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⁽¹⁾ Text with EEA relevance.

II

*(Information)*INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES
AND AGENCIES

EUROPEAN COMMISSION

COMMUNICATION FROM THE COMMISSION

**Guidelines on the adoption of Union-wide derogations for medical devices in accordance with
Article 59 of Regulation (EU) 2017/745**

(2020/C 171/01)

1. Background

The Medical Devices Regulation (EU) 2017/745 of the European Parliament and of the Council was adopted on 5 April 2017 ⁽¹⁾. This new regulatory framework sets high standards of quality and safety for medical devices and aims at ensuring the smooth functioning of the internal market.

In response to the COVID-19 pandemic, and with patient health and safety as a guiding principle, following the proposal of the Commission, the European Parliament and the Council on 23 April 2020 adopted Regulation (EU) 2020/561 ⁽²⁾, which defers by one year the date of application of Regulation (EU) 2017/745 to 26 May 2021. At the same time, Regulation (EU) 2020/561 also defers the application of the provision repealing Council Directive 90/385/EEC on active implantable medical devices ⁽³⁾ and Council Directive 93/42/EEC on medical devices ⁽⁴⁾.

Both Directives 90/385/EEC and 93/42/EEC, as well as Regulation (EU) 2017/745, empower national competent authorities, on a duly justified request, to authorise the placing on the market of medical devices for which the relevant conformity assessment procedures have not been carried out, but the use of which is in the interest of public health or patient safety or health ('national derogation').

Regulation (EU) 2017/745 also empowers the Commission to extend, in exceptional cases, the validity of a national derogation for a limited period of time to the territory of the Union ('Union-wide derogation'). Those Union-wide derogations should be regarded as a measure of last resort, only to be considered in exceptional cases to ensure patient health or safety or to protect public health. The measure enables the Commission and Member States to address potential shortages Union wide of vitally important medical devices in an effective manner.

These Guidelines provide information on the adoption of those Union-wide derogations, in particular the criteria that the Commission will take into account to determine whether the extension to the territory of the Union of a national derogation is necessary and justified for a medical device. This document also provides information on the adoption process and the general conditions that the Commission should set for Union-wide derogations by means of implementing acts.

⁽¹⁾ OJ L 117, 5.5.2017, p. 1.

⁽²⁾ OJ L 130, 24.4.2020, p. 18.

⁽³⁾ OJ L 189, 20.7.1990, p. 17.

⁽⁴⁾ OJ L 169, 12.7.1993, p. 1.

2. Legal basis

Article 59 of Regulation (EU) 2017/745 provides that national competent authorities may authorise, on duly justified request, the placing on the market and putting into service within the territory of the Member State concerned, of a specific device for which the conformity assessment procedures referred to in Article 52 of Regulation (EU) 2017/745 or, for the period from 24 April 2020 to 25 May 2021, Article 9(1) and (2) of Directive 90/385/EEC or Article 11(1) to (6) of Directive 93/42/EEC, have not been carried out but use of which is in the interest of public health or patient safety or health ⁽⁵⁾.

Pursuant to Article 59(2) of Regulation (EU) 2017/745, Member States shall inform the Commission and other Member States of any national derogation granted for a medical device. To facilitate this process and to strengthen coordination between the Member States, the Commission will set up and administer a central repository ⁽⁶⁾ allowing national competent authorities to share with the Commission and each other information on the derogations they have granted.

There is no legal obligation to inform the Commission and other Member States of national derogations adopted prior to 24 April 2020. However, Article 59(2), second subparagraph, sets out that Member States may submit a notification to the Commission in order to ensure that those national derogations can be considered for the purpose of adopting Union-wide derogations. In this case, the national notifications should be submitted to the central repository mentioned above.

Pursuant to Article 59(3) of Regulation (EU) 2017/745, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of an implementing act, extend for a limited period of time the validity of a national derogation granted by a Member State in accordance with the above-mentioned provisions, to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. The Commission may adopt Union-wide derogations only in response to national derogations notified to the Commission by a Member State.

3. General requirements

In considering the adoption of a Union-wide derogation, in a first step the Commission will consult the Member States, by means of the Medical Device Coordination Group (MDCG) established under Regulation (EU) 2017/745, to identify whether a notified national derogation for a certain medical device could be of Union relevance.

Where it has been determined that there could be Union-relevance, in a second step the Commission will assess whether the procedural requirements referred to in sub-section A have been met. In a third step, the Commission, based on the requirements referred to in sub-section B, will determine whether adopting a Union-wide derogation in the case at hand would be duly justified.

A. Procedural requirements

1. At least one national derogation has been granted and notified to the Commission for the medical device in question;
2. For each notified national derogation, the complete set of justifications that were taken into account when granting the notified national derogation has been made available to the Commission and all other Member States;
3. The content of each notified national derogation in terms of validity period, specific conditions or requirements, as well as the outcome of any surveillance or monitoring activities, has been made available to the Commission and all other Member States;
4. Each notified national derogation clearly identifies the medical device for which it is granted, including a description of the device, the intended purpose, and the manufacturer's information;
5. Any (technical) documentation submitted by manufacturer(s) related to the medical device benefiting from the notified national derogation(s), as well as the outcome of the national competent authority's assessment of that submission, have been made available to the Commission and all other Member States.

⁽⁵⁾ Article 1(8)(iv) of Regulation (EU) 2020/561 sets out that Article 59 of Regulation (EU) 2017/745 applies from 24 April 2020.

⁽⁶⁾ The central repository service will be based on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC).

B. *Due justification*

1. The documentation referred to in sub-section A demonstrates that the manufacturer has done what can be reasonably expected in order to complete the conformity assessment without delay or, where applicable, there is sufficient evidence that the manufacturer has been prevented from completing, or initiating, the conformity assessment due to exceptional and unforeseeable circumstances;
2. The medical device(s) ⁽⁷⁾ concerned is of vital importance relating to public health or patient safety or health;
3. There is a lack of suitable substitutes available;
4. Where applicable, there are no indications in the technical dossier, or from vigilance or market surveillance activities, concerning devices of previous generations or with similar characteristics, that the device could be harmful for patient health or safety or public health;
5. Each notified national derogation is of temporary nature and its period of validity is limited to what can be reasonably expected necessary to complete the applicable conformity assessment procedure or, alternatively, to ensure patient safety or health or the protection of public health;
6. There is clear Union-relevance for extending the validity of the notified national derogation(s) to Union territory.

The information referred to in points 1 to 5 of sub-section B is required to allow the Commission to assess whether the adoption of a Union-wide derogation would be duly justified. This additional documentation will complement the information initially notified to the Commission as part of the national derogation(s) concerned. It should in particular outline the following information:

- (a) An explanation why the conformity assessment has not been initiated or completed before the placing on the market; an explanation of the vital importance of the use of the medical device; a detailed plan on how to ensure compliance or withdrawal of the device from the market after the temporary derogation expired;
- (b) An explanation of the vital importance of the use of the medical device in the respective Member State should be supported by statement(s) of health institution(s), including the reasons for why the device cannot be substituted.

For the purpose of point 6 of sub-section B, the Commission intends to consult the Member States by means of the MDCG. The Commission will conclude whether there is Union-interest for extending the national derogation taking into account the feedback received from the MDCG.

4. **Adoption process**

The Commission will conclude on the need for adoption of a Union-wide derogation based on the information referred to in sub-sections A and B of section 3. This is necessary to ensure patient safety or health or the protection of public health, while safeguarding the smooth functioning of the internal market.

Pursuant to Article 59(3), first subparagraph, of Regulation (EU) 2017/745, the Commission shall adopt Union-wide derogations by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure established under Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽⁸⁾.

On duly justified imperative grounds of urgency relating to the health and safety of humans, Article 59(3), second subparagraph, of Regulation (EU) 2017/745 stipulates that the Commission shall adopt immediately applicable implementing acts without its prior submission to the relevant Comitology committee as provided for in Article 8 in conjunction with Article 5 of Regulation (EU) No 182/2011. In those cases, at the latest 14 days after its adoption, the Commission will submit the implementing act to the relevant committee in order to obtain its opinion taking into account the information referred to in section 3. In the event of the committee delivering a negative opinion, the Commission will immediately repeal the implementing act.

⁽⁷⁾ Medical devices are specified, for instance, by reference to a certificate number issued by a Notified Body and/or any particular category of device or group of devices covered by that certificate.

⁽⁸⁾ OJ L 55, 28.2.2011, p. 13.

5. General conditions

Article 59(3) of Regulation (EU) 2017/745 requires that the Commission sets out the conditions of a Union-wide derogation adopted by means of an implementing act. In setting those conditions, the Commission will base its decision in particular on the information submitted in accordance with sub-section A of section 3. The Commission may also consider any other comments submitted to it, for example, from Member States in the MDCG.

