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Contents



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EN

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

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

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[1] Text with EEA relevance

(Continued on inside back cover)

II

*(Non-legislative acts)*

# REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) No 1127/2013

**of 7 November 2013**

**approving minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (Montasio (PDO))**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular the second subparagraph of Article 53(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected designation of origin 'Montasio', registered under Commission Regulation (EC) No 1107/96 [2], as amended by Implementing Regulation (EU) No 355/2011 [3].

(2) The purpose of the application is to amend the specification by clarifying the production method.

(3) The Commission has examined the amendments in question and decided that they are justified. Since the amendments are minor within the meaning of the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012, the Commission may approve them without following the procedure set out in Articles 50 to 52 of the Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The specification for the protected designation of origin 'Montasio' is hereby amended in accordance with Annex I to this Regulation.

*Article 2*

Annex II to this Regulation contains the consolidated Single Document setting out the main points of the specification.

*Article 3*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 148, 21.6.1996, p. 1.
[3] OJ L 98, 13.4.2011, p. 6.

*ANNEX I*

In the specification for the protected designation of origin 'Montasio', the following amendments are approved:

*1st amendment*

The sentence: 'The milk used must come from the evening and morning milking, up to a maximum of four consecutive milkings' is replaced by the following sentence: 'The milk must come from consecutive milkings and be collected within 48 hours of the first milking'.

Initially, the milk delivered within the 48 hour period came from only traditional milkings, which were 4 in number. With the introduction of automatic milking, the number of consecutive milkings possible in a 48 hour period can be increased. The time period has therefore been maintained; only the total number of milkings has been changed. From a technical and scientific point of view, the use of automatic milking systems does not affect the properties of the milk; in particular, its composition is statistically comparable, in terms of fats and protein content, to that of milk obtained by traditional milking. The cows' health is even improved, since these systems eliminate the stress caused, during peaks of high lactation, by the practice of only two milkings. The possibility of obtaining large quantities of milk more than twice a day also has the effect of subjecting the udder and teats to less stress, improving the microbiological quality of the milk and reducing the occurrence of mastitis.

The use of these systems also makes it possible to improve the milk's rheological behaviour, which measures the coagulation capacity, leading to both a faster enzymatic reaction in the curds and making the curds resistant to the mechanical action of the curd knife.

*2nd amendment*

Current wording: 'The milk intended for the PDO "Montasio" must not undergo pasteurisation processes and must be accompanied by a clearly positive phosphatasia analysis.'

Amended text: 'The milk intended for the PDO "Montasio" must not be pasteurised. Any analyses carried out on the heat-treated milk intended for the production of the PDO "Montasio" must show a clearly positive reaction to the phosphatasia test.'

For several years cheese self-monitoring dairies have subjected the milk to a systematic check by recording the milk's transitional temperatures each day. Thus, the phosphatasia test remains an analysis method used by the monitoring body to check compliance with the specification. This check is carried out on the basis of risk analysis.

*3rd amendment*

Current text: 'The production of the cheese for the PDO "Montasio" is carried out according to the following operational sequence:

06) cooking at 42-48 °C and rolling away from the heat for a total of 20 to 30 minutes;'

Proposed text:

06) 'cooking at + 42-48 °C and draining, away from the heat, for at least 10 minutes;'

It has been found that these two stages (the cooking and the successive draining, away from the heat) can vary greatly according to the prevailing technical and technological conditions.

As regards equipment, the cheese dairies which produce 'Montasio' use either copper vats (from 1 to 1,5 tonnes) or multi-purpose steel vats with a capacity of 3,5 to 8 tonnes.

Using these two types of vat is a factor which determines the time for heating the coagulated mass, since the speeds of steam heating are very different from those resulting from the process which takes place.

As for the draining, away from heat, a stage during which part of the whey is removed from the coagulated mass, the latter depends on the maximum temperature reached, how quickly the mass cools, which in turn depends on the type of vat used, the quantities processed in each vat, the size of the curds' kernels and the quantity of water contained which will be removed by the effect of the temperature and the mixing.

Moreover, the decanting or withdrawal of the coagulated mass with a view to moulding can be speeded up or slowed down depending on the time needed to carry out the operation and the degree of automation present.

For example, if the coagulated mass is decanted onto a moulding table from a multi-purpose vat placed above that table, the time needed for the same quantity is well below that needed for manual decanting with a linen cloth from copper vats.

Taking into account the fact that the optimum moment for decanting the curds is determined by each cheesemaker according to daily assessment criteria, experience and personal know-how, etc., it is necessary to define a minimum duration for the cooking and draining away from heat.

*ANNEX II*

**CONSOLIDATED SINGLE DOCUMENT**

Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1]

**'MONTASIO'**

EC No: IT-PDO-0317-0995-26.04.2012

**PGI ( ) PDO ( X )**

1. **Name**

'Montasio'

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 product to which the name in (1) applies*

'Montasio' is a cheese made from cow's milk, with medium or long ripening, cylindrical in shape, with a straight or almost straight heel and flat or slightly convex sides. It is produced from non-pasteurised milk based exclusively on natural lactic leavens or authorised fermenting agents. The minimum ripening period is 60 days and the moisture content is monitored by boring at 10 and 60 days of ripening. At 60 days of ripening, cheese bearing the PDO 'Montasio' must have the following characteristics: a maximum moisture content less than or equal to 36,72 %; fat content in dry extract: at least 40 %; weight: 6 to 8 kg; diameter: 30 to 35 cm; heel: at most 8 cm; rind: smooth, regular and elastic; paste: compact with a few openings; colour: natural, drawing on straw yellow; aroma: typical; flavour: agreeable, tending towards spicy in the case of long-ripened 'Montasio'.

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

The PDO 'Montasio' is produced from milk from farms located in the production area.

The main breeds reared are Brown Swiss, Italian Red Pied and Black Pied.

No preservatives are added and no heat treatment is authorised, except for cooling to a minimum temperature of 4 °C.

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

The cows' feed comprises 75-85 % raw cereals, dry and green fodder and silage. The remaining 15 to 25 % raw feed comprises concentrates and protein cattle-cake. The use of mineral and vitamin supplements is authorised. 60 % of the feed comes from the geographical area. Feed which traditional cheesemakers regard as adversely affecting tyrosis is banned, such as fodder from marshy land or located beside busy roads. Also not authorised are vegetables, fruit and rape, or the by-products of processing rice, meal of animal origin, industrial feed for medical use, moist or ensilaged fresh beet pulp, by-products of beer or of distilled products, ensilaged fodder (except ensilaged hay and ensilaged maize) and fermented substances from the industrial processing of fruit, beet, beer and distilled products.

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

The whole production process (cattle rearing and milk production, coagulation, processing the curds, moulding, draining, salting and ripening) must take place in the area defined under point 4.

[1] OJ L 93, 31.3.2006, p. 12. Replaced by Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

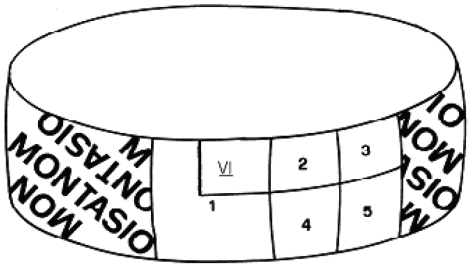
3.6. *Specific rules concerning slicing, grating, packaging, etc.*

—

3.7. *Specific rules concerning labelling*

The product is identified by marking, at the outset, in a specific mould which states the producer's code, the provincial acronym and the production date (year, month, day). The 'stamp of origin' of the PDO 'Montasio' consists of the name 'Montasio' written obliquely the right way up and upside down (Figure No 1).

The 'stamp of origin' is put on all the production of the associated and non-associated holdings, on condition that the production has been obtained in compliance with the specification.




(Figure No 1)

1) Branding of the name 'Montasio' and sticker bearing the letters 'PDM'

2) Month of production/3) Day of production/4) Cheesemaker's code/5) Provincial acronym/VI) Year of production

The product logo comprises a stylised capital 'M', below which 'MONTASIO' is written. This logo must always be reproduced using the 'HORATIO' font. It must comply with the proportions of Figure No 2 (for example, 8 cm wide and 6 cm tall).


