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## Information and Notices

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[1] Text with EEA relevance

IV

*(Notices)*

# NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

# COUNCIL

## COUNCIL DECISION

## of 4 October 2012

## appointing the members and alternate members of the Advisory Committee on freedom of movement for workers

(2012/C 302/01)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Regulation (EU) No 492/2011 of the European Parliament and of the Council of 5 April 2011 on freedom of movement for workers within the Union [1], and in particular Articles 23 and 24 thereof,

Having regard to the lists of candidates submitted to the Council by the governments of the Member States,

Whereas:

(1) By its Decision of 21 October 2010 [2], the Council appointed the members and alternate members of the Advisory Committee on freedom of movement for workers (Committee) for the period from 25 September 2010 to 24 September 2012.

(2) The members remain in office until they are replaced or reappointed.

(3) Members and alternate members of the Committee should be appointed for a period of two years,

HAS ADOPTED THIS DECISION:

*Article 1*

The following are hereby appointed members and alternate members of the Advisory Committee on freedom of movement for workers for the period from 25 September 2012 to 24 September 2014:

I. GOVERNMENT REPRESENTATIVES

| Country | Members | Alternates |
|---|---|---|
| Belgium | Ms Annelies LAGAE<br>Ms Anne ZIMMERMAN | Mr Jacques OUZIEL |
| Bulgaria | Mr Hristo SIMEONOV<br>Ms Tatiana GUEORGUIEVA | Ms Dimitrina KOSTADINOVA |
| Czech Republic | Mr Roman SEIDL<br>Ms Ladislava STEINICHOVÁ | Ms Andrea PLAČKOVÁ |

[1] OJ L 141, 27.5.2011, p. 1.
[2] OJ C 294, 29.10.2010, p. 1.

| Country | Members | Alternates |
|---|---|---|
| Denmark | Mr Stig Hansen NØRGAARD<br>Ms Vibe WESTH | Ms Simone HEINECKE |
| Germany | Ms Vera BADE<br>Mr Johannes RASCHKA | Mr Henning GRUB |
| Estonia | Ms Jana JÄRVIK<br>Ms Liis REITER | Ms Kristi SUUR |
| Ireland | Ms Mary Joan KEHOE<br>Mr Anthony MORRISSEY | Ms Aedin DOYLE |
| Greece | Ms Athina DIAKOUMAKOU<br>Mr Georgios NERANTZIS | Ms Panagiota STAMATIOU |
| Spain | Ms Paloma MARTÍNEZ GAMO<br>Mr Miguel Ángel AZNAR NIETO | Mr Juan Pablo PARRA GUTIÉRREZ |
| France | Ms Nadia MAROT<br>Mr Albert MARTINO | Mr Laurent FRIBOULET |
| Italy | | |
| Cyprus | Mr Demetris MICHAELIDES<br>Mr Constantinos KARMELLOS | Mr Andreas CHRISTOU |
| Latvia | Ms Linda PAUGA<br>Ms Līga EMULE-KONONE | Ms Ilze ZVĪDRIŅA |
| Lithuania | Ms Rasa MALAIŠKIENĖ<br>Ms Agnė KUNIGONYTĖ | Mr Vytautas JURŠĖNAS |
| Luxembourg | Mr Tom GOEDERS<br>Mr Laurent PEUSCH | Ms Anne-Catherine THILL |
| Hungary | Ms Rita ANTÓNI<br>Ms Judit KATONA | Ms Orsolya KISGYÖRGY |
| Malta | Ms Mariella GRECH<br>Mr Nicola CINI | Mr George CAMILLERI |
| Netherlands | Ms Conny W. OLDE OLTHOF<br>Mr Martin G. BLOMSMA | Ms Cristel VAN TILBURG |
| Austria | Mr Heinz KUTROWATZ<br>Mr Helmut GERL | Ms Barbara BOHACZEK |
| Poland | Ms Magdalena SWEKLEJ<br>Mr Marcin WIATRÓW | Ms Agnieszka ZDAK |
| Portugal | Mr Octávio OLIVEIRA<br>Mr Paulo GOMES | Ms Helena SANTOS |
| Romania | Mr Auraș MARINESCU<br>Ms Oana BARBUT | Mr Bogdan-Tiberius PAȘCA |
| Slovenia | Ms Sonja MALEC<br>Mr Radivoj RADAK | Ms Mateja GOLJA |
| Slovakia | Ms Agnesa SKUPNÍKOVÁ | Mr Jaroslav KOVÁČ |
| Finland | Ms Katri NISKANEN<br>Mr Olli SORAINEN | Ms Mirkka MYKKÄNEN |
| Sweden | Mr Ricky IFWARSSON<br>Ms Madeleine ÖHBERG | Mr Torbjörn WALLIN |
| United Kingdom | Ms Fiona KILPATRICK<br>Ms Deborah MORRISON | Mr Jonathan PIGGINS |

II. TRADE UNION REPRESENTATIVES

| Country | Members | Alternates |
|---|---|---|
| Belgium | Mr Jean-François MACOURS<br>Mr Koen MEESTERS | Ms Yvienne VAN HOLSBEECK |
| Bulgaria | Ms Atanaska TODOROVA<br>Mr Daniel YANEV | Ms Antonia ZLATEVA |
| Czech Republic | Ms Jaroslava BAUEROVÁ<br>Mr Pavel JANÍČKO | Mr Vít SAMEK |
| Denmark | Ms Anette BERENTZEN<br>Mr Torben Dam JENSEN | Ms Käthe Munk RYOM |
| Germany | Ms Alexandra KRAMER<br>Ms Raja NEJEDLO | Mr Christian MOOS |
| Estonia | Mr Urmas LIPSO<br>Ms Liina CARR | Ms Aija MAASIKAS |
| Ireland | Ms Esther LYNCH<br>Mr John DOUGLAS | |
| Greece | Mr Georgios PERENTIS<br>Ms Metaxia STEKOULEA | Mr Konstantinos MYTILINOU |
| Spain | Ms Ana María CORRAL JUAN<br>Ms Concepción ROJO | Ms Pilar ROC ALFARO |
| France | Ms Francine BLANCHE<br>Ms Corinne MARES | Mr Ommar BENFAÏD |
| Italy | | |
| Cyprus | Mr Nicos GREGORIOU<br>Mr Nicos EPISTITHIOU | Mr Diomides DIOMIDOUS |
| Latvia | Ms Ruta PORNIECE<br>Mr Māris SIMULIS | Mr Jānis KAJAKS |
| Lithuania | Ms Janina ŠVEDIENĖ<br>Ms Janina MATUIZIENĖ | Ms Jovita MEŠKAUSKIENĖ |
| Luxembourg | Mr Eduardo DIAS<br>Mr Vincent JACQUET | Mr Jean-Claude REDING |
| Hungary | Ms Judit CZUGLERNÉ IVÁNYI<br>Ms Andrea AGÓCS | Mr László KOZÁK |
| Malta | Ms Antoinette AQUILINA<br>Mr Andrew MIZZI | Mr John BENCINI |
| Netherlands | Ms Caroline RIETBERGEN<br>Mr Martijn HORDIJK | Ms H. de GEUS |
| Austria | Mr Johannes PEYRL<br>Mr Oliver RÖPKE | Mr Franz FRIEHS |
| Poland | Mr Jakub KUS<br>Ms Halina PEPLIŃSKA | Mr Bogdan OLSZEWSKI |
| Portugal | Ms Catarina Maria BRANCO FERREIRA TAVARES<br>Mr Carlos Manuel ALVES TRINDADE | Mr Georges CASULA |
| Romania | Mr Valentin MOCANU<br>Mr Liviu APOSTOIU | Mr Dragos FRUMOSU |

| Country | Members | Alternates |
|---|---|---|
| Slovenia | Mr Goran LUKIČ<br>Mr Jakob POČIVAVŠEK | Ms Nadja GÖTZ |
| Slovakia | Ms Vlasta SZABOVÁ<br>Ms Beata ĎURANOVÁ | |
| Finland | Ms Eve KYNTÄJÄ<br>Mr Ralf SUND | Ms Jenni KARJALAINEN |
| Sweden | Ms Sofie REHNSTRÖM<br>Ms Eva OSCARSSON | Mr Mats ESSEMYR |
| United Kingdom | Mr Sean BAMFORD<br>Mr Mohammed TAJ | Mr Wilf SULLIVAN |

III. EMPLOYERS' ASSOCIATIONS REPRESENTATIVES

| Country | Members | Alternates |
|---|---|---|
| Belgium | Ms Michèle CLAUS<br>Ms Hilde THYS | Ms Monica DE JONGHE |
| Bulgaria | Mr Ivan ZAHARIEV<br>Mr Martin STOYANOV | Ms Daniela SIMIDCHIEVA |
| Czech Republic | Ms Vladimíra DRBALOVÁ<br>Ms Marie ZVOLSKÁ | Ms Jitka HLAVÁČKOVÁ |
| Denmark | Mr Henning GADE<br>Mr Flemming DREESEN | Ms Karen ROIY |
| Germany | Mr Alexander WILHELM<br>Ms Christina LANG | Ms Anne ROBRA |
| Estonia | Mr Marek SEPP<br>Ms Mare HIIESALU | Mr Tarmo KRIIS |
| Ireland | Mr Tony DONOHOE<br>Ms Kara McGANN | |
| Greece | Ms Rena BARDANI<br>Mr Nikos DIMAS | Ms Evangelia ARANITOU |
| Spain | Mr Santiago SOLER PÉREZ<br>Mr Javier IBARS ALVARO | Mr Luis MÉNDEZ LÓPEZ |
| France | Ms Catherine HAQUENNE<br>Ms Natacha MARQUET | Ms Pascale DESSEN |
| Italy | | |
| Cyprus | Ms Lena PANAYIOTOU<br>Mr Emilios MICHAEL | Mr Michael ANTONIOU |
| Latvia | Ms Anita LĪCE<br>Ms Ilona KIUKUCĀNE | |
| Lithuania | Mr Justinas USONIS<br>Mr Aidas VAIČIULIS | Ms Dovilė BAČKYTĖ |
| Luxembourg | Mr Marc KIEFFER<br>Mr François ENGELS | Mr Dany HAUSTGEN |
| Hungary | Ms Terézia BOROSNÉ BARTHA<br>Mr István KOMORÓCZKI | Ms Adrienn BÁLINT |