Union-wide derogations may lay down stricter conditions for the temporary placing on the market of a medical device than those established by means of national derogations already in place for a device. Conversely, Member States, by means of national measures, should be able to introduce conditions that are stricter than those laid down in Union-wide derogations. In those cases, the stricter conditions should prevail.

Unless determined otherwise, Union-wide derogations should remain in force for a period not exceeding six months. Any substantial change in circumstances or the information referred to in section 3, or information otherwise available to the Commission or the Member States, in particular through market surveillance, should warrant a re-assessment of the Union-wide derogation and its conditions. In such cases, the Commission may propose to amend or, where appropriate, repeal the implementing act by which it established the Union-wide derogation. This process will be subject to consultation of Member States in the MDCG.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Euro exchange rates ⁽¹⁾

18 May 2020

(2020/C 171/02)

1 euro =

Currency	Exchange rate	Currency	Exchange rate		
USD	US dollar	1,0832	CAD	Canadian dollar	1,5202
JPY	Japanese yen	116,31	HKD	Hong Kong dollar	8,3964
DKK	Danish krone	7,4548	NZD	New Zealand dollar	1,8096
GBP	Pound sterling	0,89153	SGD	Singapore dollar	1,5426
SEK	Swedish krona	10,6103	KRW	South Korean won	1 332,42
CHF	Swiss franc	1,0521	ZAR	South African rand	19,8913
ISK	Iceland króna	157,10	CNY	Chinese yuan renminbi	7,7068
NOK	Norwegian krone	10,9663	HRK	Croatian kuna	7,5580
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	16 077,45
CZK	Czech koruna	27,610	MYR	Malaysian ringgit	4,7320
HUF	Hungarian forint	353,39	PHP	Philippine peso	55,102
PLN	Polish zloty	4,5596	RUB	Russian rouble	78,9080
RON	Romanian leu	4,8388	THB	Thai baht	34,684
TRY	Turkish lira	7,4276	BRL	Brazilian real	6,2701
AUD	Australian dollar	1,6736	MXN	Mexican peso	25,6337
			INR	Indian rupee	82,1435

⁽¹⁾ Source: reference exchange rate published by the ECB.

Commission notice on current State aid recovery interest rates and reference/discount rates applicable as from 1 May 2020/1 June 2020

(Published in accordance with Article 10 of Commission Regulation (EC) No 794/2004 of 21 April 2004 (OJ L 140, 30.4.2004, p. 1))

(2020/C 171/03)

Base rates calculated in accordance with the Communication from the Commission on the revision of the method for setting the reference and discount rates (OJ C 14, 19.1.2008, p. 6.). Depending on the use of the reference rate, the appropriate margins have still to be added as defined in this communication. For the discount rate this means that a margin of 100 basis points has to be added. The Commission Regulation (EC) No 271/2008 of 30 January 2008 amending Regulation (EC) No 794/2004 foresees that, unless otherwise provided for in a specific decision, the recovery rate will also be calculated by adding 100 basis points to the base rate.

Modified rates are indicated in bold.

Previous table published in OJ C 83, 13.3.2020, p. 5.

From	To	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK
1.6.2020	...	-0,22	-0,22	0,00	-0,22	1,77	-0,22	0,05	-0,22	-0,22	-0,22	-0,22	-0,22	0,26	0,78	-0,22	-0,22	-0,22	-0,22	-0,22	-0,22	-0,22	1,35	-0,22	3,21	0,32	-0,22	-0,22	0,94
1.5.2020	31.5.2020	-0,31	-0,31	0,00	-0,31	2,25	-0,31	-0,05	-0,31	-0,31	-0,31	-0,31	-0,31	0,26	0,52	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	1,84	-0,31	3,21	0,26	-0,31	-0,31	0,94
1.4.2020	30.4.2020	-0,31	-0,31	0,00	-0,31	2,25	-0,31	-0,05	-0,31	-0,31	-0,31	-0,31	-0,31	0,26	0,40	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	1,84	-0,31	3,21	0,26	-0,31	-0,31	0,94
1.3.2020	31.3.2020	-0,31	-0,31	0,00	-0,31	2,25	-0,31	-0,05	-0,31	-0,31	-0,31	-0,31	-0,31	0,26	0,30	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	1,84	-0,31	3,21	0,26	-0,31	-0,31	0,94
1.2.2020	29.2.2020	-0,31	-0,31	0,00	-0,31	2,25	-0,31	-0,07	-0,31	-0,31	-0,31	-0,31	-0,31	0,26	0,30	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	1,84	-0,31	3,21	0,18	-0,31	-0,31	0,94
1.1.2020	31.1.2020	-0,31	-0,31	0,00	-0,31	2,25	-0,31	-0,12	-0,31	-0,31	-0,31	-0,31	-0,31	0,26	0,30	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	-0,31	1,84	-0,31	3,21	0,11	-0,31	-0,31	0,94

NOTICES FROM MEMBER STATES

Information to be provided pursuant to Article 5(2)

Establishment of a European Grouping of Territorial Cooperation (EGTC)

(Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 (OJ L 210, 31.7.2006, p. 19))

(2020/C 171/04)

I.1) Name, address and contact point

Registered name: EVTZ Eurodistrict Region Freiburg – Centre et Sud Alsace

Registered office: Ile du Rhin, 68600 Vogelgrun, France

Contact point: Silke Tebel-Haas

Internet address of the Grouping: www.eurodistrict-freiburg-alsace.eu

I.2) Duration of the Grouping:

Duration of the Grouping: Unlimited

Date of registration: 14.4.2020

Date of publication: 6.5.2020

II. OBJECTIVES

Eurodistrict Region Freiburg – Centre et Sud Alsace aims to boost cross-border cooperation to create and further develop a cross-border region with a geographical identity. The EGTC will operate in particular in the following areas, when the set objectives have a cross-border dimension: mobility, labour market, meetings with school children and the general public, sport and culture, healthcare, energy and tourism.

III. ADDITIONAL DETAILS ON NAME OF THE GROUPING

Name in English: EGTC Eurodistrict Region Freiburg – Centre et Sud Alsace

Name in French: GECT Eurodistrict Region Freiburg – Centre et Sud Alsace

IV. MEMBERS

IV.1) Total number of members in the Grouping: 10

IV.2) Nationalities of the members of the Grouping: France and Germany

IV.3) Member information ⁽¹⁾

Official name: Landkreis Emmendingen
Postal address: Bahnhofstraße 2-4, 79312 Emmendingen, Germany
Internet address: www.landkreis-emmendingen.de
Type of member: Local authority

Official name: Landkreis Breisgau-Hochschwarzwald
Postal address: Stadtstraße 2, 79104, Freiburg, Germany
Internet address: www.breisgau-hochschwarzwald.de
Type of member: Local authority

Official name: Stadt Freiburg
Postal address: Rathausplatz 2-4, 79098 Freiburg, Germany
Internet address: www.freiburg.de
Type of member: Local authority

⁽¹⁾ Please add for each member.

Official name: Région Grand Est
Postal address: Maison de la Région, 1, place Adrien Zeller, 67000 Strasbourg, France
Internet address: www.grandest.fr
Type of member: Regional authority

Official name: Département du Bas-Rhin
Postal address: Hôtel du Département, Place du Quartier Blanc, 67000 Strasbourg, France
Internet address: www.bas-rhin.fr
Type of member: Local authority

Official name: Département du Haut-Rhin
Postal address: 100, Avenue d'Alsace, 67006 Colmar, France
Internet address: www.haut-rhin.fr
Type of member: Local authority

Official name: PETR Sélestat-Alsace Centrale
Postal address: BP 20195, 1, Rue Louis Lang, 67604 Sélestat, France
Internet address: www.selestat-alsace-centrale.fr
Type of member: Local authority

Official name: PETR du Pays Rhin-Vignoble-Grand Ballon
Postal address: 170, Rue de la République, 68500 Guebwiller, France
Internet address: www.rvgn.fr
Type of member: Local authority

Official name: Mulhouse Alsace Agglomération
Postal address: 2, Rue Pierre et Marie Curie, 68948 Mulhouse, France
Internet address: www.mulhouse-alsace.fr
Type of member: Local authority

Official name: Colmar Agglomération
Postal address: 32, Cours Sainte Anne, BP 80197, 68004 Colmar, France
Internet address: www.agglo-colmar.fr
Type of member: Local authority

V

(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION
POLICY

EUROPEAN COMMISSION

Prior notification of a concentration
(Case M.9844 – Société Générale/Mitsubishi/JV)
Candidate case for simplified procedure

(Text with EEA relevance)

(2020/C 171/05)

1. On 11 May 2020, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ⁽¹⁾.

This notification concerns the following undertakings:

- ALD S.A. ('ALD', France), controlled by Société Générale (France),
- Mitsubishi UFJ Lease & Finance Company Limited ('Mitsubishi', Japan).