(Figure No 2)

When the whole production process — from producing the milk to ripening for at least 60 days — takes place in a mountain area, as defined in the national legislation in force, located within the production area of the PDO 'Montasio', the cheese's label may state 'mountain product'. To that end, a sticker with the letters 'PDM' ('prodotto della montagna' = 'mountain product') will be affixed to the heel.

On cheese loaves of 'Montasio' which have ripened for more than 100 days, the Consorzio per la Tutela del Formaggio Montasio may, at the request of all the associated or non-associated producers, brand onto the part of the heel intended for that purpose the logo of the name, after its prior verification (Figure No 2).

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

The production area of the PDO 'Montasio' comprises: Friuli-Venezia Giulia: the whole territory. Veneto: the whole territory of the provinces of Belluno and Treviso and part of the territory of the provinces of Padua and Venice delimited as follows: 'from the intersection with the border between the province of Treviso and that of Padua, the perimeter follows that line until the Serenissima motorway. It continues along that line until the motorway bridge crossing the River Brenta, then it follows the bank of the river until its mouth'.

5. **Link with the geographical area**

5.1. *Specificity of the geographical area*

The natural factors are linked to the climatic conditions in the production area, comprising mainly mountains and foothill areas where mountain and meadow grazing are still practised, which influences the quality of the fodder intended to feed the dairy cows.

'Montasio' was added to the market price list of San Daniele and Udine in 1773/1775. This attests to the marketing of 'Montasio' and shows that it was not only a local product or intended for domestic consumption. The close link between 'Montasio' and the production area is also attested by the strong impetus which the production of this cheese gave to the development of cooperatives. 'Montasio' and its specific production method quickly spread in Friuli and western Venice, because of both human and structural factors (such as the invention of cooperative cheese dairies or the establishment of a school for cheesemakers) — to the point where there were more than 650 cheese dairies active in the 1960s — and because of the environment itself within which that method first developed.

As regards the characteristics of the production area, the eastern part of Italy has always been and is still marked by considerable spring and autumn precipitation, which favours pasture and cereal-growing (wheat and barley), which is the basis of dairy cow feed. Maize-growing and therefore the use of maize as fresh feed and for ensilage also gained in importance over time. More recently, the cultivation of soya, a protein supplement, has expanded in the production area.

5.2. *Specificity of the product*

The main characteristic of 'Montasio' is its great suitability for medium- to long-term ripening. In the range of national cheeses, 'Montasio' is among the semi-hard cheeses, but as it can be ripened for up to 36 months, it is also among the category of rare long-ripened hard cheeses.

Another characteristic of 'Montasio' is in the dimensions of the loaf.

Moreover, the PDO 'Montasio' has retained in its specification the ban on pasteurising the milk, thereby preserving to the absolute maximum extent possible the spontaneous bacterial load of the milk produced in the production area.

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 suitability for medium-/long-term ripening is the result of 'soft' technology. Small doses of lactic fermenting agents are used (about 1 %), cooking is done at low temperatures (between 42 and 48 °C) and the draining and pressing give the cheese a medium firmness, with a moisture content at two months (which corresponds to the minimum level for marketing the cheese) of about 36 %.

The environment in which 'Montasio' developed has microbiological characteristics adapted to its development and dissemination. 'Montasio' is characterised by the presence of a thermophilic microbial flora which has always made it possible to obtain a unique cheese product of its type, to be consumed fresh (at least two months' ripening nowadays, because it is produced from non-pasteurised milk) but it can also be ripened for up to 36 months; this cheese therefore has organoleptic characteristics, a consistency, flavours and aromas which vary over time, precisely thanks to the bacterial load naturally present in the meadows/pastures and the fodder in the production area.

In fact, at two months' ripeness 'Montasio' is a medium-firm cheese with a delicate flavour reminiscent of the milk from which it is produced. As ripening is extended and substances concentrate, 'Montasio' acquires more marked and slightly spicy flavours and the cheese becomes firmer and crumblier.

With the improvement in rearing methods, crop rationalisation and the introduction of ever more hygienic milking methods, it became necessary to enrich the milk with cheese micro-organisms useful for the production of 'Montasio'. Thus lactic fermenting agents (high in cocci and low in bacilli), from the milk in the production area, started to be used, a practice which subsequently became widespread.

**Reference to publication of the specification**

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

The authority responsible launched the national opposition procedure by publishing the proposal for recognition of the PDO 'Montasio' in Official Gazette of the Italian Republic No 271 of 21.11.2011.

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 by going directly to the home page of the Ministry of Agricultural, Food and Forestry Policy (www.politicheagricole.it) and clicking on 'Qualità e sicurezza' (Quality and safety) (at the top right of the screen) and then on 'Disciplinari di Produzione all'esame dell'UE' (Specifications submitted for examination by the EU).

# COMMISSION IMPLEMENTING REGULATION (EU) No 1128/2013

## of 7 November 2013

## approving minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (Morbier (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular the second subparagraph of Article 53(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined France's application for the approval of amendments to the specification for the protected designation of origin 'Morbier' registered under Commission Regulation (EC) No 1241/2002 [2], as amended by Regulation (EC) No 1027/2009 [3].

(2) The purpose of the application is to amend the specification by giving more detailed information on the product description, the proof of origin, the method of production, labelling, national requirements and the structures responsible for monitoring the designation.

(3) The Commission has examined the amendments in question and decided that they are justified. Since the amendments are minor within the meaning of the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012, the Commission may approve them without following the procedure set out in Articles 50 to 52 of the Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The specification for the protected designation of origin 'Morbier' is hereby amended in accordance with Annex I to this Regulation.

*Article 2*

Annex II to this Regulation contains the consolidated Single Document setting out the main points of the specification.

*Article 3*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 181, 11.7.2002, p. 4.
[3] OJ L 283, 30.10.2009, p. 34.

*ANNEX I*

In the specification for the protected designation of origin 'Morbier', the following amendments are approved:

1.1. **Description of product**

*Organoleptic properties*

All the descriptors of the cheese have been analysed in order to give a more realistic description of the product:

As regards the black mark, the word 'well' before 'bound' has been deleted because it is subjective.

As regards the rind, the words 'smooth and homogeneous' have been replaced by the more precise description 'rubbed, of regular appearance, smeared, showing the frame of the mould'. As regards its colour, 'light grey to orangey beige' has been replaced by the more precise description 'beige to orangey with orangey brown, orangey red and orangey pink shades'.

As regards the cheese, it has been added that it is 'homogeneous' and specified that it is soft 'to the touch'. The openings are described more realistically: instead of 'possibly discreet openings' the text now reads 'frequently a number of scattered openings the size of a redcurrant or small flattened bubbles'. It has been added that the cheese is 'not very sticky in the mouth' and that its texture 'is smooth'.

As regards taste, instead of 'a light, creamy taste; its flavour is clear, fruity and persistent', the text now states 'The taste is clear with nuances of milk, caramel, vanilla and fruit. With ageing, the aromatic range becomes enriched by roasted, spicy and vegetable nuances. The flavours are balanced.'

*Analytical characteristics*

A minimum level of moisture content of fat-free cheese of 58 % has been added in order to avoid atypical cheeses which are too dry.

1.2. **Proof of origin**

The section 'Information proving that the product originates from the geographical area' has been consolidated and brings together in particular the declarative requirements and the requirements regarding the keeping of registers on the traceability of the product and the monitoring of production conditions.

Moreover, this section has been added to and supplemented by several provisions on registers and declarative documents enabling the cheeses' traceability to be guaranteed.

1.3. **Production method**

*Milk production*

— Breeds:

In order to facilitate checks, the breed type has been specified and the local breeds requirement has been extended to 'dairy herd' and 'to all the dairy cows present on the holding'. The 'products of crossing the two breeds of certified descent' are likewise allowed. The two pure breeds and their crossing are historically of local origin. The crossing has no observable impact on the specificity of the product.

— Grazing area:

The sentence 'The herd is managed in accordance with local customs' has been deleted because it is too general and does not allow for monitoring.

The sentence 'The areas considered as grazing areas for the production of "Morbier" are those grass areas which permanently have at least 3 different plant species and include at least one type of grass and one type of legume.' has been added in order to favour natural grassland with the floristic diversity of pasture.