| Country | Members | Alternates |
|---|---|---|
| Malta | Mr Lawrence MIZZI<br>Mr Michael GALEA | Mr John HUBER |
| Netherlands | Mr Rob SLAGMOLEN<br>Mr A.P.M.G. SCHOENMAECKERS | Mr G.A.M. Gerard VAN DER GRIND |
| Austria | Ms Margit KREUZHUBER<br>Mr Andreas GRUBER | Ms Ulrike KLEIN |
| Poland | Ms Wioletta ŻUKOWSKA<br>Mr Przemysław OSUCH | Mr Andrzej STĘPNIKOWSKI |
| Portugal | Ms Cristina NAGY MORAIS<br>Ms Adília LISBOA | Mr Marcelino PENA COSTA |
| Romania | Ms Roxana PRODAN<br>Mr Daniel Sorin MOLDOVEANU | Mr Dan ANGHELESCU |
| Slovenia | Ms Maja SKORUPAN<br>Mr Igor ANTAUER | Ms Tatjana ČERIN |
| Slovakia | Mr Peter LÍŠKA<br>Mr Peter MOLNÁR | Mr Martin HOŠTÁK |
| Finland | Ms Riitta WÄRN<br>Mr Mikko RÄSÄNEN | Mr Vesa RANTAHALVARI |
| Sweden | Ms Karin EKENGER<br>Mr Örjan LUTZ | Mr Patrik KARLSSON |
| United Kingdom | Ms Sinead LAWRENCE<br>Mr Jim BLIGH | |

*Article 2*

The members not yet nominated will be appointed by the Council at a later date.

*Article 3*

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 4 October 2012.

*For the Council*
*The President*
S. CHARALAMBOUS

# EUROPEAN COMMISSION

## Euro exchange rates [1]

**5 October 2012**

(2012/C 302/02)

**1 euro =**

| | Currency | Exchange rate | | Currency | Exchange rate |
|---|---|---|---|---|---|
| USD | US dollar | 1,3002 | AUD | Australian dollar | 1,2682 |
| JPY | Japanese yen | 102,02 | CAD | Canadian dollar | 1,2750 |
| DKK | Danish krone | 7,4556 | HKD | Hong Kong dollar | 10,0805 |
| GBP | Pound sterling | 0,80325 | NZD | New Zealand dollar | 1,5775 |
| SEK | Swedish krona | 8,5728 | SGD | Singapore dollar | 1,5951 |
| CHF | Swiss franc | 1,2112 | KRW | South Korean won | 1 444,13 |
| ISK | Iceland króna | | ZAR | South African rand | 11,1983 |
| NOK | Norwegian krone | 7,3935 | CNY | Chinese yuan renminbi | 8,2226 |
| BGN | Bulgarian lev | 1,9558 | HRK | Croatian kuna | 7,4810 |
| CZK | Czech koruna | 24,915 | IDR | Indonesian rupiah | 12 467,96 |
| HUF | Hungarian forint | 282,75 | MYR | Malaysian ringgit | 3,9691 |
| LTL | Lithuanian litas | 3,4528 | PHP | Philippine peso | 53,831 |
| LVL | Latvian lats | 0,6961 | RUB | Russian rouble | 40,2520 |
| PLN | Polish zloty | 4,0735 | THB | Thai baht | 39,721 |
| RON | Romanian leu | 4,5782 | BRL | Brazilian real | 2,6258 |
| TRY | Turkish lira | 2,3375 | MXN | Mexican peso | 16,5844 |
| | | | INR | Indian rupee | 67,4220 |

[1] *Source*: reference exchange rate published by the ECB.

# Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006

(2012/C 302/03)

## 1. CONTEXT

This guidance document sets out aspects of the implementation of Article 57(2), third subparagraph of Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency ([1]), and of Article 41(2) of Regulation (EC) No 1901/2006 on medicinal products for paediatric use ([2]).

It addresses the posting and publishing of result-related information relating to clinical trials, thus implementing the EU legislation aiming to make the results of clinical trials publicly available — a policy aim which is maintained in the proposal of the Commission for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ([3]). This guidance document also gives guidance as to how non-compliance and factual inaccuracy are addressed.

This guidance document completes the following Commission guidance documents:

— Guideline 2010/C82/01 on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and declaration of the end of the trial (hereinafter 'detailed guidance CT-1') ([4]), and in particular Section 4.3 thereof,

— Guideline 2008/C168/02 on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004 ([5]), and in particular Sections 3 to 5 thereof, and

— Guideline 2009/C28/01 on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMEA), in accordance with Article 41 of Regulation (EC) No 1901/2006 ([6]), and in particular Sections 3.2 to 3.4 and Section 5 thereof.

Those Commission guidance documents had been further detailed by two implementing technical guidances published in 'EudraLex — the rules governing medicinal products in the European Union' on the 'List of fields to be made public from EudraCT for Paediatric Clinical Trials in accordance with Article 41 of Regulation (EC) No 1901/2006' and the 'List of fields contained in the "EudraCT" clinical trials database to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004.' ([7]).

## 2. SCOPE

This guidance document addresses the posting and publication of clinical trials as defined in Article 2(a) of Directive 2001/20/EC with at least one of the following characteristics:

— the clinical trial is regulated or was regulated by Directive 2001/20/EC, which took effect at the latest on 1 May 2004 (on the posting of result-related information on clinical trials which have ended in the past, see section 4.6.1). This implies that at least one investigator site of the clinical trial is located in the European Union (EU) or in a contracting State of the European Economic Area,

— the clinical trial forms part of a paediatric investigation plan including those where the investigator sites are outside the European Union (EU) ([8]),

— the clinical trial falls within Article 45 of Regulation (EC) No 1901/2006,

— the clinical trial falls within Article 46 of Regulation (EC) No 1901/2006.

## 3. CONTENT OF POSTED RESULT-RELATED INFORMATION

The result-related information should be posted in accordance with this Guideline for all clinical trials referred to in Section 2.

The content of the results-related information is set out in the Guideline 2009/C28/01. The information set out there applies for paediatric as well as non-paediatric clinical trials.

The implementing technical guidance on the format of the data fields (hereinafter 'full data set') is published in a separate

([1]) OJ L 136, 30.4.2004, p. 1.
([2]) OJ L 378, 27.12.2006, p. 1.
([3]) COM(2012) 369 final, 17.7.2012.
([4]) OJ C 82, 30.3.2010, p. 1.
([5]) OJ C 168, 3.7.2008, p. 3.
([6]) OJ C 28, 4.2.2009, p. 1.
([7]) http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm
([8]) Article 41(1) of Regulation (EC) No 1901/2006.

document in 'EudraLex — the rules governing medicinal products in the European Union', thus completing the two implementing technical guidances on the 'List of fields to be made public from EudraCT for Paediatric Clinical Trials in accordance with Article 41 of Regulation (EC) No 1901/2006' and the 'List of fields contained in the "EudraCT" clinical trials database to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004.' ([9]).

The data fields in that detailed technical guidance take account of international harmonisation efforts. The content of the data fields is kept identical with the U.S.-database 'clinicaltrials.gov', with limited exceptions to take account of particularities like the EU paediatric investigation plan, as well as evolving changes of international databases or international harmonisation efforts.

## 4. MODALITIES OF POSTING AND PROCESSING OF RESULT-RELATED INFORMATION

By posting result-related information to the European database referred to in Article 11(1) of Directive 2001/20/EC (hereinafter 'EudraCT') the sponsor, the addressee of the decision on a paediatric investigation plan or the marketing authorisation holder, as appropriate, comply with Article 41(2) of Regulation (EC) No 1901/2006. Moreover, this posting is considered as the submission of the clinical trial summary report as part of the end-of-trial-declaration to national competent authorities as set out in Section 4.3 of the detailed guidance CT-1. Where the result-related information is published (see Section 5), it is considered as submission to the Ethics Committee as set out in Section 4.2.1 of the detailed guidance CT-1.

### 4.1. Posting of data

The result-related information is posted to EudraCT either directly entering data using a web interface provided by the European Medicines Agency (hereinafter 'the Agency'), by uploading a XML file via the web interface, or using a gateway technology. The data are posted to a secure module of EudraCT.

The information should be provided in accordance with an XML schema established and published by the Agency.

The information is posted:

— by the addressee of the decision on a paediatric investigation plan, where the clinical trial forms part of a paediatric investigation plan,

— by the marketing authorisation holder, where the clinical trial falls within Articles 45 and 46 of Regulation (EC) No 1901/2006,

— by the sponsor of the clinical trial for all other clinical trials referred to in Section 2.

To this end the party responsible for posting the information is provided with a secure account to enable uploading and editing of these data in the system. That party has access only to their own data. This access will enable the posting and maintenance of the data in a secure part of the system. The further processing and making public of this information is controlled by the Agency.

Certain fields of the protocol-related data will be used to present the context of the trial facilitating the presentation of the result-related information. The corresponding protocol-related information will automatically be loaded, from EudraCT, into these fields when result-related information is provided via the web interface or on a pre-populated XML downloaded. On the occasion of posting result-related information, these fields may be updated by means of the web interface or alternatively via posting of an updated XML-file with protocol-related information.

In general, a comment field is made available linked to data fields other than free text fields. The comment field is intended to allow for inclusion of information supplementing the fixed field contents. The structure of the collected data accommodates the large majority of clinical trials; however, the comment field may be used if data fields do not adequately accommodate the required information.

### 4.2. Processing

In the secure part of the system, an automated technical validation may take place. In case issues are identified, the posting of the information will be blocked. A validation report will be provided to the posting party with instructions on how to resolve or clarify the issues.

The data are then entered into EudraCT, and information on clinical trials to be made public are selected by the applicable business rules and made public in the EU Clinical Trials Register of EudraPharm (see Section 5). They will be linked to the protocol-related data, where the latter are available in EudraCT.

It is not possible for the public to access the secure module. The posting of result-related information does not overwrite existing protocol-related information that is stored in EudraCT.

([9]) See footnote 7.

