exchange of letters of 25 January 1972 between the Community and Switzerland.

⁽²⁾ Including 170 tonnes of Bresaola under the terms of the exchange of letters of 25 January 1972 between the Community and Switzerland.

⁽³⁾ Subject to an overall annual quota of 60 000 plants.

⁽⁴⁾ Including the contribution to the guarantee fund for compulsory storage.

⁽⁵⁾ Covers only products specified in Annex 7 to the Agreement.

⁽⁶⁾ Description: 'Port' means a quality wine produced in a specified region (Oporto in Portugal) in accordance with Regulation (EC) No 1493/1999.

⁽⁷⁾ Description: 'Retsina' means a table wine within the meaning of the Community provisions referred to in point A.2 of Annex VII to Regulation (EC) No 1493/1999.

⁽⁸⁾ Concession granted by Switzerland to the European Community under the exchange of letters of 30 June 1996.

ANNEX 2

EUROPEAN UNION CONCESSIONS

The tariff concessions set out below are granted by the European Union for the following products originating in Switzerland and are, where applicable, subject to an annual quantity:

CN code	Description	Customs duty applicable (EUR/100 kg net weight)	Annual quantity (tonnes net weight)
0102 29 41 0102 29 49 0102 29 51 0102 29 59 0102 29 61 0102 29 69 0102 29 91 0102 29 99 ex 0102 39 10 ex 0102 90 91	Live bovine animals of a live weight exceeding 160 kg	0.00	4 600 head
ex 0210 20 90	Meat of bovine animals, boneless, dried	0.00	1 200
ex 0401 40 10 0401 40 90 0401 50 11 0401 50 19 0401 50 31 0401 50 39 0401 50 91 0401 50 99	Cream, of a fat content, by weight, exceeding 6 %	0.00	2 000
0403 10	Yoghurt		
0402 29 11 ex 0404 90 83	Special milk, for infants, in hermetically sealed containers of a net content not exceeding 500 g, of a fat content, by weight, exceeding 10 % (*)	43.80	unlimited
0602	Other live plants (including their roots), cuttings and slips; mushroom spawn	0.00	unlimited
0603 11 00 0603 12 00 0603 13 00 0603 14 00 0603 15 00 0603 19	Cut flowers and flower buds of a kind suitable for bouquets or for ornamental purposes, fresh	0.00	unlimited
0701 10 00	Seed potatoes, fresh or chilled	0.00	4 000
0702 00 00	Tomatoes, fresh or chilled	0.00 (?)	1 000
0703 10 19 0703 90 00	Onions (other than seed) Leeks and other alliaceous vegetables, fresh or chilled	0.00	5 000
0704 10 00 0704 90	Cabbages, cauliflowers, kohlrabi, kale and other similar edible brassicas with the exception of Brussels sprouts, fresh or chilled	0.00	5 500
0705	Lettuce (<i>Lactuca sativa</i>) and chicory (<i>Cichorium</i> spp.), fresh or chilled:	0.00	3 000

CN code	Description	Customs duty applicable (EUR/100 kg net weight)	Annual quantity (tonnes net weight)
0706 10 00	Fresh or chilled carrots and turnips	0.00	5 000
0706 90 10 0706 90 90	Salad beetroot, salsify, celeriac, radishes and similar edible roots, with the exception of horseradish (<i>Cochlearia armoracia</i>), fresh or chilled	0.00	3 000
0707 00 05	Cucumbers, fresh or chilled	0.00 (?)	1 000
0708 20 00	Beans (<i>Vigna</i> spp., <i>Phaseolus</i> spp.), fresh or chilled	0.00	1 000
0709 30 00	Aubergines (eggplants), fresh or chilled	0.00	500
0709 40 00	Celery other than celeriac, fresh or chilled	0.00	500
0709 51 00 0709 59	Mushrooms and truffles, fresh or chilled	0.00	unlimited
0709 70 00	Fresh or chilled spinach, New Zealand spinach and orache spinach	0.00	1 000
0709 99 10	Salad vegetables, other than lettuce (<i>Lactuca sativa</i>) and chicory (<i>Cichorium</i> spp.), fresh or chilled	0.00	1 000
0709 99 20	Fresh or chilled chard (white beet) and cardoons	0.00	300
0709 99 50	Fresh or chilled fennel	0.00	1 000
0709 93 10	Fresh or chilled courgettes	0.00 (?)	1 000
0709 93 90 0709 99 90	Other vegetables, fresh or chilled	0.00	1 000
0710 80 61 0710 80 69	Mushrooms (uncooked or cooked by steaming or boiling in water), frozen	0.00	unlimited
0712 90	Dried vegetables, whole, cut, sliced, broken or in powder, whether or not obtained from cooked vegetables, but not further prepared, with the exception of onions, mushrooms and truffles	0.00	unlimited
ex 0808 10 80	Apples, other than cider apples, fresh	0.00 (?)	3 000
0808 30 0808 40	Pears and quinces, fresh	0.00 (?)	3 000
0809 10 00	Fresh apricots	0.00 (?)	500
0809 29 00	Cherries, other than sour cherries (<i>Prunus cerasus</i>), fresh	0.00 (?)	1 500 (?)
0809 40	Plums and sloes, fresh	0.00 (?)	1 000
0810 10 00	Strawberries	0.00	200
0810 20 10	Raspberries, fresh	0.00	100
0810 20 90	Blackberries, mulberries and loganberries, fresh	0.00	100
1106 30 10	Flour, meal and powder of bananas	0.00	5
1106 30 90	Flour, meal and powder of other fruits of Chapter 8	0.00	unlimited