— Grassland management and enrichment:

A limit on nitrogenous mineral manure of 50 units per hectare of grazing area per year has been added in order to preserve the grassland's floristic diversity. To the same end, the authorised types of organic manure have been listed: solid manure, slurry, liquid manure and stabilised sewage sludge. In order to avoid milk quality problems, any use of the forage area (grazing or mowing) is prohibited at least 4 weeks after the date of spreading the organic manure.

— Grazing:

In order to maintain the link between the product and its region, grazing has been made compulsory: 'The dairy cows graze after the snow has melted and as soon as the soils' bearing capacity allows. In the grazing season, the cows in production use at least 20 acres of grassland per dairy cow.'

— The dairy cows' basic intake:

'Only sodium chloride is authorised to improve the keeping of fodder.' in order to avoid changing its characteristics.

Moistening the feed is prohibited in order to avoid the development of undesirable bacteria.

'In the case of supplementary green feed, the green fodder is distributed in cleaned troughs and consumed within at most 4 hours of mowing.' in order to avoid fermentation of the green feed. Similarly, 'When beet is cut into pieces, it is prepared each day.'.

In order to maintain the link between the product and its region: 'The supply of concentrates in the dairy cows' intake (including the supply of dried plants) is limited on average for the herd to 1 800 kg per cow per year.'

The ban on fermented feed has been broadened from 'dairy cows' to the 'dairy herd (cows in production, dry cows and replacement animals after weaning)'.

The possibility of feeding another herd, clearly separated, with this type of feed is nevertheless envisaged, subject to certain conditions.

In order to maintain the link between the product and its region, transgenic feed is banned.

In order to avoid a deterioration in the milk's quality: 'The following is banned from the dairy herd's feed: fodder which adversely affects the milk's smell or taste.'

*Milking*

The milk's natural flora must be preserved. Increasing the number of milkings per day harms the milk's natural flora. One daily milking causes imbalances in the microflora: 'Milking is carried out twice a day, in the morning and in the evening. Omitting a milking is prohibited. In a bid to respect the milk's natural flora, the products used do not contain disinfectants except in the case of established anomalies.'

*Processing*

— Milk used:

The milk must be collected daily and used quickly in accordance with the time limits of local tradition.

This milk must be separated from other milk in order to authorise monitoring.

'The only types of milk which may enter the premises where "Morbier" is made are those which comply with this specification, or types of milk intended for other designations of origin of the region provided that the traceability is sufficient to enable verification of compliance with this specification by the types of milk actually used to make "Morbier".'. The microbial flora of the types of milk complying with the specifications of the region's other PDOs is compatible with that of 'Morbier'. The producers of milk for those other PDOs are identified and the types of milk coming from those holdings comply with the same essential rules as for the PDO 'Morbier': feeding dairy cows on the basis of grass and hay in the area, grazing, keeping the milk for a limited period, etc. That makes it possible to maintain an appropriate microbial atmosphere in the workshop. Other types of milk which comply neither with the specification for 'Morbier' nor with the specifications for the other PDOs do not provide the same guarantees. Moreover, different cheeses are of course made in different ways, either in other places (different production chain) or at different times (successive production).

— Processing

The sentence 'With the exception of partial skimming, the addition of rennet, lactic starters, salt or water in order to clean the curd, nothing may be removed from or added to the milk.' is replaced by:

'With the exception of partial skimming, nothing may be removed from or added to the milk, including during production, except for: — salt (sodium chloride), — rennet, — selected cultures of fermenting agents, obtained either by subculturing or by direct seeding, — water, — vegetable carbon (carbo medicinalis vegetalis).'

It is specified that 'Production must take place in a stainless steel or copper vat.' for technological and traditional reasons.

The size of the curds' grains has been deleted because this is impossible to check and is not specific to this product.

The conditions for the removal of lactose are specified as well as the temperature conditions in the vat.

The sentence 'The loaves are formed by light pressing.' is deleted because this is not a technological requirement.

It is specified that coating with vegetable carbon must be 'done by hand' so that the cheesemaker can demonstrate his know-how at this important stage of producing 'Morbier'. The use of traditional wooden moulds and linen cloth are authorised because these are materials traditionally used in this sector.

It has been added to the specification that 'Morbier' must be salted dry or in brine and that, in the case of brining, chemical purification of the brine is prohibited. This important technological stage was forgotten in the previous specification.

*Maturing*

Wood is the best maturing medium because it enables excellent exchanges, particularly with water and salt, by regulating them. Wood also strengthens the link with the region by favouring surface microflora. The following sentence has therefore been added: 'The cheese is matured on wooden planks.'. There is no requirement as to the origin of these planks.

However, in order not to penalise a cheese dairy which currently matures on stainless steel, the following transitional measure is proposed: 'By way of derogation, stainless steel media used to make "Morbier" before 1 January 2006 may be used until their replacement and at the latest until 31 December 2014.'

It has been added that the minimum duration is 45 days 'without interruption of the cycle'.

It is specified that: 'During storage before marketing, the matured cheeses must be kept at a positive temperature'.

1.4. **Labelling**

The requirement to use the national logo 'INAO' no longer applies. The requirement to use the European Union logo 'PDO' has been added. The requirement to give the details of the producer has been replaced by the requirement to give the details of the maturer.

It is specified that, irrespective of the regulatory references applicable to all cheeses, the use of any term or other reference accompanying the designation of origin is prohibited on the labelling, advertising, invoices or commercial documents, with the exception of specific trademarks.

1.5. **National requirements**

In the 'National requirements' it is considered useful to indicate the 'main points to check' with their reference values and assessment methods.

1.6. **Other**

The details of the organisations involved in monitoring the production conditions are given, and in particular the details of the new Certifying Body chosen by the group as the control body. The National Institute of Origin and Quality is no longer involved under this heading.

*ANNEX II*

**CONSOLIDATED SINGLE DOCUMENT**

Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1]

**'MORBIER'**

EC No: FR-PDO-0205-0933-29.12.2011

**PGI ( ) PDO ( X )**

1. **Name**

'Morbier'

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 the product to which the name in (1) applies*

'Morbier' is a cheese made from raw cow's milk, with an uncooked pressed paste, in the shape of a flat cylinder 30 to 40 centimetres in diameter, 5 to 8 centimetres high, weighing 5 to 8 kg, with flat sides and a slightly convex heel.

Throughout each slice the cheese has a continuous, joined, horizontal, central black mark.

Its rind is natural, rubbed, of regular appearance, smeared, and bears the imprint of the frame of the mould. Its colour is beige to orange with shades of orangey brown, orangey red and orangey pink. Its paste is homogeneous and ivory to pale yellow in colour, with frequently a number of scattered openings the size of a redcurrant or small flattened bubbles. It is soft to the touch, smooth and melting and not very sticky in the mouth and its texture is smooth and fine. The taste is clear with hints of milk, caramel, vanilla and fruit. With ageing, the aromatic range becomes enriched by roasted, spicy and vegetable nuances. The flavours are balanced. The cheese has a minimum fat content of 45 grams per 100 grams after complete desiccation. The moisture content of the fat-free cheese must be between 58 % and 67 %. The maturing of the cheese is carried out over a minimum period of 45 days from the day of production, without interrupting the cycle.

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

The milk used to produce 'Morbier' must come solely from a dairy herd of Montbéliarde cows of breed type 46, or from French Simmental cows of breed type 35, or from crosses of these two breeds of certified descent.

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

The dairy cows' basic intake comprises grass grazed throughout the growing period, and during the winter hay or second-cut hay likewise harvested in the geographical area.

In order to guarantee a close link between the region and the product by specific feed from the geographical area, supplementary feed is limited to 1 800 kg per dairy cow per year. On the holding, the grazing area actually used must be at least equal to 1 hectare per dairy cow.

In order to maintain the traditional practice of grazing, farm production systems where all the feed is supplied in troughs are forbidden. The dairy cows graze after the snow has melted and as soon as the soils' bearing capacity allows. In the grazing season, the cows in production use at least 20 acres of grassland per dairy cow. These restrictions mean that at least 70 % of the feed comes from the geographical area.