### 4.3. **Timing**

Result-related information should be posted within the time-frames set out in the Regulation (EC) No 1901/2006 and the guidelines referred to under Section 1, i.e. (relating to paediatric clinical trials) within six months ([10]) and otherwise within one year of the end of the trial ([11]).

It is recommended that result-related data should be posted prior to these dates if such information is already available. This is the case, for example, if results have already been published in scientific journals, or if a primary completion date is foreseen before the end of the trial.

If the clinical trial ends prematurely, that date should be considered the end of the trial.

Only one set of result-related data may be provided per planned analysis and trial. If the outcome is analysed on several occasions, each of these analyses should be posted.

### 4.4. **Language**

The result-related information is largely numerical, or based on value list definitions, using pre-defined options or terminology-lists.

Regarding free text fields the system will permit the entry of more than one language (from the official languages of the EU). In accordance with WHO standard and to facilitate the international use outside the EU, information should be posted in English. In addition, the information may be posted in any other official EU language.

### 4.5. **Data updates and follow-up posting**

Some protocol-related information, as well as the result-related information (e.g. contact points for further information or enrolment status), will be available for update by the posting party, in such a way that the updated information is made directly available in the public domain subject to technical controls being met.

Each version of protocol-related information and result-related data will be stored and posting of new versions will not result in deletion of previously posted versions, thus providing a record of changes.

### 4.6. **Provisions for results of clinical trials which have ended in the past**

#### 4.6.1. *Clinical trials within the scope of Directive 2001/20/EC*

Result-related information on clinical trials which ended less than one year prior to finalisation of the programming referred to in Section 6 should be posted within one year of the finalisation of the programming by using the full data set (see Section 4.1).

Result-related information on clinical trials which ended one year or more prior to finalisation of the programming referred to in Section 6 may be posted either by using the full data set (see Section 3) or by using the method for clinical trials within the scope of Article 45 of Regulation (EC) No 1901/2006 (see below). This should be done within 24 months of the finalisation of the programming referred to in Section 6.

#### 4.6.2. *Clinical trials referred to in Regulation (EC) No 1901/2006*

An alternative posting process will be made available for clinical trials referred to in Article 45 of Regulation (EC) No 1901/2006. For these clinical trials the posting of result-related information to the Agency for the purpose of publication may be done as a copy, authorised by the copy-right-holder, of a medical journal article (as PDF file), as the synopsis in accordance with Annex I to the ICH Topic E 3 guidance (as PDF file), or any other appropriate document containing the information of that synopsis (as PDF file). For these cases, a set of fields will be established in EudraCT to identify the clinical trial involved, to facilitate searching and to allow attachment of the PDF file. This result-related information should be posted within 24 months of the finalisation of the programming referred to in Section 6.

Result-related information of clinical trials included in an agreed paediatric investigation plan (Article 41(1) of Regulation (EC) No 1901/2006), and of marketing authorisation holder-sponsored trials which involve the use in the paediatric population of a medicinal product covered by a marketing authorisation (Article 46 of Regulation (EC) No 1901/2006), and which ended prior to finalisation of the programming referred to in Section 6, should be posted within one year of the finalisation of the programming by using the full data set (see Section 4.1).

### 4.7. **Non-compliance, factual inaccuracy**

Member States should verify that for clinical trials authorised by them the result-related information is posted to the Agency.

Clinical trials for which no result-related information has been posted 9 months after the end of the trial (see Section 4.3) for paediatric trials or 15 months for other trials will be flagged. This information will be publicly available. The anticipated duration of the trial is entered at the time of the clinical trial application. The actual end of the trial is notified through the 'Declaration of the end of trial form'.

All corrections to published information will be made by the party posting that information, sometimes upon request by the Agency.

([10]) Section 2.2.2 of Guideline 2009/C28/01.

([11]) For the term 'end of the trial' see Section 4 of the detailed guidance CT-1.

If inspections of compliance with good clinical practice (GCP) reveal that there are serious doubts about the accuracy or reliability of the result-related data, the Agency will be informed immediately.

The Agency will retain the possibility of:

— removing information from the public view,

— highlighting that the result-related information may not be valid in view of GCP non-compliance, or

— adding a notice to the public record, where necessary for reasons of factual accuracy or compliance with regulatory requirements.

## 5. PRESENTATION OF THE RESULT-RELATED INFORMATION TO THE PUBLIC

The posted result-related information is made public through the EU Clinical Trials Register of EudraPharm in accordance with the Commission guidance documents set out under Section 1, i.e. only result-related information on non-paediatric Phase-I clinical trials is not made public.

The result-related information is made public within 15 working days from the posting of a valid data set.

The results-related information of each clinical trial is linked to the corresponding protocol-related information which is already stored in the system.

Regarding follow-up posting (see Section 4.5), by default, the current version will be presented first for public access, but previous versions may also be viewed by the public.

In addition to being readable *in situ* on the web, the data will also be made available in a printable format and in a downloadable format.

The web interface is going to provide tools to facilitate the searching, reading and browsing of the public information on clinical trials and their results.

## 6. IMPLEMENTATION

This guidance document applies as soon as the programming of the relevant databases has been finalised.

Finalisation of the programming will be publicly announced by the Agency.

# NOTICES FROM MEMBER STATES

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/04)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 17.9.2012 |
| Duration | 17.9.2012-31.12.2012 |
| Member State | Sweden |
| Stock or group of stocks | SOL/3A/BCD. |
| Species | Common sole (*Solea solea*) |
| Zone | IIIa; EU waters of Subdivisions 22-32 |
| Type(s) of fishing vessels | — |
| Reference number | FS50TQ43 |

[1] OJ L 343, 22.12.2009, p. 1.

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/05)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 17.9.2012 |
| Duration | 17.9.2012-31.12.2012 |
| Member State | Sweden |
| Stock or group of stocks | COD/03AN. |
| Species | Cod (*Gadus morhua*) |
| Zone | Skagerrak |
| Type(s) of fishing vessels | — |
| Reference number | FS49TQ44 |

[1] OJ L 343, 22.12.2009, p. 1.

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/06)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 17.8.2012 |
| Duration | 17.8.2012-31.12.2012 |
| Member State | Estonia |
| Stock or group of stocks | RED/N3M |
| Species | Redfish (*Sebastes* spp.) |
| Zone | NAFO 3M |
| Type(s) of fishing vessels | — |
| Reference number | FS51TQ44 |

[1] OJ L 343, 22.12.2009, p. 1.

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/07)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 10.9.2012 |
| Duration | 10.9.2012-31.12.2012 |
| Member State | Latvia |
| Stock or group of stocks | RED/N3M |
| Species | Redfish (*Sebastes* spp.) |
| Zone | NAFO 3M |
| Type(s) of fishing vessels | — |
| Reference number | FS46TQ44 |

[1] OJ L 343, 22.12.2009, p. 1.

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/08)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 7.9.2012 |
| Duration | 7.9.2012-31.12.2012 |
| Member State | Belgium |
| Stock or group of stocks | PLE/7FG |
| Species | Plaice (*pleuronectes platessa*) |
| Zone | VIIf and VIIg |
| Type(s) of fishing vessels | — |
| Reference number | FS44TQ43 |

[1] OJ L 343, 22.12.2009, p. 1.

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/09)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 24.8.2012 |
| Duration | 24.8.2012-31.12.2012 |
| Member State | Spain |
| Stock or group of stocks | RED/N3M |
| Species | Redfish (*Sebastes* spp.) |
| Zone | NAFO 3M |
| Type(s) of fishing vessels | — |
| Reference number | FS47TQ44 |

[1] OJ L 343, 22.12.2009, p. 1.

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/10)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 11.9.2012 |
| Duration | 11.9.2012-31.12.2012 |
| Member State | Spain |
| Stock or group of stocks | ANE/9/3411 |
| Species | Anchovy (*Engraulis encrasicolus*) |
| Zone | ZONE IX and X; EU waters of CECAF 34.1.1 |
| Type(s) of fishing vessels | — |
| Reference number | FS48TQ43 |

[1] OJ L 343, 22.12.2009, p. 1.

## Information communicated by Member States regarding closure of fisheries

(2012/C 302/11)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], a decision has been taken to close the fishery as set down in the following table:

| | |
|---|---|
| Date and time of closure | 17.9.2012 |
| Duration | 17.9.2012-31.12.2012 |
| Member State | Lithuania |
| Stock or group of stocks | RED/N3M |
| Species | Redfish (*Sebastes* spp.) |
| Zone | NAFO 3M |
| Type(s) of fishing vessels | — |
| Reference number | FS52TQ44 |

[1] OJ L 343, 22.12.2009, p. 1.

V

*(Announcements)*

# PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION POLICY

# EUROPEAN COMMISSION

## DECISION TO CLOSE THE FORMAL INVESTIGATION PROCEDURE AFTER WITHDRAWAL BY MEMBER STATE

**State aid — Italy**

**(Articles 107 to 109 of the Treaty on the Functioning of the European Union)**

**Commission notice pursuant to Article 108(2) of the TFEU — Withdrawal of notification**

**State aid SA.28642 (C 17/10 (ex N 315/09)) — Firmin Srl**

**(Text with EEA relevance)**

(2012/C 302/12)

The Commission has decided to close the formal investigation procedure under Article 108(2) of the TFEU, initiated on 20 July 2010 ([1]) in respect of the measure referred to above, recording that Italy has withdrawn its notification on 27 June 2012.

([1]) OJ C 278, 15.10.2010, p. 28.

OTHER ACTS

# EUROPEAN COMMISSION

**Publication of an amendment application pursuant to Article 6(2) of Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs**

(2012/C 302/13)

This publication confers the right to object to the application pursuant to Article 7 of Council Regulation (EC) No 510/2006 [1]. Statements of objection must reach the Commission within six months of the date of this publication.