ALD and Mitsubishi acquire within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation joint control of the JV.

The concentration is accomplished by way of purchase of shares in a newly created company constituting a joint venture.

2. The business activities of the undertakings concerned are:

- for ALD: provides full service vehicle leasing and fleet management to large corporates, small to medium sized companies and private individuals across 43 countries. ALD is controlled by Société Générale, a financial services group active in France and worldwide,
- for Mitsubishi: active in Japan and globally, providing a variety of financial services including finance lease, operating lease focused on asset values, auto lease, real estate leases etc. It is also involved in rental services, trading of used equipment, insurance operations and services to customers,
- for the JV: will provide a multi-brand, full service operational leasing and fleet management business with related mobility products in Malaysia.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under the Council Regulation (EC) No 139/2004 ⁽²⁾ it should be noted that this case is a candidate for treatment under the procedure set out in the Notice.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

⁽²⁾ OJ C 366, 14.12.2013, p. 5.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. The following reference should always be specified:

M.9844 – Société Générale/Mitsubishi/JV

Observations can be sent to the Commission by email, by fax, or by post. Please use the contact details below:

Email: COMP-MERGER-REGISTRY@ec.europa.eu

Fax +32 22964301

Postal address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

Prior notification of a concentration
(Case M.9839 – VGRD/Auto Wichert Assets)

(Text with EEA relevance)

(2020/C 171/06)

1. On 11 May 2020, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ⁽¹⁾.

This notification concerns the following undertakings:

- VGRD GmbH ('VGRD', Germany), a wholly-owned subsidiary of Volkswagen AG ('VW AG') belonging to the VW Group,
- Certain assets of Auto Wichert GmbH ('Target assets', Germany), owned by Auto Wichert GmbH ('Wichert', Germany).

VGRD (indirectly) acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control of the Target assets.

The concentration is accomplished by way of purchase of assets.

2. The business activities of the undertakings concerned are:

- for VGRD: the operation of several retail outlets in Germany. As regards the VW Group, it is active in the development, manufacture, marketing and sale of passenger cars, light commercial vehicles, trucks, buses, coaches, chassis for buses and diesel engines, and motor bikes, each including spare parts and accessories,
- for the Target assets: four VW dealership outlets in the metropolitan area of Hamburg, Germany, which are active in the retail distribution of new and used passenger cars and light commercial vehicles of the VW Group brands, VW-branded OEM spare parts, non-OE spare parts and related services.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. The following reference should always be specified:

M.9839 – VGRD/Auto Wichert Assets

Observations can be sent to the Commission by email, by fax, or by post. Please use the contact details below:

E-mail: COMP-MERGER-REGISTRY@ec.europa.eu

Fax +32 22964301

Postal address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

OTHER ACTS

EUROPEAN COMMISSION

Publication of a communication of approval of a standard amendment to a product specification for a name in the wine sector referred to in Article 17(2) and (3) of Commission Delegated Regulation (EU) 2019/33

(2020/C 171/07)

This communication is published in accordance with Article 17(5) of Commission Delegated Regulation (EU) 2019/33 ⁽¹⁾.

COMMUNICATING THE APPROVAL OF A STANDARD AMENDMENT

‘Duna/Dunai’**Reference number PDO-HU-A1345-AM02****Date of communication: 9.2.2020**

DESCRIPTION OF AND REASONS FOR THE APPROVED AMENDMENT

1. Addition of the municipalities of Kömpöc, Petőfiszállás, Pálmonostora, Újszilvás and Bácsszentgyörgy to the demarcated area

- (a) Product specification headings affected: IV. Demarcated area
- (b) Single document heading affected: Demarcated geographical area
- (c) Reasons:

— The Wine Community Council of the Kunság Region (Kunsági Borvidék Hegyközségi Tanácsa) amended the product specification for the ‘Kunság/Kunsági’ PDO. The areas of the municipalities of Kömpöc, Petőfiszállás, Pálmonostora and Újszilvás classified as Class I and II according to the vineyard cadastre of wine-producing regions were added to the demarcated area. The change affects the demarcated area in the product specification for the ‘Duna/Dunai’ PDO and has been included in this application. The characteristics of the areas included in the vineyard cadastre correspond to the demarcated area of the ‘Duna/Dunai’ PDO. Vine-growing is one of the traditional economic activities of local inhabitants. The classification of the wine region and the possibility to produce the ‘Duna/Dunai’ PDO generates significant employment and income in these municipalities and contributes greatly towards the local tourism industry.

⁽¹⁾ OJ L 9, 11.1.2019, p. 2.

- The Wine Community Council of the Hajós-Baja Region (Hajós-Bajai Borvidék Hegyközségi Tanácsa) amended the product specification for the 'Hajós-Baja' PDO. The areas of the municipality of Bácsszentgyörgy classified as Class I and II according to the vineyard cadastre of wine-producing regions were added to the demarcated area. Border areas of the municipality of Bácsszentgyörgy correspond to the wine-producing municipalities of Csátalja and Dávod. In Bácsszentgyörgy, an area of 6,8109 ha is registered in the vineyard cadastre, and two simplified warehouse keepers are in operation. The amendment of the demarcated area does not affect the link between the production area and the product, because the characteristics of the area included in the vineyard cadastre correspond to the demarcated area of the 'Hajós Baja' and 'Duna/Dunai' PDOs. Vine-growing is one of the traditional economic activities of local inhabitants. The classification of the wine region and the possibility to produce the 'Duna/Dunai' PDO generates significant employment and income in these municipalities and contributes greatly towards the local tourism industry.

2. Deletion of the section on bud load from the heading 'Specific oenological practices'

- (a) Product specification headings affected: III. Specific oenological practices
- (b) Single document heading affected: Wine-making practices – Specific oenological practices
- (c) Reasons: The amendment is of a technical nature. The amendment of the regulation (deletion of bud load) makes the method for restricting production clearer.

SINGLE DOCUMENT

1. Name of the product

Duna

Dunai

2. Geographical indication type

PDO – Protected Designation of Origin

3. Categories of grapevine product

1. Wine

4. Description of the wine(s)

White wines

Lively and fresh in character, with a medium finish, the varietal wines have fruity and flowery aromas and tastes typical of the variety used; these are dry, semi-dry, semi-sweet or sweet wines, depending on the sugar content.

- * The maximum total alcoholic strength and maximum total sulphur dioxide content correspond to the limit values laid down in EU legislation.

General analytical characteristics	
Maximum total alcoholic strength (in % volume)	
Minimum actual alcoholic strength (in % volume)	9
Minimum total acidity	3,5 g/l expressed as tartaric acid
Maximum volatile acidity (in milliequivalents per litre)	16,67
Maximum total sulphur dioxide (in milligrams per litre)	

Rosé wines

Light, fresh wines with vivid acidity, made from red grapes, with lively and fresh fruity aromas and tastes (of raspberry, peach, sour cherry, blackcurrant, strawberry, etc.) and occasionally flowery aromas; these are dry, semi-dry, semi-sweet or sweet wines, depending on the sugar content.

- * The maximum total alcoholic strength and maximum total sulphur dioxide content correspond to the limit values laid down in EU legislation.

General analytical characteristics	
Maximum total alcoholic strength (in % volume)	
Minimum actual alcoholic strength (in % volume)	9
Minimum total acidity	3,5 g/l expressed as tartaric acid
Maximum volatile acidity (in milliequivalents per litre)	13,33
Maximum total sulphur dioxide (in milligrams per litre)	

Siller wines

The varietal wines have aromas and tastes that are typical of the variety used, with rounded acids; the coupage wines have a character reflecting the relative proportions of the varieties used; these are full-bodied wines with moderate tannins; they can be dry, semi-dry, semi-sweet or sweet, depending on the sugar content.

- * The maximum total alcoholic strength and maximum total sulphur dioxide content correspond to the limit values laid down in EU legislation.

General analytical characteristics	
Maximum total alcoholic strength (in % volume)	
Minimum actual alcoholic strength (in % volume)	9
Minimum total acidity	3,5 g/l expressed as tartaric acid
Maximum volatile acidity (in milliequivalents per litre)	20
Maximum total sulphur dioxide (in milligrams per litre)	

Red wines

The red varietal wines have aromas and tastes that are typical of the variety used, with rounded acids; the coupage wines have a tannin content reflecting the relative proportions of the varieties used and a velvety taste and body; these wines have fruity (sour cherry, raspberry, walnut, blackcurrant, etc.) and spicy (cinnamon, vanilla), chocolate and tobacco aromas; they can be dry, semi-dry, semi-sweet or sweet, depending on the sugar content.