Fermented fodder, whether silage products or other, are not to be used in the feed of the dairy herd at any time of the year owing to the technological risks related to these practices during the production and maturing of cheeses.

[1] OJ L 93, 31.3.2006, p. 12. Replaced by Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

Only raw materials and supplementary feed derived from non-transgenic products are authorised for the dairy herd so as to preserve the traditional nature of the feed.

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

The milk is produced and the cheese manufactured and matured in the geographical area.

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

—

3.7. *Specific rules concerning labelling*

The labelling of the cheeses qualifying for the designation of origin 'Morbier' must include the name of the designation written in characters at least equal in size to the largest characters appearing on the label.

The labelling must include the European Union 'PDO' symbol.

The identification (name or business name and address) of the maturing plant is clearly shown on the whole cheeses.

It is specified that, irrespective of the regulatory references applicable to all cheeses, the use of any term or other reference accompanying the designation of origin is prohibited on the labelling, advertising, invoices or commercial documents, with the exception of specific trademarks.

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

The geographical area extends over the territory of the following municipalities:

Department of Ain: municipalities of Apremont, Bellegarde-sur-Valserine as regards the part corresponding to the former municipality of Coupy, Belleydoux, Champfromier, Charix, Chezery-Forens, Confort, Echallon, Giron, Lancrans, Leaz, Lelex, Mijoux, Plagne, Montanges and Saint-Germain-de-Joux.

Department of Doubs: all the municipalities of the department.

Department of Jura: all the municipalities with the exception of Annoire, Aumur, Champdivers, Chemin, Longwy-sur-le-Doubs, Molay, Peseux, Petit-Noir, Saint-Aubin, Saint-Loup, Tavaux.

Department of Saône and Loire: municipalities of Beaurepaire-en-Bresse, Beauvernois, Bellevesvre, Champagnat, Cuiseaux, Flacey-en-Bresse, Fretterans, Joudes, Mouthier-en-Bresse, Sagy, Saillenard, Savigny-en-Revermont and Torpes.

5. **Link with the geographical area**

5.1. *Specificity of the geographical area*

Natural factors

The geographical area comprises the arc of the Jura mountains, a set of limestone plateaux, and its extension into a small part of the adjoining plain. The altitude is often high. The landscape is divided between grassland and woodland. The grassland's natural limestone flora is very varied.

The whole of the area is characterised by a continental type of climate, with large differences in temperature between winter and summer, and precipitation which, although spread throughout the year, is considerable in summer. The whole of the area is also defined by a northern climate with a low annual average temperature (despite considerable heat in the summer) and a large number of days of frost. It is a very wet mountain or submountain environment with annual rainfall always in excess of 900 mm and generally in excess of 1 000 mm. This rainfall is already considerable at low altitude and increases towards the interior of the mountain ranges. Seasonal distribution is characterised by the lack of a dry season. This climate particularly favours the growth of grass.

Human factors

In the centre and the north of the Jura mountains the importance of grazing has shaped the regional economy based essentially on livestock rearing and above all on dairy production.

The oldest document referring to 'Morbier' dates from 1799. The cheese was already known in Paris at that time, which indicates that its origin was older.

Originally it was produced at a time when the level of milk was low and in particular insufficient for the production of a wheel of 'Comté'. The production of 'Morbier' and 'Comté' are closely linked.

There are currently several theories about the origin of the making of 'Morbier'. According to one theory, 'Morbier' was made out of necessity, on the farms, in order to use two successive milkings to produce a cheese of 8 to 10 kilograms. The first curd loaf was coated with soot taken from under the cauldron in order to provide protection against external contamination and avoid superficial alteration before being put together with the curds of the following batch. The residual layer marked the join between the two batches.

The application of carbon by hand presupposes an exact balance between coating curds which were too dry and coating curds which were too moist. Maintaining a stage performed by hand guarantees that cheesemakers' know-how in relation to 'Morbier' is maintained, as well as respect for tradition.

The livestock rearers in the Jura mountains have over the generations opted for a breed of cow, the 'Montbéliarde', which is particularly suited to the local natural conditions and whose milk is well-suited to the regional cheese-making technologies. Secondarily, they have also opted for the 'Simmental', which is less prevalent.

5.2. *Specificity of the product*

'Morbier' is a cow's milk cheese weighing 5 to 8 kg.

'Morbier' is a cheese which is recognisable by a horizontal, central black line which runs through the whole slice like a weld. The black line is obtained solely by coating vegetable carbon on the side of one of the loaves of curds before pressing. With the cheese marked in the centre by this famous black line, its paste is homogeneous in colour from ivory to pale yellow with frequently a number of scattered openings.

The taste is clear with hints of milk, caramel, vanilla and fruit. With ageing, the aromatic range becomes enriched by roasted, spicy and vegetable nuances.

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 dominant share of grass in the dairy cows' feed influences the characteristics of the milk and the organoleptic features of 'Morbier'. Each variation in the floristic composition of the grassland translates into variations in the cheese's aromatic nuances. This effect can easily be verified over the course of the seasons. That is why several production conditions in the specification aim to preserve the natural floristic diversity. These grass resources are preserved by banning genetically modified crops, which could alter the floristic composition or limit its diversity. The richness of the grassland's flora is also preserved by restricting fertiliser inputs.

The shape of the cheese (a medium-sized cylinder) was originally adapted to production on mountain farms. Dual production, corresponding to two milkings, makes it possible to obtain quite a large size, limiting losses during storage. This size will subsequently be taken over by the cheese dairies (cheesemaking cooperatives), thereby enabling cheese production when the level of milk production is low. This link with the making of cooked pressed pastes, and in particular 'Comté', is found in the rind smearing techniques. This type of care contributes, beyond appearance, to the special taste of the cheese.

Using wood for maturing constitutes a direct link with the technological requirements and with the existence nearby of large coniferous forests which are part of the natural environment.

In order to obtain a fine, smooth texture and the expression of fine nuances in the taste of 'Morbier', it is essential to use raw milk with a particular lactic flora. The removal of lactose, while contributing to the texture of 'Morbier', enables the expression of these secondary aromatic nuances.

The central black line was initially obtained by using soot from the cauldron. This technique affirms the link with the production of cooked pressed pastes in Franche-Comté.

**Reference to publication of the specification**

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

https://www.inao.gouv.fr/fichier/CDCMorbier.pdf

# COMMISSION IMPLEMENTING REGULATION (EU) No 1129/2013

## of 7 November 2013

## entering a name in the register of protected designations of origin and protected geographical indications [Fal Oyster (PDO)]

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EU) No 1151/2012 repealed and replaced Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ([2]).

(2) Pursuant to Article 6(2) of Regulation (EC) No 510/2006, the United Kingdom's application to register the name 'Fal Oyster' was published in the *Official Journal of the European Union* ([3]).

(3) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, the name 'Fal Oyster' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name contained in the Annex to this Regulation is hereby entered in the register.

*Article 2*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ L 93, 31.3.2006, p. 12.
([3]) OJ C 384, 13.12.2012, p. 17.

*ANNEX*

Agricultural products intended for human consumption listed in Annex I to the Treaty:

**Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom**

UNITED KINGDOM

Fal Oyster (PDO)

# COMMISSION IMPLEMENTING REGULATION (EU) No 1130/2013

## of 7 November 2013

## entering a name in the register of protected designations of origin and protected geographical indications [Maccheroncini di Campofilone (PGI)]

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Italy's application to register the name 'Maccheroncini di Campofilone' was published in the *Official Journal of the European Union* [2].

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Maccheroncini di Campofilone' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name contained in the Annex to this Regulation is hereby entered in the register.

*Article 2*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 78, 16.3.2013, p. 5.

*ANNEX*

Agricultural products and foodstuffs listed in Annex I(I) to Regulation (EU) No 1151/2012:

**Class 2.7. Pasta**

ITALY

Maccheroncini di Campofilone (PGI)

# COMMISSION IMPLEMENTING REGULATION (EU) No 1131/2013

## of 7 November 2013

## entering a name in the register of protected designations of origin and protected geographical indications (Poperingse hopscheuten/Poperingse hoppescheuten (PGI))

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Belgium's application to register the name 'Poperingse hopscheuten'/'Poperingse hoppescheuten' was published in the *Official Journal of the European Union* [2].