AMENDMENT APPLICATION

**COUNCIL REGULATION (EC) No 510/2006**

**AMENDMENT APPLICATION IN ACCORDANCE WITH ARTICLE 9**

**'MONT D'OR'/'VACHERIN DU HAUT-DOUBS'**

**EC No: FR-PDO-0217-0124-30.03.2006**

**PGI ( ) PDO ( X )**

1. **Heading in the specification affected by the amendment:**

— ☐ Name of product

— ☒ Description of product

— ☒ Geographical area

— ☒ Proof of origin

— ☒ Method of production

— ☒ Link

— ☒ Labelling

— ☒ National requirements

— ☒ Other (references to inspection bodies)

2. **Type of amendment(s):**

— ☐ Amendment to single document or summary sheet

— ☒ Amendment to specification of registered PDO or PGI for which neither the single document nor the summary sheet has been published

— ☐ Amendment to specification that requires no amendment to the published single document (Article 9(3) of Regulation (EC) No 510/2006)

— ☐ Temporary amendment to specification resulting from imposition of obligatory sanitary or phytosanitary measures by public authorities (Article 9(4) of Regulation (EC) No 510/2006)

[1] OJ L 93, 31.3.2006, p. 12.

3. **Amendment(s):**

3.1. *Competent service in Member State and applicant group:*

Updating details.

3.2. *Product description:*

— The following clarifications have been added: 'whole cream cow's milk that is processed raw and renneted' and 'spruce box'.

— The sentence 'The weight of the cheese, including the box, ranges from 480 grams to 3,2 kilograms' has replaced 'The cheese, including the box, weighs either 480 grams to 1,3 kilograms or 2 to 3,2 kilograms.' The entire range of weights from 480 grams to 3,2 kilograms allows all traditional forms of packaging to be maintained. The characteristic flavour associated with the designation of origin is unchanged between 1,3 and 2 kilograms.

— The paragraph describing the boxes has been completed with respect to the thickness and height of the rim and the size of the lid.

— 'Mont d'Or' cheese must be presented in its traditional box. The characteristics of this box are thus defined in order to avoid any non-traditional presentation.

— New paragraph: ' "Mont d'Or" or "Vacherin du Haut-Doubs" cheese, packaged whole, is presented in an individual spruce box with a protective packaging.' 'Mont d'Or' may be wrapped in household film before sale, making it possible to regulate the natural evaporation of the cheese under optimal marketing conditions. This protection allows for better preservation of the product's essential qualities.

3.3. *Geographical area:*

The definition of the geographical area is unchanged, but two clarifications have been added:

— all operations (milk production, cheese processing and maturation) must take place in the geographical area made up of the parts of the listed municipalities lying at an altitude of over 700 meters,

— as the cheese is placed into spruce boxes during maturation, this process must, for technical reasons, take place in the geographical area.

3.4. *Proof of origin:*

The amendments requested are linked to reform of the inspection system for designations of origin. In particular, provisions have been included for authorising operators so as to acknowledge their ability to meet the specifications of the designation from which they wish to benefit. Inspection of the PDO specification takes place according to an inspection plan drawn up by an inspection body.

Moreover, this heading contains several new provisions on registers and declaration documents allowing for product traceability.

3.5. *Method of production:*

Some clarifications have been added in relation to the method of production. These concern:

— maintenance of pastures, in particular manure; measures to limit the impact of manure in order to preserve natural flora,

— authorised and prohibited feedingstuffs, concentrated feed and supplements for dairy cows: measures to preserve the link between feed given to cows and the natural environment,

— milking and the collection and storage of milk: measures taken to ensure optimal milk quality,

— equipment in cheese dairies: a list has been drawn up of minimum equipment required to guarantee the use of traditional production methods,

— preparation of wooden bands surrounding the cheese: stipulated methods for storing and soaking,

— brine: defined characteristics,

— refining cellars: defined characteristics of equipment.

The following amendments have also been made:

Milk production

— Breeds of cows: the following text has been added: 'or cows of certified parentage obtained from crossing these two breeds.' The aim of this amendment is to respond to the special cases of rare animals obtained from the certified crossing of the two breeds included in the designation, as such crossing is part of normal stockbreeding practice, especially since the 'Montbeliarde' and French 'Simmental' breeds are descendants of the same genetic branch — 'Pie Rouge de l'Est'.

— Feed for dairy cows: the following text has been added: 'In exceptional circumstances, mainly as a result of adverse weather conditions, the Institut National des Appellations d'Origine may grant temporary derogations to ensure continued feeding of the herd.' This provision aims to allow proper feeding of animals in such conditions.

— Feed for ruminants: the following text has been added: 'Only plants and supplementary feeding-stuffs derived from non-transgenic products are authorised in animal feed. No transgenic crops may be planted anywhere on a holding producing milk for processing in a "Mont d'Or" or "Vacherin du Haut-Doubs" PDO. This prohibition applies to all types of plant likely to be given as feed to animals on the holding and to any culture likely to contaminate such plants.' This provision makes it possible to preserve the traditional nature of animal feed.

Cheese production

— The words 'and including' have been added in the sentence: 'Cheese is produced in the period from 15 August to and including 15 March'. This clarification as to when production ends has been added in order to avoid divergent interpretation.

— The text 'harmless cultures of bacteria, yeast and mould' has been replaced by 'selected starter and surface flora cultures'. This wording seems more appropriate.

— New paragraph: 'The milk may not be concentrated by partially removing the watery part before coagulation.'

— New paragraph: 'Dairy raw materials, partly finished products, curd […] may not be conserved at a temperature below 0 °C.'

New techniques, some of which concern treatments and additives, such as microfiltration, partial concentration of milk, or enzymes for the maturing process, have a potential impact on the characteristics of cheeses with designations of origin. In particular, certain enzyme additives appear to be incompatible with preservation of the key characteristics of PDO products. It was therefore necessary for the specifications to define, in point 5, the current practice regarding the use of treatments and additives for milk and for cheese production, in order to prevent future practices not covered by the rules from compromising the characteristics of PDO cheese.

— The following text has been added: 'The band must be placed immediately after production, which includes removal from the mould. The cheese may be brined before or after the band has been placed.' This clarifies the order of placing bands and brining so as to provide a better guarantee of traditional practice.

Maturation

— The text 'The maturation period is 21 days from the day of production' has been replaced by 'The minimum maturation period is 21 days from the day of renneting …' This clarifies the period of maturation in order to facilitate inspection and to prevent misinterpretation.

— New sentence: 'Before being placed in its box, which must be at least 12 days after renneting, the cheese must be left on a spruce board, where it is turned and rubbed by hand using water, possibly salted.' This provision aims to provide a stronger guarantee that traditional methods will be used.

— New paragraph: 'The placing of protective packaging around the cheese and its box is not authorised until the 19th day after renneting.' The placing of protective packaging requires optimum timing; the minimum period between renneting and packaging has been set at 19 days.

— New paragraph: 'Fresh cheese and cheese undergoing maturation may not be conserved under a modified atmosphere.' It was necessary for the specifications to define current practice in cheese production, in order to prevent future practices not covered by the rules from compromising the characteristics of 'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese.

Placing on the market

— The text 'The cheese is placed on the market between 10 September and 10 May' has been replaced by 'The cheese may only be sold to consumers between 10 September and 10 May'. This clarification aims to distinguish between making the product available to distributors and actual sale to consumers.

— New paragraph: 'Absence of a protective packaging at any stage of placing on the market renders the holder of the goods liable for product quality.' It should be possible to hold retailers liable for removing protective material placed by producers under the designation (in order, for example, to 'over-ripen' the cheese, i.e. to mature it again under unregulated conditions and sometimes outside of the geographical area beyond the legal minimum maturation period).

— The following text has been added: 'The cheese may be cut and wrapped at the point of sale if the period between cutting and sale to the consumer is not longer than the current day plus the two following working days until the closing time of the shop, and provided that all customary health rules are respected.' These clarifications have been added in order to ensure that the cheese may be cut at the point of sale, subject to rules limiting the risk of product deterioration.

3.6. *Elements justifying the link with the geographical area:*

This chapter has been reorganised into three parts: 'Specificity of the geographical area', 'Specificity of the product' and 'Causal link between specificity of the area and specificity of the product'. Some editorial amendments have been introduced under this heading; these provide additional explanations, without altering the substance of the text.

3.7. *References to the inspection body:*

References to the Institut National des Appellations d'Origine have been eliminated and replaced with references to an accredited Certifying Body, as provided for in Standard 45011.

3.8. *Specific rules on labelling:*

— Use of the 'INAO' logo is no longer compulsory, in keeping with national legislation.

— Use of the EU 'PDO' symbol is now compulsory.

— The text 'Other information required under general rules must appear on the rim of the box' has been replaced by 'Other information required under general rules must appear on the fold (rim) of the box'. The term 'fold' (*pliure*) is more customary than 'rim' (*targe*).

— The following text has been added to the 2nd paragraph: 'These markings must be visible until the stage of sale to consumers.' This provision guarantees product traceability and provides additional information to consumers.

3.9. *National requirements:*

In the light of changes to national legislation and rules, the 'National requirements' heading now contains a table indicating the main items to be checked, their reference values and the evaluation methods to be used.

SINGLE DOCUMENT

**COUNCIL REGULATION (EC) No 510/2006**

**'MONT D'OR'/'VACHERIN DU HAUT-DOUBS'**

**EC No: FR-PDO-0217-0124-30.03.2006**

**PGI ( ) PDO ( X )**

1. **Name:**

'Mont d'Or'/'Vacherin du Haut-Doubs'

2. **Member State or Third Country:**

France

3. **Description of the agricultural product or foodstuff:**

3.1. *Type of product:*

Class 1.3 — Cheeses

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

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is made exclusively from whole cow's milk that is processed raw and renneted. The milk comes from dairy herds made up solely of cows of the 'Montbeliarde' or French 'Simmental' breeds or cows of certified parentage obtained from crossing these two breeds.

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is a soft, uncooked, lightly pressed cheese of creamy consistency in the form of a flat cylinder. The cheese is white to ivory in colour and lightly salted. The rind, which is covered with a faint flowery shape, is yellow to light brown in colour.

It has a minimum fat content of 45 grams per 100 grams of completely desiccated cheese. The water content of the defatted cheese must not exceed 75 %.

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is ringed by a spruce band and placed in a spruce box. In the box, the cheese has a wrinkled appearance.

The weight of the cheese, including the box, ranges from 480 grams to 3,2 kilograms.