- * The maximum total alcoholic strength and maximum total sulphur dioxide content correspond to the limit values laid down in EU legislation.

General analytical characteristics	
Maximum total alcoholic strength (in % volume)	
Minimum actual alcoholic strength (in % volume)	9
Minimum total acidity	3,5 milliequivalents per litre
Maximum volatile acidity (in milliequivalents per litre)	20
Maximum total sulphur dioxide (in milligrams per litre)	

5. Wine-making practices

a. Essential oenological practices

Cultivation method and planting density

Cultivation practice

In the case of vineyards established after 3 February 2006, the following training methods are used: head, umbrella, Moser, improved Moser, single curtain, and Sylvoz.

Row and vine spacing: twin-row and/or vine-planting arrangements and evenly spaced rows and vines. The distance between rows must be at least 1,00 m and no more than 3,60 m, whereas the distance between vines must be at least 0,60 m and no more than 1,20 m. In the case of twinned vines, the average distance between the vines is the determining factor.

In the case of existing vineyards planted before 3 February 2006, wines bearing the 'Duna/Dunai' PDO may be produced from grapes originating from the vineyard, as long as the vineyard remains in operation, regardless of its training method.

Only grapes originating from vineyards with a vine loss of 10 % or less can be used to produce 'Duna/Dunai' PDO wines.

Date and method of harvesting; grape quality

Cultivation practice

The date on which harvesting begins is set by the competent wine community council each year and is determined on the basis of test harvests carried out every week from 1 August each year.

Any product made from grapes harvested before the start date of the harvest set by the wine community cannot be granted a certificate of origin for 'Duna/Dunai' PDO-labelled wine and cannot be marketed using the 'Duna/Dunai' PDO label. The date of the harvest is published in the form of an announcement by the wine communities.

Grape quality requirements

Cultivation practice

The minimum sugar content of the grapes is 14,82° in Hungarian must grade, and the minimum potential alcoholic strength of the grapes is 9 % by volume, for all wine types.

b. Maximum yields

Wine

100 hl/ha

Grapes

14 300 kg of grapes per hectare

6. Demarcated geographical area

1. Csongrád wine region: The areas of the following municipalities that are classified as Class I and II according to the vineyard cadastre: Ásotthalom, Balástya, Bordány, Csengele, Csongrád, Domaszék, Forráskút, Hódmezővásárhely, Kistélek, Mórahalom, Öttömös, Pusztamérges, Pusztaszer, Ruzsa, Szatymaz, Szeged, Üllés, Zákányszék, Zsombó.
2. Hajós-Baja wine region: The areas of the following municipalities that are classified as Class I and II according to the vineyard cadastre: Baja, Bácsszentgyörgy, Bátmonostor, Borota, Császártöltés, Csátalja, Csávoly, Dávod, Dusnok, Érsekcsanád, Érsekhalma, Hajós, Nagybaracska, Nemesnádudvar, Réim, Sükösd, Vaskút.
3. Kunság wine region: The areas of the following municipalities that are classified as Class I and II according to the vineyard cadastre: Abony, Akasztó, Albertirsa, Apostag, Agasegyháza, Ballószög, Balotaszállás, Bácsalmás, Bácsszőlős, Bénye, Bócsa, Bugac, Cegléd, Ceglédbercel, Cibakháza, Csemő, Csengőd, Cserkeszőlő, Csépa, Csíkéria, Csólyospálos, Dány, Dunapataj, Dunavecse, Dömsöd, Felsőlajos, Fülöpháza, Fülöppjakab, Fülöpszállás, Harta, Gomba, Harkakötöny, Helvécia, Hernád, Imrehegy, Inárcs, Izsák, Jakabszállás, Jánoshalma, Jászberény, Jászszentandrás, Jászszentlászló, Kakucs, Kaskantyú, Kecel, Kecskemét, Kelebia, Kerekegyháza, Kéleshalom, Kiskőrös, Kiskunfélegyháza, Kiskunhalas, Kiskunmajsa, Kíszállás, Kocsér, Kóka, Kömpöc, Kunbaja, Kunbaracs, Kunfehértó, Kunszállás, Kunszentmiklós, Ladánybene, Lajosmizse, Lakitelek, Mélykút, Monor, Monorierdő, Móricgát, Nagykáta, Nagykőrös, Nagyrév, Nyárlőrinc, Nyársapát, Ócsa, Orgovány, Örkény, Páhi, Pálmonostora, Petőfiszállás, Pilis, Pirtó, Ráckeve, Solt, Soltszentimre, Soltvadkert, Szabadszállás, Szank, Szelevény, Szentkirály, Szigetcsép, Szigetszentmárton, Szigetújfalu, Tabdi, Tápiószentmárton, Tápiószéle, Tázlár, Tiszaalpár, Tiszajenő, Tiszaföldvár, Tiszainoka, Tiszakécske, Tiszakürt, Tiszasas, Tiszaug, Tompa, Tóalmás, Tököl, Újlengyel, Újszilvás, Zsana.

7. Main grape varieties

tramini – traminer
királyleányka – feteasca regale
kadarka – jenei fekete
hamburgi muskotály – muscat de hamburg
kékoportó – portugizer
sauvignon – sovinjon
kövidinka – a dinka crvena
pinot noir – kék rulandi
pinot noir – savagnin noir
pinot noir – pinot cernii
leányka – leányszőlő
olasz rizling – nemes rizling
tramini – roter traminer
nektár
tramini – savagnin rose
pinot blanc – weissburgunder
olasz rizling – taljanska grasevina
pinot noir – pignula
csabagyöngye – perle di csaba
sauvignon – sauvignon bianco
olasz rizling – grasevina
leányka – dievcenske hrozno
szürkebarát – auvergans gris
irsaí olivér – zolotis
kékfrankos – blaufränkisch
királyleányka – galbena de ardeal
rizlingszilváni – müller thurgau blanc
szürkebarát – pinot gris
rizlingszilváni – müller thurgau bijeli
csabagyöngye – pearl of csaba
sauvignon – sauvignon blanc
ezerjő – korponai
rizlingszilváni – rizvanac
kadarka – negru moale
pinot noir – pinot tinto
irsaí olivér – muskat olivér
kékoportó – portugais bleu
kadarka – kadarka negra
kadarka – gamza
tramini – gewürtztraminer
pinot noir – kisburgundi kék
pinot noir – spätburgunder
zöld veltelíni – zöldveltelíni

arany sárfehér – huszár szőlő
szürkebarát – pinot grigio
zöld veltelíni – grüner muskateller
kövidinka – steinschiller
tramini – traminer rosso
zöld veltelíni – grüner veltliner
pinot noir – pino csernúj
csabagyöngye – zsemcsug szaba
rizlingszilváni – rivaner
tramini – tramin červené
kékfrankos – moravka
csabagyöngye – perla di csaba
kékfrankos – blauer lemlberger
irsai olivér – irsai
rajnai rizling – rhine riesling
hamburgi muskotály – muszkat gamburgszkij
ezerjő – tausendachtgute
királyleányka – erdei sárga
kékoportó – portugalske modré
kadarka – katar
ezerjő – szadocsina
rajnai rizling – rheinriesling
királyleányka – little princess
cabernet franc – kaberne fran
rajnai rizling – riesling
zweigelt – zweigeltrebe
merlot
királyleányka – königstochter
hamburgi muskotály – muscat de hainaut
olasz rizling – welschriesling
ottonel muskotály – muskat ottonel
csabagyöngye – vengerskii muskatnii rannúj
kadarka – törökszőlő
leányka – feteasca alba
kadarka – szkadarka
rajnai rizling – weisser riesling
királyleányka – königliche mädchentraube
rajnai rizling – johannisberger
kövidinka – a dinka rossa
pinot noir – rulandski modre
kövidinka – a ruzsica
pinot blanc – pinot beluj

olasz rizling – risling vlassky
hamburgi muskotály – miszket hamburgszki
cabernet sauvignon
chardonnay – ronci bilé
szürkebarát – grauburgunder
szürkebarát – ruländer
cserszegi fűszeres
ottonel muskotály – muscat ottonel
kékoportó – blauer portugieser
rizlingszilváni – müller thurgau
kékfrankos – limberger
sauvignon – sauvignon bijeli
zweigelt – rotburger
csabagyöngye – perla czabanska
kadarka – csetereska
pinot blanc – fehér burgundi
ezerjő – trummertraube
leányka – mädchentraube
hamburgi muskotály – moscato d’Amburgo
kövidinka – a dinka mala
karát
ezerjő – tausendgute
pinot noir – pinot nero
ottonel muskotály – miszket otonel
királyleányka – dánosi leányka
kadarka – fekete budai
kövidinka – a kamena dinka
kékfrankos – blauer limberger
olasz rizling – riesling italien
pinot noir – kék burgundi
pinot blanc – pinot bianco
ezerjő – kolmreifler
blauburger
rajnai rizling – riesling blanc
zöld veltelíni – veltlinské zelené
zweigelt – blauer zweigeltrebe
csabagyöngye – perle von csaba
pinot noir – blauer burgunder
olasz rizling – olaszrizling
szürkebarát – graumönch
irsai olivér – zolotisztüj rannüj
zefír
kékoportó – modry portugal

8. Description of the link(s)

Wine – Description of the demarcated area (1)

(a) Natural and cultural factors

The area covered by the 'Duna/Dunai' PDO is located in the central part of Hungary. It lies largely within an area of the Hungarian Plain bounded by the Rivers Danube and Tisza, known as the Danube-Tisza Interfluve (the Kiskunság, Észak-Bácska, Jászság and Tápióság regions), and the parts of the Tiszazug region and Csongrád County to the east of the River Tisza. It is connected to some production areas of Csepel Island to the northwest and those of the Gödöllő Hills to the north.