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Poperingse hopscheuten'/'Poperingse hoppescheuten' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name contained in the Annex to this Regulation is hereby entered in the register.

*Article 2*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 57, 27.2.2013, p. 6.

*ANNEX*

Agricultural products intended for human consumption listed in Annex I to the Treaty:

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

BELGIUM

Poperingse hopscheuten/Poperingse hoppescheuten (PGI)

# COMMISSION IMPLEMENTING REGULATION (EU) No 1132/2013

## of 7 November 2013

## approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Stelvio/Stilfser (PDO)]

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected designation of origin 'Stelvio'/'Stilfser' registered under Commission Regulation (EC) No 148/2007 ([2]).

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ([3]) as required by Article 50(2)(a) of that Regulation.

(3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

*Article 1*

The amendments to the specification published in the *Official Journal of the European Union* regarding the name contained in the Annex to this Regulation are hereby approved.

*Article 2*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ L 46, 16.2.2007, p. 14.
([3]) OJ C 77, 15.3.2013, p. 29.

*ANNEX*

Agricultural products intended for human consumption listed in Annex I to the Treaty:

**Class 1.3. Cheeses**

ITALY

Stelvio/Stilfser (PDO)

# COMMISSION IMPLEMENTING REGULATION (EU) No 1133/2013

## of 7 November 2013

## approving minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (Kaki Ribera del Xúquer (AOP))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular the second subparagraph of Article 53(2) thereof,

Whereas:

(1) In accordance with the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Spain's application for the approval of amendments to the specification for the protected designation of origin 'Kaki Ribera del Xúquer' registered under Commission Regulation (EC) No 245/2002 [2].

(2) The purpose of this application is to amend the specification in order to clarify the description of the product by including maximum tolerance limits for any slight skin imperfections that the product may have.

(3) The Commission has examined the amendments in question and decided that they are justified. Since the amendments are minor within the meaning of the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012, the Commission may approve them without following the procedure set out in Articles 50 to 52 of that Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The specification for the protected designation of origin 'Kaki Ribera del Xúquer' is hereby amended in accordance with Annex I to this Regulation.

*Article 2*

Annex II to this Regulation contains the consolidated Single Document setting out the main points of the specification.

*Article 3*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 39, 9.2.2002, p. 12.

*ANNEX I*

In the specification for the protected designation of origin 'Kaki Ribera del Xúquer', the following amendments are approved:

The part of the product description that refers to the imperfections that may be present in the product reads as follows:

'The flesh of the fruit must not be damaged, although slight imperfections of the skin that do not affect the general condition of the product, its quality, preservation and presentation in the packaging are allowed within the following limits:

— a maximum of 1 $cm^2$ of the total surface for elongated or rectangular imperfections. The maximum authorised tolerance is 2 $cm^2$ and must never exceed 20 % of the fruit. In both cases, the different limits are laid down in the quality standards of the Regulatory Board according to the type of imperfection.

— an area corresponding to a circle with a maximum diameter of 1,5 cm for roundish imperfections. The maximum authorised tolerance is 2,5 $cm^2$ and must never exceed 20 % of the fruit. In both cases, the different limits are laid down in the quality standards of the Regulatory Board according to the type of imperfection.'

*ANNEX II*

**CONSOLIDATED SINGLE DOCUMENT**

Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1]

**'KAKI RIBERA DEL XÚQUER'**

EC No: ES-PDO-0105-0114 - 1.4.2011

**PGI ( ) PDO (X)**

1. **Name**

'Kaki Ribera del Xúquer'

2. **Member State or third country**

Spain

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 the product to which the name in (1) applies*

Fruit of the persimmon tree (*Diospyros kaki*) of the 'Rojo Brillante' variety, to be consumed fresh. The fruit is a berry that is normally formed through parthenocarpy; as there is no pollination, the fruit is seedless.

Fruit characteristics: orangey-yellow in colour when picked and deep red when ripe. Semi-adhesive skin of medium thickness. The flesh is firm to the touch, orangey-red when picked and deep red when ripe. The fruit is bitter until ripe, when it acquires a sweet flavour. Its cross-section is round and its longitudinal section is slightly elongated.

On dispatch, the persimmons must be presented:

— whole,

— with the calyx and the peduncle attached,

— healthy (fruit whose flesh is damaged or rotten are excluded),

— clean, practically free from any visible foreign matter,

— free of abnormal external moisture,

— free of any foreign smell and/or taste.

Fruit eligible for the designation of origin must have a minimum diameter of 61 mm.

The flesh of the fruit must not be damaged, although slight aesthetic imperfections of the skin that do not affect the general condition of the product, its quality, preservation and presentation in the packaging may be allowed within the following limits:

— a maximum of 1 $cm^2$ of the total surface for elongated or rectangular aesthetic imperfections (that do not affect the flesh of the fruit). The maximum authorised tolerance is 2 $cm^2$ and must never exceed 20 % of the fruit. In both cases, the different limits are laid down in the quality standards for the protected designation of origin 'Kaki Ribera del Xúquer' according to the type of imperfection.

— An area corresponding to a circle with a maximum diameter of 1,5 cm for roundish aesthetic imperfections (that do not affect the flesh of the fruit). The maximum authorised tolerance is 2,5 $cm^2$ and must never exceed 20 % of the fruit. In both cases, the different limits are laid down in the quality standards for the designation of origin 'Kaki Ribera del Xúquer' according to the type of imperfection.

[1] OJ L 93, 31.3.2006, p. 12. Replaced by Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

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

—

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

—

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

All the steps in production must take place in the defined geographical area.

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

—

3.7. *Specific rules concerning labelling*

Each operator's commercial labels may be examined by the inspection body to check that the nomenclature and logos of the protected designation of origin are being used correctly. The labels must bear the words 'denominación de origen protegida "Kaki Ribera del Xúquer" '.

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

The production area comprises suitable land in the following municipalities: Albalat de la Ribera, Alberic, Alcàntera de Xúquer, L'Alcúdia, Alfarp, Algemesí, Alginet, Almussafes, Alzira, Antella, Beneixida, Benicull de Xúquer, Benifaió, Benimodo, Benimuslem, Carcaixent, Cárcer, Carlet, Catadau, Corbera, Cullera, Lènova, Favara, Fortaleny, Gavarda, Guadassuar, Llaurí, Llombai, Manuel, Masalavés, Monserrat, Montroy, La Pobla Llarga, Polinyà de Xúquer, Rafelguaraf, Real de Montroi, Riola, San Juan de Énova, Sellent, Senyera, Sollana, Sueca, Sumacàrcer, Tous, Turís and Villanueva de Castellón, all of which belong to the Province of Valencia, in the Community of Valencia.

In this area, around 1 300 ha are used for growing persimmons.

5. **Link with the geographical area**

5.1. *Specificity of the geographical area*

History

The persimmon tree is a fruit tree belonging to the Ebenaceae family. It originated in China, where its cultivation began in the 8th century. The cultivation of persimmons was introduced in Western Europe in the second half of the 19th century and in Spain in the 1870s. Today Spain's national production takes place principally in the Community of Valencia, where the area protected by the designation of origin 'Kaki Ribera del Xúquer' is located. Half of all production is concentrated in this area.

The 'Rojo Brillante' persimmon emerged by chance after seeds were sowed on the edge of a plot in the municipality of Carlet. Later, around 1960, the first homogeneous plantation was grafted in the municipality of Alcudia. This paved the way for the rapid development of the variety in the region.

Natural

Ribera del Xúquer is a natural region in the Province of Valencia. It is surrounded by a large quaternary valley or alluvial plain through which the Júcar River (*Xúquer* in Valencian) and its tributary, the Magro, flow.

Much of the agricultural land is situated on the low plain on the banks of the Júcar and Magro, where the soils are very rich and compact owing to the build-up of alluvial deposits from the Júcar and its tributaries that flow down from the upland regions. Moreover, in the lower part of the valley slopes, where the incline is gentle, there are colluvial soils, pink in colour and loose, which particularly lend themselves to intensive cultivation.