The size of the box must comply with the following specifications:

— the bottom of the box must be between 11 cm and 33 cm in diameter,

— the entire box must be between 6 cm and 7 cm in height,

— the bottom and the lid must each be less than 7 mm thick,

— the rim of the box and the lid must each be less than 2 mm thick,

— the rim of the lid must be no more than 2,5 cm wide,

— the shape and size of the lid must match those of the box.

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is presented whole in an individual spruce box with a protective packaging. It may be placed on the market for sale to consumers only between 10 September and 10 May. 'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese may not be frozen.

3.3. *Raw materials (for processed products only):*

—

3.4. *Feed (for products of animal origin only):*

The staple feed of the dairy cows is fodder originating from pastures at an altitude of at least 700 meters in the geographical area. During the growing season, grazing represents at least half of daily feed; green fodder may only be used as a supplement. When the cows are kept indoors, their staple feed is hay and aftermath harvested from pastures in the geographical area. The grazing land actually used on the holding must be at least one hectare per dairy cow.

The amount of concentrated feed given to dairy cows may not exceed 8 kilograms per lactating dairy cow per day. This means that approximately 70 % of daily feed is fodder originating from the geographical area.

Only plants and complementary feedingstuffs derived from non-transgenic products are authorised in the animal feed.

Silage products or other fermented fodder, including bales covered in plastic film, are prohibited on the holding year-round.

3.5. *Specific steps in production that must take place in the defined geographical area:*

The milk must be produced and the cheese must be made and matured within the area.

3.6. *Specific rules on slicing, grating, packaging, etc.:*

The cheese must be placed in its box within the defined geographical area, as it must mature inside the box. The cheese may not be cut except at the stage of sale to consumers.

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is packaged whole and presented in an individual spruce box with a protective packaging.

3.7. *Specific rules on labelling:*

All cheese with the designation of origin 'Mont d'Or' or 'Vacherin du Haut-Doubs' are marketed with an individual label showing the name of the designation of origin in a font at least two thirds as large as the largest font used on the label. The name 'Mont d'Or' or 'Vacherin du Haut-Doubs', the optional indication 'Protected Designation of Origin', the EU 'PDO' logo, the name of the workshop (clearly indicated) and other information required under general rules are shown on the rim of the box. These markings must be visible until the stage of sale to consumers.

No qualifiers or other indications may be placed next to the designation on the label, in marketing material, on invoices or in commercial documents, except for certain brand names or trademarks and the indication 'made in Haut-Doubs'.

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

The milk must be produced and the cheese made, boxed and matured at an altitude of at least 700 meters in the geographical area covering the following municipalities in the Department of Doubs: Les Alliés, Arc-sous-Cicon, Arçon, Barboux, Le Bélieu, Bians-les-Usiers, Le Bizot, Bonnétage, La Bosse, Boujailles, Bugny, Bulle, Chapelle-d'Huin, La Chaux, La Chenalotte, Courvières, Dompierre-les-Tilleuls, Evillers, Les Fontenelles, Fournet-Blancheroche, Frambouhans, Frasne, Gilley, Goux-les-Usiers, Grand' Combe-des-Bois, Hauterive-la-Fresse, Levier, La Longeville, Maisons-du-Bois-Lièvremont, Le Mémont, Montbenoît, Montflovin, Narbief, Noël-Cerneux, Plaimbois-du-Miroir, Le Russey, Saint-Gorgon-Main, Saint-Julien-lès-Russey, Septfontaines, Sombacour, Ville-du-Pont and the cantons of Morteau, Mouthe and Pontarlier.

5. **Link with the geographical area:**

5.1. *Specificity of the geographical area:*

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is produced in an area including the high plateau zone of the Jura, at an altitude ranging from 700 to 1 200 meters, and the high grasslands covering the ridge of the main Jura range above 1 200 meters.

Geologically, this area was formed during the upper Jurassic period. Some basins in the Haut-Doubs region also show formations dating from the Neocomian stage of the Cretaceous period. The Neocomian terrain is marl rich in iron oxide.

The area is delimited by the end of the Jura plateau zone and a mountainous zone along the border with Switzerland.

The area is bountiful in grasslands and softwood forests, especially spruce, with the land more or less evenly divided between these two types of cover.

The climate is quite rugged, with very low temperatures in the winter and a long period of snow cover, which can make transport difficult.

Although there is little official documentation, cheese production in the region can be dated to the 12th century.

At that time, the high plateau zone of the Jura was brought into agricultural use under the auspices of the big abbeys of Saint-Claude and Montbenoit, thus allowing animal breeding and dairy production. From the 14th century onward, cheese dairies known as 'fruitières' began to appear.

5.2. *Specificity of the product:*

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is made from whole raw cow's milk.

It is a soft, uncooked, lightly pressed and lightly salted cheese of creamy consistency, white to ivory in colour, with a washed, yellow to light brown rind covered with a faint flowery shape; the cheese is ringed with a spruce band immediately after removal from the mould and placed in a spruce box. In the box, the cheese continues to mature and has a wrinkled appearance. The band and the box are an integral part of the production requirements for the designation of origin 'Mont d'Or' or 'Vacherin du Haut-Doubs'. The size of the box must comply with certain rules.

Each cheese is in the form of a flat cylinder. Its weight, including the box, ranges from 480 grams to 3,2 kilograms.

The cheese is made between 15 August and 15 March, and may only be placed on the market between 10 September and 10 May, presented whole in an individual spruce box.

Because of its presentation and very creamy texture, this cheese has always been associated with celebrations.

5.3. *Causal link between the geographical area and the quality or characteristics of the product (for PDO) or a specific quality, the reputation or another characteristic of the product (for PGI):*

'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese can be made using milk produced late in the season. In autumn and winter, when the grazing season is over, the cows are kept indoors and are generally in the second stage of lactation, giving less milk and producing milk rich in fat.

The milk is also difficult to transport to cheese dairies because of the weather. Local farmers have adapted to these conditions by producing a cheese which is smaller than cooked, pressed cheeses and which is moist, making it easy to conserve in its spruce band and box.

Although now made in cheese dairies rather than on farms, 'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese is still a seasonal product and is not made in the spring or summer.

Traditionally, the milk was quickly curdled with rennet at milking temperature (more than 33 °C). This quick renneting time, together with the high fat content of the milk, resulted in 'soft' curds. Local woodworking expertise led to the production of soft bands made of stretched bark from spruce trees,

traditionally felled in the autumn. This provided a 'single-use' mould for holding the curds. This band gives 'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese its characteristic woody flavour.

Modern production techniques have further reduced renneting time by increasing the renneting temperature. The band still serves to conserve the moist, fatty cheese.

After the cheese is made, it is generally matured at a high temperature, resulting in a creamy consistency because of protein breakdown. This high temperature yields a milky aroma and a slightly bitter taste, so that the cheese has a lingering flavour when eaten. The cheese is washed regularly, resulting in a clean-looking, homogenous rind due to the growth of surface bacteria. This traditional smearing technique has been refined over the ages in the area.

Because of its very soft (nearly runny) consistency, the cheese is matured in a box made of peeled spruce wood. When placed in the box, the cheese is slightly compressed, with a wrinkled surface not unlike the contours of a mountain. To this day, cheese-makers regard the wrinkled appearance of 'Mont d'Or' or 'Vacherin du Haut-Doubs' cheese when it is placed in the box as a hallmark of manufacturing success and quality. In the box, a faint flowery shape comes to cover the surface of the cheese. The box is thus an important part of the maturation process. It also serves as packaging for transport and for presentation at the time of sale. The box bears identification of the product and the producer.

The care taken in raising 'Montbeliarde' and 'Simmental' cows, which are showcased at local farmers' events, reflects local milk producers' expertise, which is based on animal hygiene and welfare.

Strict rules also define the feeding of purebred cows of the 'Montbeliarde' and French 'Simmental' breeds and of cows produced by crossing these two breeds. The staple feed of the dairy cows must be fodder originating from the geographical area. Fodder from outside the geographical area may be used, but only in exceptional circumstances.

The cheese is produced according to very specific expertise and tradition, which is always reflected in the conditions of production: seasonal production and use of spruce boxes and bands.

**Reference to publication of the specification:**

http://agriculture.gouv.fr/IMG/pdf/CDC_Mont_d_Or_cle8515b3.pdf

**Publication of an amendment application pursuant to Article 6(2) of Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs**

(2012/C 302/14)

This publication confers the right to object to the application pursuant to Article 7 of Council Regulation (EC) No 510/2006 [1]. Statements of objection must reach the Commission within six months of the date of this publication.

AMENDMENT APPLICATION

**COUNCIL REGULATION (EC) No 510/2006**

**AMENDMENT APPLICATION IN ACCORDANCE WITH ARTICLE 9**

**'MIEL DE LA ALCARRIA'**

**EC No: ES-PDO-0117-0079-22.09.2010**

**PGI ( ) PDO ( X )**

1. **Heading in the product specification affected by the amendment:**

— ☐ Name of product

— ☒ Description of product

— ☒ Geographical area

— ☒ Proof of origin

— ☒ Method of production

— ☒ Link

— ☒ Labelling

— ☒ National requirements

— ☒ Other (inspection body)

2. **Type of amendment(s):**

— ☒ Amendment to Single Document or Summary Sheet

— ☐ Amendment to Specification of registered PDO or PGI for which neither the Single Document nor the Summary has been published

— ☐ Amendment to Specification that requires no amendment to the published Single Document (Article 9(3) of Regulation (EC) No 510/2006)

— ☐ Temporary amendment to Specification resulting from imposition of obligatory sanitary or phytosanitary measures by public authorities (Article 9(4) of Regulation (EC) No 510/2006)

3. **Amendment(s):**

3.1. *Description:*

The drafting of the physico-chemical and pollen characteristics has been improved and mathematical symbols have been introduced to define the limits for each parameter.

[1] OJ L 93, 31.3.2006, p. 12.

The limits for certain physico-chemical and pollen characteristics have been amended on the basis of experience over the more than 16 years since 'Miel de La Alcarria' was registered as a Protected Designation of Origin and on the basis of studies of the results of analyses carried out on honey covered by the 'Miel de La Alcarria' designation at the honey laboratory of the Agricultural Centre of the Government of Castile-La Mancha, which have enabled us to describe the characteristics of the product more accurately.