The production area's environmental features are determined mainly by its low-lying nature: height above sea level is less than 200 m; most of the area is less than 150 m above sea level. The terrain is flat, with differences in altitude of not more than 10–20 m.

The soils of the production area covered by the 'Duna/Dunai' PDO show little variation, as most of the area is located on calcareous sandy soils, and to a lesser extent brown forest soils, chernozem, meadow and alluvial soils. The formation of these sandy soils is attributable primarily to the River Danube, which deposited sandy sediments in the Danube-Tisza Interfluve over thousands of years as it shifted from east to west. It is a characteristic of sandy soils that they warm up rapidly and, being light in colour, reflect solar radiation more, thus helping the grapes to ripen. The quartz content of those soils makes the vines immune to phylloxera. On the other hand, such soils have poor nutrient supply and water retention capacities and a relatively low mineral content.

The climate conditions of the production area are mainly determined by the continental climate predominant in Hungary, which is characterised above all by hot summers and cold winters. The climate conditions, low-lying nature and relatively low height above sea level combine to make the occurrence of frosts likely in spring and autumn. The average temperature is around 10–11 °C. The average number of sunshine hours is over 2 000 hours per year. Average annual precipitation is 450–500 mm, which largely meets the grapes' needs, albeit with an uneven annual distribution.

Wine – Description of the demarcated area (2)

(b) Human factors

Due to its large geographical size, the production area has rich vine-growing and wine-making traditions.

The first written record of the production area's already flourishing vine-growing industry is a charter establishing St Benedict's Abbey from 1075, as evidenced by further records as of the 13th century (e.g. Csepel Island). Hungary's central region had a large population in the Middle Ages, who grew grapes and made wine mainly for their own and local consumption. The wine mainly served to replace the relatively poor-quality drinking water. It was at this time that two-tier production (grape and fruit-growing in a single area) developed, a tradition that endured until the 1960s, when purely industrial grape and fruit production was introduced.

The vine-growing tradition of the Middle Ages was set back by the Turkish occupation of the 16th and 17th centuries, which led to a sharp decline in population and a fall in production, despite efforts by the Turkish authorities to stimulate production with lower taxes. Vine-growing areas were primarily confined to the edges of the remaining settlements (e.g. market towns), although owners often continued production by returning to their abandoned settlement several times a year. Vine and wine production underwent a revival after the Turkish occupation had ended. From then on, the stabilisation and economic exploitation of previously abandoned sandy areas mainly involved the planting of vineyards and orchards, centred once again around the region's market towns. Wine increasingly became a commercial product.

Since sandy soils proved to be immune to phylloxera, the epidemic (which broke out in 1875) not only left vine-growing virtually untouched, but also largely enhanced its role. The research centre set up at Miklóstelep, outside Kecskemét, in 1883 was at the centre of the fight against phylloxera and, alongside a vocational education system devised in the early 20th century, was instrumental in developing the region's vine-growing and wine-making industry. This period witnessed significant growth in the market and reputation of wines from this region, as the area under vines increased several times over. This was facilitated by the development of the rail and road network. 40–60-hectare vineyards and 2 000–3 000-hectolitre wineries entered production.

After the Second World War, the larger wineries were nationalised, but the structure of vine-growing remained unchanged up to the 1960s, when large-scale industrial production and the planting of traditional varieties (e.g. Ezerjő, Kadarka, Kövidinka) and varieties originating from other wine regions (such as Kékfrankos, Leányka, Muscat ottonel, or Olasz rizling) got underway. Various forms of cultivation techniques involving larger distances between rows, as well as high and medium-high vine-training, came to predominate. In addition to further changes in varieties (the planting of world-famous varieties such as Chardonnay or Cabernet Sauvignon), an increase in the size of the cultivated area and a change in cultivation method, the late 1970s also saw the development of modernised, high-capacity wine production plants.

Following political and economic changes in Hungary, the early 1990s saw further restructuring, with the setting-up of numerous smaller and larger vineyards and wineries better able to meet changing market demands, and considerable fragmentation of areas under vines.

Hungary's accession to the European Union in 2004 marked the start of further changes in varieties and cultivation methods (partly financed by EU restructuring funds) and a reduction of areas under cultivation by eliminating outdated vineyards, though this period also saw the modernisation and concentration of the remaining vineyards and wineries. Today, as restructuring continues, Hungarian-bred varieties (such as Cserzezi fűszeres) that are suited to ecological conditions, use favourable cultivation techniques and meet market demands, occupy an increasing proportion of the area under cultivation.

Wine – Description of the demarcated area (3)

2. Description of the wines

A general feature of the wines is their elegant appearance, lively and fresh character, fine acid composition and medium finish, while the varietal wines have fruity and flowery aromas and tastes that are typical of the variety used.

3. Link between the production area, human factors and the product

The ecological conditions of the demarcated area can be clearly discerned in the wines. Wines produced here generally mature more quickly, are softer in character, and have low alcohol strength. Thanks to the sandy soil, these wines have a relatively low mineral content and are lighter.

Accounting for just under half of the country's total grape production, the 'Duna/Dunai' wine region plays a key role in the vine-growing and wine-producing sector of Hungarian agriculture.

In addition to its economic weight, vine production also plays a significant social role by helping to retain the local population.

Due to local ecological conditions (e.g. sandy soils, lack of precipitation), vine-growing is one of the most cost-effective farming activities in this region. Vineyards have been effective in preventing the spread of wind-borne sands, and vines tend to survive better than other plants on soils with poor water-retention capacity.

The proportion of indigenous and newly bred Hungarian grape varieties planted in the vineyards of the 'Duna/Dunai' wine region stands at over 60 %.

Traditionally, the aromatic grape varieties have been used to produce mustkotály (Muscat) wines.

9. Essential further conditions (packaging, labelling, other requirements)

Rules on indications

Legal framework:

In national legislation

Type of further condition:

Additional provisions relating to labelling

Description of the condition:

The names of smaller geographical units cannot be displayed.

Use of traditional and other restricted expressions

Legal framework:

In national legislation

Type of further condition:

Additional provisions relating to labelling

Description of the condition:

Traditional expressions, other restricted expressions, and expressions referring to the colour of the wine shall not be indicated on the label in lettering which is bigger than that used for the designation of origin.

Use of traditional and other restricted expressions

Legal framework:

In national legislation

Type of further condition:

Additional provisions relating to labelling

Description of the condition:

Traditional expressions, other restricted expressions, and expressions referring to the colour of the wine shall not be indicated on the label in lettering which is bigger than that used for the designation of origin.

Use of variety names

Legal framework:

In national legislation

Type of further condition:

Additional provisions relating to labelling

Description of the condition:

- (a) Variety names may be displayed on the label provided that the lettering in which they appear is not bigger than that used for the designation of origin.
- (b) The variety name 'Arany sárfehér' cannot be used to indicate the 'Duna/Dunai' PDO.
- (c) In the case of blended wines, the word 'küvé', 'cuvée' or 'házasítás' [coupage/blending] may be used.

Link to the product specification

https://boraszat.kormany.hu/download/b/5c/82000/Duna_OEM%20termekleiras_v3_2_boraszat_kormany_hu_170801.pdf

Publication of the amended single document following the approval of a minor amendment pursuant to the second subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

(2020/C 171/08)

The European Commission has approved this minor amendment in accordance with the third subparagraph of Article 6(2) of Commission Delegated Regulation (EU) No 664/2014 ⁽¹⁾.