The municipality enjoys a mild climate. The average annual temperature is 17 °C, with temperatures averaging 9-10 °C in January and 24-25 °C in August. Cloudy conditions are infrequent, and the average annual rainfall hardly exceeds 400 to 500 mm. In addition, the surrounding hills protect the crops from frost, especially in the tributary valleys.

5.2. *Specificity of the product*

The 'Rojo Brillante' is a native variety of the area. It is the result of the spontaneous mutation of another local variety and is therefore perfectly adapted to the region of Ribera del Xúquer, where full advantage is taken of the crop.

Persimmons grown in the protected area have a greater height/diameter ratio and a more pointed shape. The 'Kaki Ribera del Xúquer' is distinguished by its pointed shape, which is slightly more elongated than normal. The height/diameter ratio is thus greater and this gives fruit obtained in the protected area a characteristic shape. In addition, they are larger on average than in other production areas owing to the mild climate and the absence of extreme temperatures.

The 'Kaki Ribera del Xúquer' also has a characteristic deep red colour and a sweet flavour at maturity, which is reached at an earlier stage thanks to the prevailing conditions in the area. The fruit may also be harvested before it is ripe. The method used to remove the bitterness makes it possible to market the fruit when its flesh is firm and very sweet and has acquired the typical taste of persimmons produced in the Ribera del Xúquer region.

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)*

It is said that the Ribera del Xúquer region is the cradle of the 'Rojo Brillante' persimmon, as that is where this variety emerged as a result of a spontaneous mutation. Nowadays it is well established in the region and on the market.

The particular climatic and soil conditions in the defined geographical area are reflected in the persimmon's characteristics.

The mild climate owing to the proximity of the Mediterranean Sea and the colluvial agricultural land resulting from the Júcar and Magro watercourses surrounding the region combine to endow the 'Kaki Ribera del Xúquer' with its principal distinctive characteristics, i.e. a more pronounced pointed shape leading to a greater height/diameter ratio as well as a larger size and a distinctive colouring when ripe.

**Reference to publication of the specification**

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

http://www.agricultura.gva.es/documents/170659/179611/030712+Pliego+de+condiciones+kaki+def.pdf/b354d4a8-425e-40fa-8e8b-0ae6d3588fe6

# COMMISSION IMPLEMENTING REGULATION (EU) No 1134/2013

## of 7 November 2013

## approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Caballa de Andalucía (PGI)]

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EU) No 1151/2012 repealed and replaced Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ([2]).

(2) Pursuant to the first subparagraph of Article 9(1) of Regulation (EC) No 510/2006, the Commission has examined Spain's application for the approval of amendments to the specification for the protected geographical indication 'Caballa de Andalucía' registered under Commission Regulation (EC) No 289/2009 ([3]).

(3) Since the amendments in question are not minor, the Commission published the amendment application in the *Official Journal of the European Union* ([4]), as required by Article 6(2) of Regulation (EC) No 510/2006. As no statement of objection under Article 7 of that Regulation has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

*Article 1*

The amendments to the specification published in the *Official Journal of the European Union* regarding the name contained in the Annex to this Regulation are hereby approved.

*Article 2*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ L 93, 31.3.2006, p. 12.
([3]) OJ L 94, 8.4.2009, p. 15.
([4]) OJ C 387, 15.12.2012, p. 22.

*ANNEX*

Agricultural products intended for human consumption listed in Annex I to the Treaty:

**Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom**

SPAIN

Caballa de Andalucía (PGI)

# COMMISSION IMPLEMENTING REGULATION (EU) No 1135/2013

## of 7 November 2013

## approving minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (Prosciutto Toscano (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular the second subparagraph of Article 53(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected designation of origin 'Prosciutto Toscano' registered under Commission Regulation (EC) No 1263/96 [2], as amended by Regulation (EU) No 777/2010 [3].

(2) The purpose of the application is to amend the specification by making clear that the use of additives or preservatives in the production of 'Prosciutto Toscano' is no longer authorised.

(3) The Commission has examined the amendments in question and decided that they are justified. Since the amendments are minor within the meaning of the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012, the Commission may approve them without following the procedure set out in Articles 50 to 52 of that Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The specification for the protected designation of origin 'Prosciutto Toscano' is hereby amended in accordance with Annex I to this Regulation.

*Article 2*

Annex II to this Regulation contains the consolidated Single Document setting out the main points of the specification.

*Article 3*

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

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

Done at Brussels, 7 November 2013.

*For the Commission,*
*On behalf of the President,*
Dacian CIOLOȘ
*Member of the Commission*

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 163, 2.7.1996, p. 19.
[3] OJ L 233, 3.9.2010, p. 11.

*ANNEX I*

In the specification for the protected designation of origin 'Prosciutto Toscano' the following amendments are approved:

The use of additives or preservatives in the production of 'Prosciutto Toscano' is no longer authorised. The processing of 'Prosciutto Toscano' in accordance with the typical method guarantees the absence of that type of substance. In particular, the ban on using nitrites and nitrates strengthens the link with the historical method of producing 'Prosciutto Toscano' and rules out the presence of additives and preservatives (E251 - E252) in the end product.

*ANNEX II*

*Consolidated single document*

Council Regulation (EC) No 510/2006 of 20 March 2006 on protected geographical indications and protected designations of origin for agricultural products and foodstuffs ([1])

**'PROSCIUTTO TOSCANO'**

EC No: IT-PDO-0317-01009-2.7.2012

**PGI ( ) PDO (X)**

1. **Name**

'Prosciutto Toscano'

2. **Member State or third country**

Italy

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

3.1. *Type of product*

Class 1.2. Meat products (cooked, salted, smoked, etc.)

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

When released for consumption, 'Prosciutto Toscano' has the following physical, organoleptic, chemical and physico-chemical characteristics: the top is rounded owing to the presence of a ridge of meat which extrudes no more than 8 cm beyond the end of the femur; the weight is about 8-9 kg but never less than 7,5 kg; when sliced open, the product reveals pale red to bright red meat with little fat infiltration in the muscle tissue; pure white subcutaneous fat with slight pink streaks, compact, with no lines separating the layers and firmly attached to the surface of the muscle. 'Prosciutto Toscano' may be released for consumption within a maximum period of 30 months after the start of processing the fresh legs. 'Prosciutto Toscano' may also be marketed boned, in portions, i.e. cut up into pieces of varying shape and weight, or in slices.

'Prosciutto Toscano' has a delicate taste, typically savoury, with a characteristic fragrant aroma as a result of the traditional methods of processing and ageing.

The physico-chemical characteristics are as follows:

| | | |
|---|---|---|
| Salt (expressed as NaCl) | % | max. 8,3 |
| Muscle moisture content | % | max. 61,0 |
| Protein breakdown index | % | max. 30,0 |

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

The fresh legs used to produce 'Prosciutto Toscano' come from pigs born, reared and slaughtered within the area defined under point 4 of this document. The pigs must weigh at least 160 kg, plus or minus 10 %, and be at least nine months old. 'Prosciutto Toscano' is produced from the fresh legs of heavy pure-bred pigs or those derived from the basic traditional breeds Large White or Landrace. A fresh trimmed leg must not weigh less than 11,8 kg.

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

The types of feed used come mainly from the defined area corresponding to that for rearing the pigs as specified under point 4 of this Single Document, given that they are subject to management based on a sector-specific integrated system.

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

The specific stages in the production of 'Prosciutto Toscano' - salting, drying, coating with fat and ageing — must take place in the traditional production area, which includes the entire territory of the Tuscany region.

([1]) OJ L 93, 31.3.2006, p. 12. Replaced by Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

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

All the product types — boned, cut up into pieces or sliced — and marked beforehand, must be marketed after packaging in suitable and correctly sealed food containers or packs. Slicing and packaging of 'Prosciutto Toscano' must be carried out at the end of the ageing process and in the production area referred to under point 4, in order to ensure that the different ageing periods for the sliced product are complied with and that the characteristics relating to the moisture content and appearance of the muscular and fatty parts of the slice, as described in point 3.2, are preserved. Allowing the legs which are to be sliced or cut up into boned pieces to be kept for unspecified periods in environments which differ from those specified could result in the development of characteristics inconsistent with those for which 'Prosciutto Toscano' is known, such as the formation of abnormal mould, abnormal protein degradation with a resulting change in the protein breakdown index, or even rancidity of the fat, which may give rise to aromas and flavours which differ from those traditionally appreciated by consumers. In addition, exposure of the pieces and slices of meat to the air before packaging may result in high oxidation of the edible surfaces, turning the meat brown and drying out the surface of the exposed muscle tissue, or in limp meat in the case of excess moisture.