3.2. *Geographical area:*

The geographical area has been updated to take account of the recognition or establishment of new local administrative areas, since it had been noted that certain local areas within the protected area were not mentioned, although they are surrounded by others that were and there was no reason to exclude them. These have therefore now been included.

In addition, hives are appearing in neighbouring municipalities and therefore, bearing in mind the findings of the study of the Agricultural Centre of the Government of Castile-La Mancha, new municipalities have been added to promote beekeeping to the maximum in the area, while maintaining the specified qualities of 'Miel de La Alcarria' and taking account of the similar variety of flora throughout the area.

3.3. *Proof of origin:*

The inspection body responsible for checking the specification has changed and so the section 'Checks and Certification' has been redrafted, with references to the 'Regulatory Board' being replaced by references to the 'Inspection body responsible for certification' in the relevant sections of the specification. In addition, the conditions to be fulfilled by packaging undertakings and the product itself have been amended.

3.4. *Method of production:*

Since the inspection body has changed, this section, which described the method of production, has been replaced by a new version setting out the requirements for and the certifiable characteristics of 'Miel de La Alcarria'. Therefore, the methods referred to in the section on the link with the area are included here. These methods are also updated, since many of them are not characteristic of 'Miel de La Alcarria' but are rather statutory sanitary and food-health requirements.

3.5. *Link with the area:*

In the section on soil and vegetation and in the paragraph on wild flora, the list of labiates is updated to include marjoram (*Thymus mastichina* L. subsp. *mastichina)* and the following is inserted in the paragraph on arable land: 'Aromatic plants and plants for seasoning, principally lavandin (*Lavandula hybrida Rev*) are also grown.'

As stated above, the description of the methods used has been moved to the section on the 'Method of production'.

3.6. *Inspection body:*

In accordance with Regulation (EC) No 510/2006, we request that the inspection body for 'Miel de La Alcarria' PDO be the 'GEACAM.S.A.' certification body, which is accredited by ENAC for the agri-food sector as fulfilling the requirements of Standard UNE-EN 45011 'General requirements for bodies operating product certification systems'.

3.7. *Labelling:*

The text is redrafted so as to better identify packaging.

3.8. *National requirements:*

The Community and national provisions are updated.

SINGLE DOCUMENT

**COUNCIL REGULATION (EC) No 510/2006**

**'MIEL DE LA ALCARRIA'**

**EC No: ES-PDO-0117-0079-22.09.2010**

**PGI ( ) PDO ( X )**

1. **Name:**

'Miel de La Alcarria'

2. **Member State or Third Country:**

Spain

3. **Description of the agricultural product or foodstuff:**

3.1. *Type of product:*

Class 1.4. Other products of animal origin (eggs, honey, various dairy products except butter, etc.)

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

The following types of 'Miel de La Alcarria' are produced:

Monofloral rosemary honey (*Rosmarinus officinalis* L.);

Monofloral lavender honey (*Lavandula latifolia Medicus*);

Multifloral honey.

On packing, it has the following characteristics:

A. Physico-chemical characteristics

| | |
|---|---|
| Moisture content | ≤ 17,5 % |
| Hydroxymethylfurfural | ≤ 15,0 mg/kg |
| Free acidity | ≤ 35,0 meq/kg |
| Electrical conductivity | ≤ 0,62 mS/cm |
| Colorimetry | $L^*_{10} \geq 55{,}0$; $-2{,}0 \leq a^*_{10} \leq +22{,}0$; $h_{ab,\ 10} \geq 74{,}0$ |

B. Pollen characteristics

| Type of 'Miel de La Alcarria' | Percentage of pollen grains |
|---|---|
| Monofloral lavender honey | Lavender pollen > 10 % |
| Monofloral rosemary honey | Rosemary pollen ≥ 15 % |
| Multifloral honey | Total grains of thyme (*Thymus* t.), savory (*Satureja* spp.), rosemary and lavender pollen ≥ 5 % |

The following requirements shall also apply.

— The percentage of grains of pollen of plants of the heath family (*Ericaceae*), with the exception of common bearberry (*Arctostaphylos uva-ursi* L. *Sprengel*), is ≤ 1 %.

— The percentage of grains of pollen of rockrose (*Cistus ladanifer* L.) is ≤ 3 %.

— The percentage of grains of pollen of French lavender (*Lavandula stoechas* L.) is ≤ 3 %.

— The total percentage of pollens of non-ornamental plants, excluding aromatic plants, cultivated in the production area is ≤ 15 %.

C. Organoleptic characteristics

The honeys must have the organoleptic characteristics, as far as colour, aroma and flavour are concerned, that are specific to the flower from which they originate.

Monofloral rosemary honey:

— Colour: from extra-white to light amber.

— Aroma: subtle floral aroma. Slight to average intensity and persistence.

— Taste: sweet with acid notes. Slight to average intensity and persistence. Slight aftertaste.

Monofloral lavender honey:

— Colour: from extra-light amber to amber.

— Aroma: aromatic, with balsamic notes. Average to high intensity and persistence.

— Flavour: sweet with varying levels of acidity. Average to high intensity and persistence. Intense aftertaste.

Multifloral honey:

— Colour: from extra-light amber to amber.

— Aroma: very varied. Fruity, aromatic, warm, subtle, animal, from a fairly intense flowery aroma to a fresh green plant aroma. Varying intensity and persistence.

— Flavour: sweet with varying levels of acidity. Varying intensity and persistence. Generally fresh aftertaste.

3.3. *Raw materials (for processed products only):*

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3.4. *Feed (for products of animal origin only):*

—

3.5. *Specific steps in production that must take place in the defined geographical area:*

The production and processing of 'Miel de La Alcarria' must take place in the defined geographical area.

3.6. *Specific rules concerning slicing, grating, packaging, etc.:*

The honey must be packed in the production area, because the physico-chemical properties (moisture and hydroxymethylfurfural content) of the honey deteriorate (the values increase) if the honey is transported in bulk, moved or has to wait to be packed, and so to maintain the product's specific characteristic it must be packed in the production area.

The net content of the packaging is as laid down in the applicable legislation, with a maximum content of 1 kg.

The container must have a hermetic seal.

The container must be of clear, transparent glass.

Containers may not be reused.

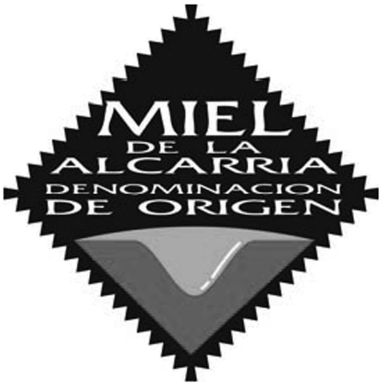
3.7. *Specific rules concerning labelling:*

Honey to be marketed with the 'Miel de La Alcarria' designation of origin and labelled as such, must meet the requirements of the specification and be identified by means of a numbered label issued by the Regulatory Board of the 'Miel de La Alcarria' designation of origin and checked by the inspection body and bear a guarantee seal and a commercial label giving at least the following information:

— the following words in a prominent position: 'Denominación de Origen Miel de La Alcarria' (Miel de La Alcarria Designation of Origin) or 'Denominación de Origen Protegida Miel de La Alcarria' (Miel de La Alcarria Protected Designation of Origin),

— the type of honey based on its botanical origin: rosemary, lavender or multifloral.

All packed honey that passes the quality checks and meets the requirements set out in the section 'Description of product' must bear the following logo:




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

The area where the hives are located is in the centre of the peninsula and covers various municipalities in the District of Agraria de La Alcarria in the Provinces of Guadalajara and Cuenca.

The total area of this zone is 10 354 $km^2$.

The honey is packed in the production area, which comprises the following municipalities in the Provinces of Guadalajara and Cuenca:

In the Province of Cuenca: Abía de la Obispalía, Albalate de las Nogueras, Albendea, Alcantud, Alcázar del Rey, Alcohujate, Altarejos (comprising exclusively the locality of Poveda de la Obispalía), Arandilla del Arroyo, Arrancacepas, Barajas de Melo, Bascuñana de San Pedro, Beteta (including Beteta and the locality of Valtablado de Beteta), Buciegas, Buendía, Campos del Paraíso, Canalejas del Arroyo, Cañamares, Cañaveras, Cañaveruelas, Cañizares, Carrascosa, Castejón, Castillo-Albaráñez, Cuenca (comprising exclusively the localities of Cólliga, Colliguilla and Villanueva de los Escuderos), Cueva del Hierro, Frontera (La), Fuentenava de Jábaga, Gascueña, Huelves, Huerta de la Obispalía, Huete, Leganiel, Olmeda de la Cuesta, Olmedilla de Eliz, Paredes, Peraleja (La), Pineda de Cigüela, Portalrubio de Guadamejud, Pozuelo (El), Priego, Puebla de Don Francisco, Rozalén del Monte, Saceda-Trasierra, Saelices, Salmeroncillos, San Pedro Palmiches, Sotorribas (including the localities of Collados, Pajares, Ribagorda, Ribatajada, Ribatajadilla, Torrecilla and Villaseca), Tinajas, Torralba, Torrejoncillo del Rey, Uclés, Valdecolmenas (Los), Valdeolivas, Valsalobre, Vellisca, Villaconejos de Trabaque, Villalba del Rey, Villanueva de Guadamejud, Villar de Domingo García, Villar del Infantado, Villar de Olalla (comprising exclusively the localities of Barbalimpia, Hortizuela and Villarejo Seco), Villar y Velasco, Villarejo de la Peñuela, Villas de la Ventosa and Vindel.