The application for approval of this minor amendment can be consulted in the Commission's eAmbrosia database.

SINGLE DOCUMENT

'PATATA DEL FUCINO'

EU No: PGI-IT-01217-AM01 – 10.1.2020

PDO () PGI (X)

1. Name(s)

'Patata del Fucino'

2. Member State or third country:

Italy

3. Description of the agricultural product or foodstuff

3.1. Type of product

Class 1.6. Fruit, vegetables and cereals, fresh or processed

3.2. Description of product to which the name in 1 applies

The name 'Patata del Fucino' denotes ripe tubers of the *Solanum tuberosum* species in the *Solanaceae* family. They are obtained using seed tubers of potato varieties that are registered in the common catalogue of agricultural plant varieties.

The tubers have a size (diameter) that is greater than 35 mm but does not exceed 80 mm and their shape ranges from round to round-oval, oval and elongated oval. The skin does not separate from the flesh; the flesh is firm and does not yield to pressure; and the colour is typical of the variety, i.e. from white to various shades of yellow. The edible part is not less than 95 %.

The chemical characteristics (per 100 grams of the edible part) are as follows:

Dry residue \geq 14;

starch \geq 8 g;

potassium \geq 300 mg;

phosphorus \geq 35 mg.

The 'Patata del Fucino' is harvested when the potatoes are completely ripe, from the end of July onwards. The potatoes are stored in suitable containers and can be kept until the end of the month of May following the harvest without any deterioration in their typical characteristics.

Quality tolerances

⁽¹⁾ OJ L 179, 19.6.2014, p. 17.

Potatoes eligible for protection, when marketed in the chosen packaging, must have the following characteristics:

- (a) Uniformity of tuber size: the size of the tubers may not be less than 35 mm or more than 80 mm; the maximum difference allowed in individual packs is 30 mm;
- (b) The tubers must be intact, firm, clean, without sprouts and free from biotic or abiotic damage.

3.3. *Feed (for products of animal origin only) and raw materials (for processed products only)*

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3.4. *Specific steps in production that must take place in the identified geographical area*

The 'Patata del Fucino' must be planted, grown and harvested in the defined geographical area.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

The potatoes must be stored in bins at a temperature of 4 – 10 °C with relative humidity of between 88 and 95 %. The tubers may also be kept in the refrigerator for long periods, but no longer than 9 months. Treatments to prevent sprouting on stored tubers are allowed in accordance with the appropriate legislation in force.

When marketed for consumption, 'Patata del Fucino' PGI must be packaged using:

- Net sacks: 2 kg to 20 kg;
- Small nets: 0,500 kg to 2,5 kg;
- Packs: vertbags, quickbags, girsacs and bags weighing 0,500 kg to 5 kg;
- Cartons or crates: 3 kg up to a maximum of 20 kg;
- Food trays: 0,500 kg to 5 kg;
- Baskets: 0,500 kg to 5 kg.

All types of packaging must contain cleaned (brushed and/or washed) potatoes and must be sealed in such a way that the tubers cannot be removed without breaking the packaging, with the exception of cartons and crates.

3.6. *Specific rules concerning labelling of the product the registered name refers to*

In addition to the symbol of the European Union and the information required by law, the label on the packaging also contains the following wordings and information:

- 'Patata del Fucino' followed by the abbreviation 'IGP' ('PGI') or by the wording 'Indicazione Geografica Protetta' ['Protected Geographical Indication'];
- Name and address, or company name and registered office, of the individual producer and/or association of producers and/or the packer;
- Net weight as sold;
- Variety;
- The following product logo:



It is forbidden to add any description that is not expressly provided for.

4. Concise definition of the geographical area

The border of the growing area is marked by the Circonfucense provincial road and the area includes parts of the territory, divided by farm roads into numbered plots of land, of the following municipalities of the Province of L'Aquila: Avezzano, Celano, Cerchio, Aielli, Pescina, S. Benedetto dei Marsi, Ortucchio, Trasacco and Luco dei Marsi.

5. Link with the geographical area

'Patata del Fucino' is grown on the bed of the lake of the same name, Lake Fucino, which was drained and reclaimed in 1875. This area is situated at 700 metres above sea level.

The main morphological characteristics of the land have created three distinct areas: the depression of the former lake; a terraced area at an altitude of between 670 and 720 metres; and an area with a complex morphology located above the other two areas. Due to the presence of a former lake basin, sedimentary accumulation has outweighed the effects of erosion. The silty-clayey soil has a large quantity of total and active limestone as a result of the carbonate nature of the pedogenic sediments. The reaction (pH) fluctuates between sub-alkaline and alkaline and there are high levels of organic matter, total nitrogen, assimilable phosphorus and exchangeable potassium. The high content of organic matter is preserved as a result of the large quantities of manure applied regularly by farmers. The soil composition allows good drainage and the normal development of even and regular tubers. The particular characteristics of the area, which is bounded by mountains, mean that it is not at all affected by the sea, situated just under 80 km to the east. Instead, it has the typical features of a continental climate with very harsh, wet winters and hot, often humid summers. During the productive season the variation in temperatures between day (around 30 °C) and night (10 °C-15 °C) favours plant growth. The good water retention capacity of the soil and the water rising by capillarity from underlying aquifers, combined with frequent morning dews, ensure that the crops have plenty of water available. Rain, snow and the characteristic dew, which often constitutes microprecipitation, complete the climatic profile of the area. There is a good supply of water in the area thanks to the natural streams and rivers that flow down from the mountains surrounding the plain and a geometrical network of canals. These were especially constructed as part of the water-engineering works undertaken by the then newly created Ente Fucino [Fucino Authority] during the agrarian reform years (1950s) with the dual purpose of draining the land and using the water to irrigate the crops, thus optimising growing conditions for farmers.

'Patata del Fucino' is different from potatoes grown in other areas because of its characteristic flesh that makes it suitable for both household consumption and industrial use. 'Patata del Fucino' has firm flesh which does not yield to pressure, and a skin which does not separate from the flesh. When steamed the flesh presents rather fine granulation and no signs of after-cooking blackening. Another much-appreciated feature is that the flesh shows little browning when fried. In a panel test carried out by trained tasters, 'Patata del Fucino' was judged to have a pleasant flavour or a very strong potato flavour with almost no unpleasant after-tastes (metal, grass, etc.). The potatoes keep these organoleptic qualities even after months of storage.

The production cycle of 'Patata del Fucino' spans all seasons in the geographical production area: from sowing in the spring; growth and production in the summer; to harvesting, only when potatoes are completely ripe, in late summer/autumn. This means that the potatoes benefit from the climatic effect of the different seasons. The quality of 'Patata del Fucino' is linked to the growing conditions provided by what used to be the bed of the lake. The particular features of the land mean that the potatoes can be cultivated naturally, lending the product its typical organoleptic characteristics. The light, fresh, mostly silty and very fertile soil, naturally rich in macro and micro nutrients, organic matter and the resulting humus, produced by sedimentation of organic material over the centuries, ensures that no damage and/or cracks are caused to the surface of the potatoes during growth or harvest, thus yielding regular-shaped tubers with the skin adhering well to the flesh. The climatic conditions described (soil composition, good capillary rise, temperature, water for irrigation) make the Fucino area particularly suited to growing potatoes. Thanks to the extensive experience of local growers, the constant efforts to improve agricultural techniques with a preference for green methods, and the protection of the growing environment, this area produces high-quality potatoes that have always been prized and well-known for their high quality on the national market.

Since 2002, many associated producers in the Fucino area have been producing potatoes in accordance with the 'integrated production' certification scheme and have adopted a specification that relates expressly to the 'Patata del Fucino'; this demonstrates that the name is also used in farming/commercial language.

Several articles have been published in specialist magazines such as 'L'Informatore Agrario' which mention the name 'Patata del Fucino', the Fucino area as an area highly suited to the production of potatoes and the Fucino area as a place to test potato varieties:

- 'Le varietà di patata coltivate in Italia e la loro destinazione d'uso' ('Potato varieties grown in Italy and their uses') (No 2/2002, p. 61);
- 'Ecco perchè in Italia non si produce patata da seme' ('Why seed potatoes are not produced in Italy') (No 46/2008, pp. 34-36);
- 'Produzione di patata da seme: contributo per la valorizzazione dell'agricoltura montana' ('Seed potato production: helping to develop mountain farming') (No 18/1997, pp. 27-29);
- 'Sperimentazione varietale 1998 su patata comune nel centro e nel nord' ('Common potato variety testing in central and northern Italy – 1998') (No 48/1998, pp. 39-46).