3.7. *Specific rules concerning labelling*

The protected designation of origin 'Prosciutto Toscano' must be included on the label in clear and indelible characters, distinctly separate from any other writing. It must be followed immediately by the words 'Denominazione di origine protetta' or the abbreviation 'DOP'. Nothing which is not expressly permitted may be added. It is nevertheless permitted to add information referring to names, trade names or private marks, except where these are laudatory in character or likely to mislead the buyer. Similarly, the name of the farm where the pigs were reared which supplied the products may be shown on the leg, provided that the raw material comes entirely from the livestock in question.

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

Farms rearing pigs intended for the production of 'Prosciutto Toscano' must be located on the territory of the following regions: Lombardy, Emilia-Romagna, Marche, Umbria, Lazio and Tuscany. 'Prosciutto Toscano' is processed, sliced and packed in the traditional production area, which includes the entire territory of the Tuscany region.

5. **Link with the geographical area**

5.1. *Specificity of the geographical area*

The environmental factors are closely linked to the features of the production area, predominantly comprising valleys which are cool and abundant in water and wooded hills, all of which have a decisive influence on the climate and on the characteristics of the finished product. The localised production of 'Prosciutto Toscano' is justified by the conditions of the defined microzone: he landscape and geographical features of the Tuscany region make it ideal for the production of high-quality hams. Even the climate, which is very different from that of neighbouring regions, is particularly suitable for optimum ageing of the product. It is therefore a climate which is ideal for establishing a beneficial link between the environment and typical regional products, enabling slow and healthy ageing of products such as wine, olive oil, cheese and, of course, ham. In that environment human activity has made it possible to perfect specific processing techniques for trimming or salting which are better suited to the environmental features and which have been preserved up to the present day to influence decisively the characteristics of 'Prosciutto Toscano' referred to under point 3.2.

5.2. *Specificity of the product*

'Prosciutto Toscano' stands out because of its characteristic sweet-smelling aroma, delicate taste and typical flavour.

'Prosciutto Toscano' is a raw ham whose ageing period, from salting to marketing, must not be less than 10 months for hams with a final weight of between 7,5 and 8,5 kg, and 12 months for hams weighing more than 8,5 kg. 'Prosciutto Toscano' intended for slicing must be aged for two months longer than the periods stipulated above, i.e. for at least 12 months in the case of hams weighing between 7,5 and 8,5 kg, and for at least 14 months in the case of hams weighing more than 8,5 kg.

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 climate of the production area makes it possible to obtain agri-food products of very high value while favouring and characterising the ageing and refining processes for 'Prosciutto Toscano'. History has demonstrated the deep, close link between agricultural production, the processing of the product and the reference areas, a link which has been consolidated and confirmed by the development of social, economic and production factors and of human experience which has been strengthened over the centuries. As regards the defined area from which the raw material comes, the factors linked to geography, the environment and experience gained in production in the livestock-rearing sector are extremely constant and characteristic. In the area which supplies the raw material, the development of animal husbandry is linked to the widespread cultivation of cereal crops and to processing systems which have caused production to focus particularly on rearing pigs.

As regards the more limited processing area, the combination of environmental, climatic, natural and human factors forms a unique whole which has made it possible to formalise the traditional processing method by laying down the techniques specific to obtaining the characteristics of the PDO 'Prosciutto Toscano'. The characteristic aroma and taste derive from the specific processing techniques which have been regulated since the 15th century and which provide in particular for: special trimming in an arc which is characterised by a V-shaped cut from the start of the foot and enables drying of the meat which is more effective and more spread out over the course of salting; dry salting using salt, pepper and natural seasoning of plant origin; coating with fat, always with pepper and natural seasoning of plant origin and, lastly, ageing, which benefits from the environmental conditions in the production area. The long ageing, which exposes the legs to natural moisture, combined with the use, according to local customs, of pepper and flavourings during the salting and fat-coating stages, determine the sweet-smelling aroma, delicate taste and typical flavour of 'Prosciutto Toscano'.

**Reference to publication of the specification**

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

The text of the amended product specification may be consulted at:

http://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/3335

or by going directly to the home page of the Ministry of Agricultural, Food and Forestry Policy (http://www.politicheagricole.it) and clicking on 'Qualità e sicurezza' (at the top right of the screen) and then on 'Disciplinari di Produzione all'esame dell'UE'.

# COMMISSION IMPLEMENTING REGULATION (EU) No 1136/2013

## of 12 November 2013

## amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clothianidin, dimoxystrobin, oxamyl and pethoxamid

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [1], and in particular the first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 [2] sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) The approvals of the active substances clothianidin, dimoxystrobin, oxamyl and pethoxamid will expire between 31 July and 30 September 2016. Applications have been submitted for the renewal of the approval of these active substances. As the requirements laid down in Commission Implementing Regulation (EU) No 844/2012 [3] apply to those active substances, it is necessary to allow applicants sufficient time to complete the renewal procedure in accordance with that Regulation. Consequently, the approvals of those active substances are likely to expire before a decision has been taken on their renewal. It is therefore necessary to extend their approval periods.

(3) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(4) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where no supplementary dossier in accordance with Implementing Regulation (EU) No 844/2012 is submitted no later than 30 months before the respective expiry date laid down in the Annex to this Regulation, the Commission will set the expiry date at the same date as before this Regulation or at the earliest date thereafter.

(5) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

[1] OJ L 309, 24.11.2009, p. 1.

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

[3] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

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

Done at Brussels, 12 November 2013.

*For the Commission*
*The President*
José Manuel BARROSO

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*ANNEX*

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 116, oxamyl, the date 31 July 2016 is replaced by 31 January 2018;

(2) in the sixth column, expiration of approval, of row 121, clothianidin, the date 31 July 2016 is replaced by 31 January 2018;

(3) in the sixth column, expiration of approval, of row 122, pethoxamid, the date 31 July 2016 is replaced by 31 January 2018;

(4) in the sixth column, expiration of approval, of row 128, dimoxystrobin, the date 30 September 2016 is replaced by 31 January 2018.

# COMMISSION IMPLEMENTING REGULATION (EU) No 1137/2013

## of 12 November 2013

## establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors [2], and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

*Article 1*

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 12 November 2013.

*For the Commission,*
*On behalf of the President,*
Jerzy PLEWA
*Director-General for Agriculture and Rural Development*

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 157, 15.6.2011, p. 1.

*ANNEX*

**Standard import values for determining the entry price of certain fruit and vegetables**

*(EUR/100 kg)*

| CN code | Third country code (1) | Standard import value |
|---|---|---|
| 0702 00 00 | AL | 51,8 |
| | MA | 61,9 |
| | MK | 28,7 |
| | ZZ | 47,5 |
| 0707 00 05 | AL | 45,1 |
| | MK | 50,7 |
| | TR | 136,4 |
| | ZZ | 77,4 |
| 0709 93 10 | AL | 48,7 |
| | MA | 121,9 |
| | TR | 158,8 |
| | ZZ | 109,8 |
| 0805 20 10 | AU | 136,9 |
| | MA | 62,6 |
| | ZA | 148,2 |
| | ZZ | 115,9 |
| 0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90 | PE | 125,0 |
| | SZ | 56,1 |
| | TR | 74,2 |
| | UY | 92,8 |
| | ZA | 157,1 |
| | ZZ | 101,0 |
| 0805 50 10 | TR | 65,7 |
| | ZA | 74,0 |
| | ZZ | 69,9 |
| 0806 10 10 | BR | 248,2 |
| | LB | 239,8 |
| | PE | 322,3 |
| | TR | 166,2 |
| | US | 305,1 |
| | ZZ | 256,3 |
| 0808 10 80 | BA | 64,2 |
| | NZ | 132,4 |
| | US | 146,2 |
| | ZA | 164,6 |
| | ZZ | 126,9 |
| 0808 30 90 | CN | 65,8 |
| | TR | 131,0 |
| | ZZ | 98,4 |

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

# DECISIONS

## COMMISSION IMPLEMENTING DECISION

**of 6 November 2013**

**authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

*(notified under document C(2013) 4719)*

**(Only the Dutch, English and French texts are authentic)**

**(Text with EEA relevance)**

(2013/648/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1], and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 29 January 2009, Dow AgroSciences Ltd on behalf of Dow AgroSciences LLC and Monsanto Europe S.A. on behalf of Monsanto Company submitted to the competent authority of the Netherlands an application, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from MON89034 × 1507 × NK603 maize ('the application'). The application also covered all possible combinations of the single GM events.