In the Province of Guadalajara: Abánades, Alaminos, Alarilla, Albalate de Zorita, Albares, Alcocer, Alcolea del Pinar, Aldeanueva de Guadalajara, Algora, Alhóndiga, Alique, Almadrones, Almoguera,

Almonacid de Zorita, Alocén, Anguita (comprising exclusively the locality of Padilla del Ducado), Aranzueque, Arbancón, Arbeteta, Argecilla, Armallones, Armuña de Tajuña, Atanzón, Auñón, Azuqueca de Henares, Baides, Barriopedro, Berninches, Brihuega, Budia, Bujalaro, Canredondo, Cañizar, Casas de San Galindo, Caspueñas, Castejón de Henares, Castilforte, Cendejas de Enmedio, Cendejas de la Torre, Centenera, Cifuentes, Ciruelas, Cogollor, Cogolludo (including Cogolludo and the localities of Aleas, Beleña del Sorbe and Torrebeleña), Copernal, Chiloeches, Chillarón del Rey, Driebes, Durón, Escamilla, Escariche, Escopete, Espinosa de Henares, Esplegares, Estriégana, Fuencemillán, Fuentelencina, Fuentelviejo, Fuentenovilla, Gajanejos, Guadalajara (including Guadalajara and the localities of Iríepal, Taracena and Valdenoches), Henche, Heras de Ayuso, Hita, Hontoba, Horche, Hortezuela de Ocen (La), Huérmeces del Cerro, Huertahernando, Hueva, Humanes, Illana, Inviernas (Las), Irueste, Jadraque, Jirueque, Ledanca, Loranca de Tajuña, Lupiana, Luzaga, Mandayona, Mantiel, Marchamalo, Masegoso de Tajuña, Matillas, Mazuecos, Medranda, Membrillera, Millana, Mirabueno, Miralrío, Mondéjar, Montarrón, Moratilla de los Meleros, Muduex, Negredo, Ocentejo, Olivar (El), Olmeda de Cobeta (comprising exclusively the locality of La Buenafuente del Sistal), Olmeda de Jadraque (La), Pareja, Pastrana, Peñalén, Peñalver, Peralveche, Pinilla de Jadraque, Pioz, Poveda de la Sierra, Pozo de Almoguera, Pozo de Guadalajara, Puebla de Beleña, Recuenco (El), Renera, Riba de Saelices (comprising exclusively the localities of La Loma y Ribarredonda), Romanones, Sacecorbo, Sacedón, Saelices de la Sal, Salmerón, San Andrés del Congosto, San Andrés del Rey, Sauca, Sayatón, Sigüenza, Solanillos del extremo, Sotillo (El), Sotodosos, Taragudo, Tendilla, Toba (La), Torija, Torrecuadradilla, Torre del Burgo, Torremocha del Campo, Torremocha de Jadraque, Tórtola de Henares, Trijueque, Trillo, Utande, Valdarachas, Valdearenas, Valdeavellano, Valdeconcha, Valdegrudas, Valderrebollo, Valfermoso de Tajuña, Valtablado del Río, Viana de Jadraque, Villanueva de Alcorón, Villanueva de Argecilla, Villaseca de Henares, Yebes, Yebra, Yélamos de Abajo, Yélamos de Arriba, Zaorejas and Zorita de los Canes.

5. **Link with the geographical area:**

5.1. *Specificity of the geographical area:*

The District of La Alcarria is a high plateau at an altitude of between 900 and 1 000 metres, crossed by slow-moving streams that have created plains and gorges covered in aromatic plants and thicket.

The plains lie at between 700 and 800 metres above sea level. The largest is the plain of the River Tajuña, which divides the District into two.

The soil of La Alcarria is basic, marly and gypsiferous.

The wild flora is rich in labiates such as rosemary (*Rosmarinus officinalis,* L.) thyme (*Thymus* ssp.), lavender (*Lavandula latifolia Medicus*), savory (*Satureja* ssp.), hyssop (*Hissopus officinalis,* L.) and marjoram (*Thymus mastichina* L. subsp. *mastichina*) and other plants such as common bearberry (*Arctostaphylos uva-ursi,* L. *Sprengel*) and common gorse (*Genista scorpius,* L.), etc.

The District's arable land is rotated between cereal and sunflower crops. There is also a small proportion of permanent crops, the main ones being vines and olive trees. Aromatic plants and plants for seasoning, principally lavandin (*Lavandula hybrida Rev*) are also grown. A number of tree species are to be found in great numbers and oak, holm-oak, pine and savin-juniper forests are import for beekeeping.

The area has a cool, temperate Mediterranean climate. The average temperature is between 8 °C and 12 °C, with long cold periods when temperatures vary between 0 °C and 4 °C and hot periods with temperatures of between 18 °C and 22 °C.

According to the method of production established by beekeepers in the geographical area, the maximum temperature when liquefying the honey for decanting and packing is 45 °C. Pasteurisation is not permitted and producers must guarantee that the honey is not overheated. The use of sand, diatomaceous or similar filters that remove the natural pollen content is prohibited and gravity decantation must be used.

5.2. *Specificity of the product:*

A. Physico-chemical characteristics

| | |
|---|---|
| Moisture content | ≤ 17,5 % |
| Hydroxymethylfurfural | ≤ 15,0 mg/kg |
| Free acidity | ≤ 35,0 meq/kg |
| Electrical conductivity | ≤ 0,62 mS/cm |
| Colorimetry | $L^*_{10} \geq 55{,}0$; $-2{,}0 \leq a^*_{10} \leq +22{,}0$; $h_{ab,\ 10} \geq 74{,}0$ |

B. Pollen characteristics

| Type of 'Miel de La Alcarria' | Percentage of pollen grains |
|---|---|
| Monofloral lavender honey | Lavender pollen > 10 % |
| Monofloral rosemary honey | Rosemary pollen ≥ 15 % |
| Multifloral honey | Total grains of thyme (*Thymus* t.), savory (*Satureja* spp.), rosemary and lavender ≥ 5 % |

In addition, the following conditions must be complied with.

— The percentage of grains of pollen of plants of the heath family (*Ericaceae*), with the exception of common bearberry (*Arctostaphylos uva-ursi* L. *Sprengel*), must be ≤ 1 %.

— The percentage of grains of pollen of rockrose (*Cistus ladanifer* L.) must be ≤ 3 %.

— The percentage of grains of pollen of French lavender (*Lavandula stoechas* L.) must be ≤ 3 %.

— The total percentage of pollens of non-ornamental plants, excluding aromatic plants, cultivated in the production area must be ≤ 15 %.

C. Organoleptic characteristics

The honeys must have the organoleptic characteristics, as far as colour, aroma and flavour are concerned, that are specific to the flower from which they originate.

5.3. *Causal link between the geographical area and the quality or characteristics of the product (for PDO) or a specific quality, the reputation or other characteristic of the product (for PGI):*

The situation of Alcarria at an altitude of between 900 and 1 000 metres, its cool, temperate Mediterranean climate and the basic soils produce wild flora rich in labiates such as rosemary, thyme, lavender, savory, hyssop and marjoram, as well as other plants such as common bearberry and common gorse, giving multifloral, monofloral rosemary and monofloral lavender 'Miel de La Alcarria' their specific characteristics, which differ from those of other honeys and depend on the percentages of pollen they contain and the organoleptic and physico-chemical properties of moisture content, hydroxymethylfurfural content, free acidity, electrical conductivity and colorimetry.

**Reference to the publication of the specification:**

(Article 5(7) of Regulation (EC) No 510/2006)

http://pagina.jccm.es/agricul/paginas/comercial-industrial/consejosreguladores/pliegos/pliego_condiciones_miel_alcarria.pdf

**Publication of an application pursuant to Article 6(2) of Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs**

(2012/C 302/15)

This publication confers the right to object to the application pursuant to Article 7 of Council Regulation (EC) No 510/2006 ([1]). Statements of objection must reach the Commission within six months from the date of this publication.

SINGLE DOCUMENT

**COUNCIL REGULATION (EC) No 510/2006**

**'PASTEL DE TENTÚGAL'**

**EC No: PT-PGI-0005-0938-09-12.01.2012**

**PGI ( X ) PDO ( )**

1. **Name:**

'Pastel de Tentúgal'

2. **Member State or Third Country:**

Portugal

3. **Description of the agricultural product or foodstuff:**

3.1. *Product type:*

Class 2.4. Bread, pastry, cakes, confectionery, biscuits and other baker's wares

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

This is a sweet pastry originally produced in convents, the thin dough of which (0,06-0,15 mm) is made using a combination of water and flour and the creamy filling from a combination of egg yolks and eggs with sugar syrup. The product may be presented either as a thin tube ('palito'), a miniature tube, a crescent or a miniature crescent, with the following physical, chemical and sensory characteristics.

*Table 1*

**Average physical parameters for the various types of 'Pastel de Tentúgal'**

| | Tube | Crescent | Miniature tube | Miniature crescent |
|---|---|---|---|---|
| Parameters | Average values | | | |
| Weight (grams) | 70,0-90,0 | 80,0-110,0 | 30,0-60,0 | 40,0-60,0 |
| Width (cm) | 4,0-6,0 | 6,0-7,5 | 3,0-4,0 | 4,5-5,5 |
| Length (cm) | 13,0-15,0 | 10,0-14,0 | 9,0-12,0 | 7,5-10,0 |
| Height (cm) | 2,5-4,0 | 3,0-6,0 | 1,5-2,5 | 3,0-4,0 |

*Table 2*

**Average chemical parameters for 'tube' and 'crescent' types of 'Pastel de Tentúgal'**

| 'Pastel de Tentúgal' | | |
|---|---|---|
| Parameters | Tube | Crescent |
| Water activity (aw) | 0,836-0,894 | 0,836-0,894 |
| Moisture % | 26,0-31,0 | 22,0-30,0 |
| Protein (%) | 9,2-10,5 | 9,5-12,5 |

([1]) OJ L 93, 31.3.2006, p. 12.

| 'Pastel de Tentúgal' | | |
|---|---|---|
| Parameters | Tube | Crescent |
| Fat (%) | 7,7-13,0 | 10,5-23,0 |
| Carbohydrates (%) | 50,0-54,0 | 42,0-50,0 |
| Total ash (%) | 0,5 | 0,8-1,2 |
| Calorie content kcal/100g | 314,0-358,0 | 340-420 |

*Table 3*

**Sensory characteristics**

| | Tube or miniature tube | Crescent or miniature crescent |
|---|---|---|
| External appearance | A sweet formed of almost transparent layered pastry, rectangular in shape with crimped at each end; straw yellow to toasted yellow in colour. Presentation: optional dusting of icing sugar or granulated sugar | A sweet formed of layered, thin, almost transparent, pleated pastry; straw yellow to toasted yellow in colour, in a crescent shape with larger or smaller crimped ends. Optional dusting of icing sugar or granulated sugar and cinnamon |
| Internal appearance | Pastry filling is yellow to chestnut yellow in colour (due to the presence of cinnamon); filling is grainy and consistent and does not run when the product is cut but is easy to bite and melts in the mouth | Pastry filling is yellow to chestnut yellow in colour (due to the presence of cinnamon and toasted almonds); filling is grainy and consistent and does not run when the product is cut but is easy to bite and melts in the mouth |
| Texture | Layered, both delicate and crispy | Layered, both delicate and crispy |
| Consistency | Creamy but yet consistent | Creamy but yet consistent |
| Flavour | Sweet, comprising flavours of egg, sugar and cinnamon | Sweet, comprising flavours of egg, sugar, toasted almonds and cinnamon |

3.3. *Raw materials (for processed products only):*

Pastry: water, wheat flour types 45 or 55 (high levels of the proteins gliadin and glutenin), resulting in a pastry which is viscoelastic and cohesive.