Over the years, many activities have been organised by local operators for the promotion and development of 'Patata del Fucino'. These include:

- A 'Sagra della Patata' ('Potato Festival') has been organised since 1971 in the Fucino area, specifically in the municipality of Avezzano;
- In 2008, the International Year of the Potato as declared by the FAO, growers of 'Patata del Fucino' provided technical support and agricultural tools to the Zadrima region of Albania, under the 'Progetto Albania' cooperation project;
- In 2001, an episode of the television programme 'Il Gusto' ('Taste') dedicated to the 'Patata del Fucino' was broadcast on the Canale 5 channel;
- In 1993, the 'Patata del Fucino' name was brought to the attention of the nation in an episode of the television programme 'Linea Verde' ('Green Line') broadcast by state broadcaster RAI.

Reference to publication of the specification

(the second subparagraph of Article 6(1) of this Regulation)

The full text of the product specification is available on the following website: <http://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/3335>

Or alternatively:

by going directly to the home page of the Ministry of Agricultural, Food and Forestry Policy (www.politicheagricole.it) and clicking on 'Qualità' (at the top right of the screen), then on 'Prodotti DOP IGP STG' (on the left-hand side of the screen) and finally on 'Disciplinari di Produzione all'esame dell'UE'.

Publication of an application for registration of a name pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2020/C 171/09)

This publication confers the right to oppose the application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council ⁽¹⁾ within three months from the date of this publication.

SINGLE DOCUMENT

‘SZILVÁSVÁRADI PISZTRÁNG’

EU No: PGI-HU-02472 – 4.6.2018

PDO () PGI (X)

1. Name(s)

‘Szilvásváradi pizstráng’

2. Member State or Third Country

Hungary

3. Description of the agricultural product or foodstuff

3.1. Type of product

Class 1.7: Fresh fish, molluscs, and crustaceans and products derived therefrom

3.2. Description of the product to which the name in (1) applies

‘Szilvásváradi pizstráng’ is a member of the species *Salmo trutta* morpha *fario* (brown trout), part of the Salmonidae family. Viewed from above, its back is grey-green, while its flanks are golden yellow with dark and distinctive bright red spots surrounded by halos.

‘Szilvásváradi pizstráng’ is placed on the market fresh when it is 40–45 cm long and weighing 400–500 g once cleaned (gutted). Its flesh is firm and pale, with a slight pink hue and there are no muddy undertones in its subtle flavour.

Its texture is firm to the touch, with no fatty deposits, and is consistent across the entire cross-section of the fish (from back to belly). It has finer, more pleasant muscle fibres than brown trout farmed elsewhere.

3.3. Feed (for products of animal origin only) and raw materials (for processed products only)

During rearing, ‘Szilvásváradi pizstráng’ are fed mainly on feed made from hormone-, chemical- and antibiotic-free fishmeal, together with fish oil and the necessary vitamins and trace elements, and on feedstuffs produced ecologically involving no chemicals or GMOs. An important aspect of the fish-farming method is leaving in place the plants on the edges of the system of trout ponds located in the geographical area defined in point 4, which provide the fish with a natural food supplement (primarily insects).

3.4. Specific steps in production that must take place in the identified geographical area

All stages of the production process, i.e. breeding, propagation, nursery rearing, the rearing of marketable fish and harvesting, must take place within the designated geographical area.

3.5. Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to

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3.6. Specific rules concerning labelling of the product the registered name refers to

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⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

4. Concise definition of the geographical area

The administrative region of Szilvásvárad.

5. Link with the geographical area

The link between 'Szilvásváradi pizstráng' and the geographical area is based on the quality of the product.

The flavour of 'Szilvásváradi pizstráng' differs from that of other, similar fish varieties, and it also has a distinctive texture. Its pink flesh has a subtle flavour with no muddy notes and a firmer texture and finer muscle fibres than trout farmed elsewhere, without any fatty deposits.

The Szalajka valley, which is home to the 'Szilvásváradi pizstráng' and is where it is farmed, is a ravine in the Bükk mountains lying at 350–400 m above sea level, containing the Szalajka and Szikla karst springs. The fish farm ponds were formed using water from the river Szalajka flowing through the valley, and this river provides the ponds' water supply. The water of the springs descends from an altitude of 800 m in the Bükk plateau through the karst system, where it undergoes repeated natural filtration before emerging as the exceptionally clean and good-quality water that feeds the fish farm ponds. The water temperature of the springs is 11–12 °C all year round.

The fish farm ponds are located right next to the springs that supply their water. The springs and the fish farm ponds, including the hatchery, are separated by about 200 m, so uniquely in Hungary, there are no sources of pollution, inhabited areas or cultivated agricultural land between the spring and the ponds, and the water reaches the trout ponds via the surface. The entire area is contained within the Bükk National Park.

The geographical area has the following unique characteristics:

- the water temperature of the springs feeding the ponds remains constant in summer and winter, so there are only small variations in temperature in the hatchery and the rearing ponds. The fish can therefore be reared in a stable environment. The consistently cool spring water all year round and the short distance to the pond system means that the water temperature in the ponds cannot rise above 15 °C even during the summer phase of the growing season. The cool water reduces the fish's appetite and they therefore grow more slowly, making their flesh firmer, denser and leaner than average. The constant supply of fresh water from the springs prevents a muddy flavour from developing;
- the constant and fast-moving flow of water ensures good oxygenation, which is not just essential for the fish but also – by increasing their metabolism – benefits their growth and the quality of their flesh by making it firmer with finer muscle fibres;
- the consistently excellent, drinking-quality spring water, which is regularly tested at an accredited laboratory, gives the fish's flesh a subtle flavour with no muddy undertones;
- in the stress-free environment, the use of artificial aeration systems and unnecessary human presence around the rearing ponds are avoided.

All of these factors contribute to the uniform growth of 'Szilvásváradi pizstráng' and to the texture and colour of its flesh: its characteristic firmness and pinkness, and its lack of fatty deposits.

The brown trout breeding stock now found in the Szilvásvárad trout farm is the same as it has ever been and is genetically pure. No live fish in the Salmonidae family from foreign farms or bodies of water have ever been introduced to or kept in the trout farm or the river Szalajka.

The experience accumulated over generations forms the basis for the stripping of the eggs at the right time, the propagation methods used and the removal of undeveloped eggs. According to local expertise, the feeding of fry with feed should start 32–35 days after hatching, as they are ready to accept feed at this stage. Fry will reject feed if feeding starts later than this. This methodology results in a low fish mortality rate and ensures that the fish farm ponds remain clean, since the feed introduced into the pond is eaten up by the fish and no excess feed is left in the pond to contaminate it.

This experience and expertise helps to ensure that 'Szilvásváradi pizstráng' is reared using only chemical-, pharmaceutical- and stress-free methods, from roe to full-grown fish.

The unique characteristics of 'Szilvásváradai pisztráng' set out above are jointly safeguarded by the drinking-quality karst spring water and this accumulated farming and rearing experience.

On account of the original genetic stock being preserved intact and the fish being highly prized in culinary circles, in 2013 'Szilvásváradai pisztráng' was recognised as a 'Bükk National Park Product'.

Reference to publication of the product specification

(the second subparagraph of Article 6(1) of this Regulation)

<https://gi.kormany.hu/foldrajzi-arujelzok>

Publication of an application for approval of an amendment, which is not minor, to a product specification pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2020/C 171/10)

This publication confers the right to oppose the amendment application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council ⁽¹⁾ within three months from the date of this publication.

APPLICATION FOR APPROVAL OF AN AMENDMENT TO THE PRODUCT SPECIFICATION OF PROTECTED DESIGNATIONS OF ORIGIN/PROTECTED GEOGRAPHICAL INDICATIONS WHICH IS NOT MINOR

Application for approval of an amendment in accordance with the first subparagraph of Article 53(2), of Regulation (EU) No 1151/2012

‘Casatella Trevigiana’

EU No: PDO-IT-0348-AM02 – 22.11.2019

PDO (X PGI ()

1. Applicant group and legitimate interest

Consorzio per la Tutela del formaggio Casatella Trevigiana [‘Casatella Trevigiana’ Cheese Protection Association]

Viale Sante Biasuzzi, 20

31038 Paese (TV)

ITALIA

Telephone and fax number: +39 0422951480

Email: info@casatella.it

This Association meets the requirements laid down in Article 13(1) of Ministerial Decree No 12511 of 14 October 2013.

2. Member State or third country

Italy

3. Heading in the product specification affected by the amendment(s)

- Name of product
- Description of product
- Geographical area
- Proof of origin
- Method of production
- Link
- Labelling
- Other:

4. Type of amendment(s)

- Amendment to product specification of a registered PDO or PGI not to be qualified as minor in accordance with the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012.
- Amendment to product specification of registered PDO or PGI for which a Single Document (or equivalent) has not been published not to be qualified as minor in accordance with the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

⁽¹⁾ OJL 343, 14.12.2012, p. 1.