CN code	Description	Customs duty applicable (EUR/100 kg net weight)	Annual quantity (tonnes net weight)
ex 0210 19 50	Hams, in brine, boneless, enclosed in a bladder or in an artificial gut	0.00	1 900
ex 0210 19 81	Piece of boneless chop, smoked		
ex 0210 19 81 ex 1602 49 19	Pork neck, dried in air, seasoned or not, whole, in pieces or thinly sliced		
ex 1601 00	Sausages and similar products, of meat, meat offal or blood; food preparations based on these products of animals of headings 0101 to 0104, excluding wild boar		
ex 2002 90 91 ex 2002 90 99	Powdered tomatoes, whether or not containing added sugar, other sweetening matter or starch (*)	0.00	unlimited
2003 90 90	Mushrooms, other of the genus <i>Agaricus</i> , prepared or preserved other than by vinegar or acetic acid	0.00	unlimited
0710 10 00	Potatoes, uncooked or cooked by steaming or by boiling in water, frozen		
2004 10 10 2004 10 99	Potatoes, prepared or preserved other than by vinegar or acetic acid, frozen, other than products of heading No 2006, with the exception of flour, meal or flakes		
2005 20 80	Potatoes, prepared or preserved other than by vinegar or acetic acid, not frozen, other than products of heading No 2006, with the exception of flour, meal or flakes and preparations that are thinly sliced, fried or baked, whether or not salted or flavoured, in airtight packings, suitable for immediate consumption	0.00	3 000
ex 2005 91 00 ex 2005 99	Powdered preparations of vegetables and mixtures of vegetables, whether or not containing added sugar, other sweetening matter or starch (*)	0.00	unlimited
ex 2008 30	Flaked or powdered citrus fruit, whether or not containing added sugar, other sweetening matter or starch (*)	0.00	unlimited
ex 2008 40	Flaked or powdered pears, whether or not containing added sugar, other sweetening matter or starch (*)	0.00	unlimited
ex 2008 50	Flaked or powdered apricots, whether or not containing added sugar, other sweetening matter or starch (*)	0.00	unlimited
2008 60	Cherries, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included	0.00	500
ex 0811 90 19 ex 0811 90 39	Cherries, uncooked or cooked by steaming or boiling in water, frozen, containing added sugar or other sweetening matter		
0811 90 80	Cherries, other than sour cherries (<i>Prunus cerasus</i>), uncooked or cooked by steaming or boiling in water, frozen, not containing added sugar or other sweetening matter		

CN code	Description	Customs duty applicable (EUR/100 kg net weight)	Annual quantity (tonnes net weight)
ex 2008 70	Flaked or powdered peaches, whether or not containing added sugar, other sweetening matter or starch ⁽⁴⁾	0.00	unlimited
ex 2008 80	Flaked or powdered strawberries, whether or not containing added sugar, other sweetening matter or starch ⁽⁴⁾	0.00	unlimited
ex 2008 99	Other flaked or powdered fruits, whether or not containing added sugar, other sweetening matter or starch ⁽⁴⁾	0.00	unlimited
ex 2009 19	Powdered orange juice, whether or not containing added sugar or other sweetening matter	0.00	unlimited
ex 2009 21 00 ex 2009 29	Powdered grapefruit juice, whether or not containing added sugar or other sweetening matter	0.00	unlimited
ex 2009 31 ex 2009 39	Powdered juices of any other citrus fruits, whether or not containing added sugar or other sweetening matter	0.00	unlimited
ex 2009 41 ex 2009 49	Powdered pineapple juice, whether or not containing added sugar or other sweetening matter	0.00	unlimited
ex 2009 71 ex 2009 79	Powdered apple juice, whether or not containing added sugar or other sweetening matter	0.00	unlimited
ex 2009 81 ex 2009 89	Powdered juice of any other single fruit or vegetable, whether or not containing added sugar or other sweetening matter	0.00	unlimited

⁽¹⁾ For the products of this subheading, 'special milk for infants' means products that are free of pathogenic and toxicogenic germs and which contain less than 10 000 revivifiable aerobic bacteria and less than two coliform bacteria per gram.

⁽²⁾ Where relevant, a specific duty and not the minimum duty should apply.

⁽³⁾ Including 1 000 tonnes under the terms of the exchange of letters of 14 July 1986.

⁽⁴⁾ See Joint Declaration on the tariff classification of powdered vegetables and powdered fruit.

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



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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