Filling: egg yolk (pasteurised or from fresh eggs), eggs (pasteurised or fresh), sugar, margarine with 10 % butter, cinnamon and almond.

3.4. *Feed (for products of animal origin only):*

—

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

Production of pastry

This is a process whose success is very much dependent on the knowledge acquired by those involved in the production of this product. Even though a recipe exists for this type of pastry, on a day-to-day basis, climatic conditions and the stability of the flour may give rise to unexpected circumstances, requiring active intervention on the part of those producing the pastry.

Preparation of the filling

This is another part of the process in which the know-how of those involved in production is key, since the assessment of whether the filling is 'right' is done in an empirical manner and is in part dependent on know-how.

Shaping the pastry

When shaping the pastry in a tube or crescent shape, the know-how of those involved in the production process is very important, since immense skill and manual dexterity is required in order to obtain uniform dimensions, keeping the pastry in one piece while ensuring that the characteristic crimped ends are firm and of appropriate size.

After this stage, the 'pastel' can be finalised (baked) on the premises of the recipient outside of the restricted area, since this stage in the production process does not require specific knowledge.

3.6. *Specific rules concerning slicing, grating, packaging, etc.:*

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3.7. *Specific rules on labelling:*

The following must appear on the label:

— 'Pastel de Tentúgal — Indicação Geográfica Protegida' or 'Pastel de Tentúgal IGP' (following Community registration),

— EU logo (following Community registration),

— 'Pastel de Tentúgal' logo:


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

The geographical area in which 'Pastel de Tentúgal' is produced is restricted to the small town of Tentúgal and is bounded to the east by the town of Lamarosa (municipality of Coimbra), to the north by the village of Portela, to the west by the village of Póvoa de Santa Cristina (parish of Tentúgal) and by the town of Meãs (municipality of Montemor-o-Velho) and to the south by the 'Vala Real' waterway.

5. **Link with the geographical area:**

Since the 16th century, the know-how associated with the production of 'Pastel de Tentúgal' has never travelled beyond the confines of the town. Therefore, in order to obtain a product with the specific characteristics providing this product with its reputation, the stages of production for the pastry and filling and the shaping of the 'pastel' only take place in Tentúgal, the town whose name the product bears.

5.1. *Specificity of the geographical area:*

Production of 'Pastel de Tentúgal' is restricted exclusively to the town of Tentúgal. This is due both to the significant climatic factors (specifically, the mild temperatures and high levels of relative humidity in the air) and the fact that the name of the product shares that of the restricted area in which the product is well known, the latter being directly linked to the certainty of the origin of this product — the Convent of Our Lady of the Nativity — manufactured by the sisters of the Carmelite Order who resided there between 1565 and 1898.

Tentúgal's proximity to the ocean (the town of Figueira da Foz) and the fact that the River Mondego flows only a few kilometres away both create a set of natural conditions such as mild temperatures and high levels of relative humidity in the air. These are factors which significantly facilitate the production and manipulation, without large amounts of wastage, of a fine, crispy, almost transparent pastry comprising only water and flour.

The proximity of the sea and the river serves to regulate temperatures, providing Tentúgal with milder temperatures all year round: winter temperatures are not excessively low (in 2010, the monthly average in the municipality of Montemor-o-Velho was between 10 °C and 20 °C), whilst summer temperatures are not excessively high (average maximum in 2010: 26 °C).

As a rule, the region of the Lower Mondego valley, in which Tentúgal is situated, experiences high levels of relative humidity throughout the year, varying on average between 70 % in spring and summer and 87 % in autumn and winter, resulting in summers which are not very dry.

This climate facilitates both the production of the dough (low levels of humidity would make it harder to pull the dough, risking tearing it at an early stage) or handling it (without humidity handling the dough when shaping the 'pastel' would not be possible).

In addition to the importance of climate, it should be noted that, owing to the sale of sweet cakes and tarts at the Convent of Our Lady of Carmo, reference has been made to the reputation of 'Pastel de Tentúgal' as early as 1860. This reputation stems from the combination of natural factors and the know-how which have shaped the product in question. In fact, over four centuries, the women of Tentúgal have acquired expertise on the best way of producing the pastry and filling for this product and how to shape this 'pastel'. The result is a unique sweet which has acquired a reputation directly linked to the place from which it originates.

5.2. *Specificity of the product:*

The specific qualities of 'Pastel de Tentúgal' are derived firstly from the production method used to obtain a delicate and fine dough, with a thickness of between 0,06 mm and 0,15 mm. Comprising only water and wheat flour, the dough undergoes several stages in which production customs play a great part, including the way in which it is handled in order to achieve the desired thickness. This almost artisan method of production, with the exception of the kneading which is carried out mechanically, is entirely dependent on the know-how acquired in Tentúgal, constrained as it is by the characteristics of the flour and the climatic conditions.

Specifically as regards the pastry production process, initially the dough (comprising nothing more than water and flour) is prepared in a mechanical mixer, in order to achieve a uniform dough. It is then placed on a round board made from an appropriate material.

It then is placed in a wooden platform located on the floor covered with white sheets and is then stretched to its maximum in order to obtain a fine and almost transparent texture. This is the most important point in the production process; appropriate training and sensitivity is necessary to avoid tearing the dough before it has reached the desired thickness.

The dough is dried at room temperature, using fans or by use of a blowtorch to accelerate the drying process in days where humidity is higher. Once the dough has reached the recommended humidity levels, it is cut into a circular shape and picked up by hand, before being placed in trays made from a suitable material and covered with a dry white cloth. A damp cloth is placed above this cloth in order to prevent the dough from drying. The dough has a texture similar to tracing paper although it is finer.

Secondly, the expertise employed when handling this dough is fundamental to the shaping of the 'pastel'; the result is a product whose thin layers are placed in such a way that the filling does not escape.

Thirdly, the extremely fine, almost transparent dough layers, together with the egg-based creamy texture, provides an external and internal appearance, a consistency, flavour and texture which are individual and which make it a unique product.

5.3. *Causal link between the geographical area and the quality or characteristics of the product (for PDO) or a specific quality, the reputation or other characteristic of the product (for PGI):*

In addition to the importance of climate, it should be noted that this product shares the name of the restricted area in which it is well known. This is directly linked to the certainty of the origin of the product in the Convent of Our Lady of the Nativity, where it was manufactured by the sisters of the

Carmelite Order who resided there between 1565 and 1898. Since the late 16th century, it was at the Convent where the knowledge and expertise was acquired which has given rise to a unique product, something which has been attested in many sources found in a wide range of publications.

One such example is Augusto Fonseca's book 'Velharias de Coimbra' which states that prior to 1860 a seller named Rosa would sell 'the highly appreciated pastéis de Tentúgal' under the 'Arco do Bispo' (Coimbra). António Nobre, a Portuguese poet who studied in Coimbra between 1888 and 1890 wrote in his poem 'Carta a Manuel' that he would travel to Tentúgal every month to visit a pretty nun to buy cakes. The 1891 work 'Conimbricense' refers to the 'renowned' 'pastéis de Tentúgal' made in the Convent which had to be tried at least once in your life. In works describing the 1884 Exposição Distrital de Coimbra (Coimbra District Exhibition), reference is made to the 'delicious' 'pastéis de Tentúgal'. These historical references confirm the Convent as the origin of this product and also provide an understanding of how this 'pastel' has long enjoyed a superb reputation. The adjectives used to describe this product are extremely positive and help us understand how even in the 19th century 'pastéis de Tentúgal' enjoyed a wide-spread and favourable reputation.

The work 'O Doceiro Moderno' by J. M. Sousa Monteiro (late 19th century) describes these types of 'pastéis' as having a 'recipe unique to the local area … although we explain how to layer the pastry, which is the hardest part'. In Carlos Bento da Maia's work 'Tratado Completo de Cozinha e de Copa', the first edition of which dates back to 1904, reference is made to the recipe for 'pastéis de Tentúgal', describing the dough as needing to be pulled until achieving the 'thickness and transparency of tissue paper'. He also commented on the dough production process saying that 'from the description of the process, it is evident that less dextrous hands cannot achieve it properly …'

Subsequently, António Maria de Oliveira Belo, in his 1936 work 'Culinária Portuguesa', described 'pastéis de Tentúgal' as being very hard to make owing to the difficulty in preparing the dough, something which could only be achieved through long experience.

These three examples of references from published works on cooking support our claim that the specific nature of the process for producing this 'pastel' requires a very specific know-how, which the women of Tentúgal have acquired over many years.

Therefore, the combination of natural factors and know-how have contributed in a decisive manner to the production of a unique type of sweet. The temperature and humidity, two natural active pre-conditions for the production of 'pastéis de Tentúgal', together with the know-how originating from this Convent, which has been developed over four centuries and which has made the product what it is today, and in respect of which skills and experience which made it possible to make up for natural factors when optimum natural circumstances are not present. Traditional products create a special relationship with the place where they originate, whether because of material or cultural reasons, establishing links which despite being invisible, give flavour and shape to the places where they are made.

It should be noted that the know-how relating to the production of the 'Pastel de Tentúgal' has never left the confines of the town of Tentúgal.

**Publication reference of the specification:**

(Article 5(7) of Regulation (EC) No 510/2006)

http://www.gpp.pt/Valor/DOP_IGP_ETG.html

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