5. Amendments

Description of product

Article 2 of the current product specification and point 3.2 of the single document

Chemical characteristics

Current version:

'Fat: 18-25 % on a wet basis'

New version:

'Fat: 18-27 % on a wet basis'

This amendment reduces the risk of cheeses failing to comply with the rule on fat as a result of the changeable nature of the fat content of the milk used to make 'Casatella Trevigiana' PDO, mainly driven by external factors such as the cows' diet, climate, rearing system and milking intervals.

This risk is higher for small and medium-sized cheesemakers, both because they get their milk from a smaller pool of dairy farms and because it is not possible to correct the fat content of milk supplied in bulk, bearing in mind that 'Casatella Trevigiana' PDO is made using whole milk.

Method of production

Article 5 of the current product specification and point 3.4 of the single document

'At least 90 % of the diet must consist of feedstuffs originating from the area defined in Article 3.'

'At least 60 % of the diet must consist of feedstuffs originating from the area defined in Article 3.'

Point 3.4 of the single document

The following is added after the third bullet point:

As there has been an irreversible decline in the amount of agricultural land used to grow animal fodder in the Province of Treviso, part of the diet must necessarily consist of feedstuffs from outside the area defined in point 4.

This amendment is needed because the amount of agricultural land being used to grow animal fodder in the Province of Treviso – the 'Casatella Trevigiana' PDO production area – has declined considerably over the last 10 years.

This is mainly the result of:

- a) land being used for major urbanisation projects and roads;
- b) agricultural land being turned over from fodder cultivation to vine-growing.

To aid understanding of the extent of this issue, in the Province of Treviso:

- the land area used for permanent fodder crops fell by 50 % between 2010 and 2018;
- the land area used for temporary fodder crops fell by 26 % between 2010 and 2018;
- the land area under vines rose by 30 % between 2010 and 2018.

SINGLE DOCUMENT

'Casatella Trevigiana'

EU No: PDO-IT-0348-AM02 – 22.11.2019

PDO (X) PGI ()

1. Name(s)

'Casatella Trevigiana'

2. Member State or third country

Italy

3. Description of the agricultural product or foodstuff

3.1. Type of product

Class 1.3. Cheeses

3.2. Description of the product to which the name in 1 applies

A soft cheese made from whole milk from the Friesian, Italian Red Pied, Italian Brown and Burlina breeds of cow and crosses of those breeds. It has the following organoleptic characteristics when released onto the market: a soft, glossy, slightly creamy, melt-in-the-mouth consistency and a milky white to creamy white colour. Tiny, faint eyes may be apparent. 'Casatella Trevigiana' PDO has a unique consistency that does not fit into either the 'spreadable' or the 'very creamy' category.

The cheese has little to no rind, and is made in the traditional wheel shape. It has a delicate, milky and fresh aroma.

The cheese tastes sweet and milky, with slightly sour veins.

Chemical characteristics

Moisture content: 53-60 %

Fat: 18-27 % on a wet basis

Protein content: > 12 % on a wet basis

Physical characteristics

Shape: Wheel-shaped

Weight

Large round: 1,8-2,2 kg

Small round: 0,20-0,70 kg

Diameter

Large round: 18-22 cm

Small round: 5-12 cm

Heel height

Large round: 5-8 cm

Small round: 4-6 cm

3.3. Feed (for products of animal origin only) and raw materials (for processed products only)

The diet fed to the cows whose milk is used to make 'Casatella Trevigiana' PDO must meet the following requirements:

- At least 60 % of the diet must consist of feedstuffs originating from the area defined in point 4.
- At least 60 % of the dry matter fed daily to lactating cows must come from fodder.
- The following feedstuffs, which are not typical of the production area, may not be used: fodder beet; citrus fruit, olives, or residues from processing them; sainfoin and sulla; whole vegetables; or residues from processing artichokes, cauliflowers, turnips and tomatoes.

As there has been an irreversible decline in the amount of agricultural land used to grow animal fodder in the Province of Treviso, part of the diet must necessarily consist of feedstuffs from outside the area defined in point 4.

The milk used to make 'Casatella Trevigiana' PDO must come from farms within the relevant geographical area (Province of Treviso).

The milk must have a fat content of more than 3,2 % at the time of processing. The milk must not contain any preservatives and the use of beestings or milk from evidently diseased cows is prohibited. The milk must be chilled on the farm. In any event, the cheesemaking process must begin within 48 hours of milking.

3.4. *Specific steps in production that must take place in the identified geographical area*

The entire production process (cow rearing and milk production, coagulation, working the curds, forming the cheese rounds, draining off the whey, salting and maturing) must take place within the area defined in point 4.

The cheesemaking process consists of the following stages: rearing the cows, producing the milk, processing and maturing.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

'Casatella Trevigiana' PDO must be packaged when marketed. Since 'Casatella Trevigiana' PDO is a highly perishable and delicate soft cheese, long journeys in its unpackaged state could undermine its organoleptic, chemical and physical properties and in particular could affect how it is matured and how long for.

Therefore, to ensure that the product retains its typical quality features, packaging must not be left too late after production. For this reason, the product must be packaged within the production area to guarantee traceability and control and to ensure that 'Casatella Trevigiana' PDO retains its specific features and chemical, physical and organoleptic properties.

3.6. *Specific rules concerning labelling of the product the registered name refers to*

'Casatella Trevigiana' PDO cheese is identified by the following logo:



The words *Denominazione d'Origine Protetta* ['Protected Designation of Origin'] may be replaced by the acronym *DOP* ['PDO'].

The proportions of the upper and lower parts of the logo as shown above may not be changed. The logo must appear on the outer protective wrapping of the cheese.

The outer wrapping may not contain any promotional or misleading information.

The size of the logo must be proportional to the size of the packaging as follows: the total width of the word 'Casatella' may not be less than 80 % of the diameter of the package.

Given the type of cheese, no information of any kind may be displayed directly on the cheese itself.

The use of packaging containing the logo and wording as described is mandatory.

4. **Concise definition of the geographical area**

The whole of the Province of Treviso.

5. **Link with the geographical area**

The properties and quality characteristics of 'Casatella Trevigiana' PDO can be traced back to its local, family-based and rural origins, as well as developments in the craft of cheesemaking and the native strains of bacteria selected in the production area. Specifically, the quality and distinctiveness of 'Casatella Trevigiana' PDO cheese are a direct result of the characteristics of the indigenous microbiotic flora contained in the milk and of the temperatures and timings used in the cheesemaking process, as these influence the selection of species, strains and concentrations.

'Casatella Trevigiana' has a soft, glossy, slightly creamy, melt-in-the-mouth consistency and a milky white to creamy white colour. Tiny, faint eyes may be apparent.

It has very little to no rind, is made in the traditional wheel shape, and has a delicate, milky and fresh aroma, and a sweet, milky taste with slightly acidic veins.

Recent studies show that the microbial flora selected within the defined area over the years contain different strains of *Streptococcus thermophilus*, the properties and metabolic activities of which are key not only for the acidification process but also for shaping the sensory properties of the product, such as the distinctive, slightly sour taste of the mature cheese.

Likewise, the presence – albeit in a smaller concentration – of strains of *Lactobacillus thermophilus*, which have higher proteolytic activity, ensures that caseins are broken down, with the production of molecules or their precursors that influence the consistency, maturing and taste of the cheese, all of these being conditions that are unique to this specific area and cannot be reproduced elsewhere.

The particular cheesemaking technique used by the producers, consisting of coagulation at a low temperature is a tradition that was developed in order to exploit and increase the presence of strains of *Streptococcus thermophilus* and *Lactobacillus thermophilus*.

This brings out and shapes the main sensory and organoleptic characteristics of 'Casatella Trevigiana' PDO.

This typical Treviso cheese comes from a long-standing tradition of home cheesemaking. Production techniques were passed down by word of mouth and based on very simple methods. The true origin of the cheese, therefore, was at traditional Treviso dairies, classified since 1962 as 'remote'.

There are many written records testifying that Casatella cheese originates in Treviso.

Reference to publication of the product specification

(the second subparagraph of Article 6(1) of this Regulation)

The consolidated text of the product specification can be consulted on the following website: <http://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/3335>

or alternatively:

by going directly to the home page of the Ministry of Agricultural, Food and Forestry Policy (www.politicheagricole.it) and clicking on 'Qualità' (at the top right of the screen), then on 'Prodotti DOP IGP STG' (on the left-hand side of the screen) and finally on 'Disciplinari di Produzione all'esame dell'UE'.

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