(2) The application also covers the placing on the market of products other than food and feed containing or consistent of MON89034 × 1507 × NK603 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, it includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2] and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) GM crop plants which contain two or more different single GM events are called GM stacks. The harvest from maize GM stacks has specific features due to the reproductive biology of maize. When for example seeds of a maize GM stack with three different single GM events are cultivated, the resulting harvest contains not just grains with all three different GM events, but also grains containing only one or two different single GM events, and grains that do not contain any of the three single GM events (negative segregants). An authorisation of a maize GM stack should therefore cover all possible combinations of its single GM events, with the exception of those already authorised.

(4) Each of the GM maizes with a single GM event, and each of the combinations of the single GM events are to be considered as being a specific GMO in the meaning of Article 3(1) and Article 15(1) of Regulation (EC) No 1829/2003. According to Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003, no GMO for food use or food referred in Article 3(1) or for feed use or feed referred in Article 15(1) can be placed on the market unless it is covered by an authorisation granted in accordance with the Regulation. It should therefore be ensured that all possible combinations of the single GM events constituting it are authorised when the GM stack is authorised.

[1] OJ L 268, 18.10.2003, p. 1.

[2] OJ L 106, 17.4.2001, p. 1.

(5) A prerequisite for the risk assessment of a GM stack is the risk assessment of the single GM events constituting it. The three single events that constitute MON89034 × 1507 × NK603 maize have already been authorised ([1]).

(6) On 27 September 2010, the European Food Safety Authority (EFSA) published a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003. This opinion covers MON89034 × 1507 × NK603 maize and only the combinations of the individual GM events as present in its segregating progeny. EFSA considers that (i) MON89034 × 1507 × NK603 maize is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment, and (ii) there is no biological reason to expect that any of the sub-combinations originating from this GM stack in its segregating progeny would raise a safety concern in the context of its intended uses ([2]).

(7) On 10 November 2011, EFSA, on the request of the Commission, adopted a statement complementing its previous opinion on MON89034 × 1507 × NK603 maize to cover all sub-combinations independently of their origin ([3]). The EFSA GMO panel considered it unlikely that the sub-combinations of MON89034 × 1507 × NK603 maize have an adverse effect on human and animal health and the environment, in the context of its intended uses covered by this decision.

(8) In its opinions, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of that Regulation.

(9) EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicants is in line with the intended use of the products.

(10) The GM stacks MON89034 × 1507 maize, MON89034 × NK603 maize and 1507 × NK603 maize combine two specific single GM events constituting MON89034 × 1507 × NK603 maize. These GM stacks have already been authorised ([4]). By letter of 13 March 2013 the applicants clarified that the application no longer covers these GM maizes.

(11) Taking into account those considerations, authorisation should be granted.

(12) A unique identifier should be assigned to each GMO as provided for in Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms ([5]).

(13) On the basis of the EFSA opinions, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MON89034 × 1507 × NK603 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of MON89034 × 1507 × NK603 maize and products other than food and feed containing or consisting of MON89034 × 1507 × NK603 maize for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

([1]) Commission Decision 2009/813/EC of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 289, 5.11.2009, p. 21); Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea Mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium (OJ L 291, 5.11.2005, p. 42); Commission Decision 2006/197/EC of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) and renewing the authorisation to place on the market feed produced from such maize, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 70, 9.3.2006, p. 82); Commission Decision 2011/365/EU of 17 June 2011 amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 163, 23.6.2011, p. 52); Commission Decision 2004/643/EC of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L. line NK603) genetically modified for glyphosate tolerance (OJ L 295, 18.9.2004, p. 35); Commission Decision 2005/448/EC of 3 March 2005 authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 the European Parliament and of the Council (OJ L 158, 21.6.2005, p. 20).

([2]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00413

([3]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00169

([4]) Commission Implementing Decision 2013/650/EU (see page 47 of this Official Journal); Commission Decision 2010/420/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × NK603 (MON-89Ø34-3 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 197, 29.7.2010, p. 15); Commission Decision 2007/703/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 47).

([5]) OJ L 10, 16.1.2004, p. 5.

(14) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1], lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraph (1) to (5) of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(15) The authorisation holders should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council [2].

(16) The EFSA opinions do not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(17) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(18) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms [3].

(19) This Decision grants authorisation for placing on the market of the products within the scope of the application. This Decision, however, does not cover the single GM events and the combinations of the single GM events authorised by Decisions 2009/813/EC, 2005/772/EC, 2006/197/EC, 2011/365/EU, 2004/643/EC, 2005/448/EC, 2010/420/EU, 2007/703/EC and Implementing Decision 2013/650/EU. Operators should therefore pay attention to the fact that, in accordance with Articles 4(2) and/or 16(2) of Regulation (EC) No 1829/2003, all the GMOs (single GM events and the combinations of the single GM events) composing the harvest of MON89034 × 1507 × NK603 need to be authorised in order to place the harvest on the market. In the case where the authorisation of one of the GMOs composing the harvest of MON89034 × 1507 × NK603 expires without application for renewal or the authorisation is suspended or revoked, the products of this harvest cannot be placed on the market.

(20) The applicants have been consulted on the measures provided for in this Decision.

(21) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified maize (*Zea mays* L.) MON89034 × 1507 × NK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;

(b) feed containing, consisting of, or produced from MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;

(c) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 275, 21.10.2009, p. 9.
[3] OJ L 287, 5.11.2003, p. 1.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holders shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holders**

1. The authorisation holders shall be:

(a) Dow AgroSciences Ltd, United Kingdom, representing DowAgroSciences LLC, United States; and

(b) Monsanto Europe S.A., Belgium, representing Monsanto Company, United States.

2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressees**

This Decision is addressed to:

(a) Dow AgroSciences Ltd, European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom; and

(b) Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 6 November 2013.

*For the Commission*

Tonio BORG

*Member of the Commission*

*ANNEX*

(a) **Applicants and Authorisation holders**

Name: Dow AgroSciences Ltd

Address: European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom

on behalf of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States;

and

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels, Belgium

on behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.

(b) **Designation and specification of the products**

(1) foods and food ingredients containing, consisting of, or produced from MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;

(2) feed containing, consisting of, or produced from MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;

(3) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize in products containing it or consisting of it for any other use than (1) and (2), with the exception of cultivation.

The genetically modified MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize, as described in the application, is produced by crosses between maize containing MON-89Ø34-3, DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 events and expresses the Cry1A.105, Cry2Ab2, Cry1F proteins which confer protection against certain lepidopteran pests, the CP4 EPSPS protein which confers tolerance to herbicide glyphosate and the PAT protein which confers tolerance to the herbicide glufosinate-ammonium.

(c) **Labelling**

(1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize, with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— Event specific real-time quantitative PCR based methods for quantitative detection of genetically modified MON-89Ø34-3, DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 maize validated on the single-trait events and verified on MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;

— DNA extraction method validated on ground maize seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

— Reference Material: ERM®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF415 (for MON-ØØ6Ø3-6) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at https://irmm.jrc.ec.europa.eu/rmcatalogue and AOCS 0906-E and AOCS 0406-A (for MON-89Ø34-3) accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

*Note*: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION

## of 6 November 2013

## authorising the placing on the market of pollen produced from maize MON 810 (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2013) 4743)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

(2013/649/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1], and in particular Article 7(3) thereof,

Whereas:

(1) On 12 March 2012, Monsanto Europe S.A submitted to the competent authority of The Netherlands an application, in accordance with Article 5 of Regulation (EC) No 1829/2003, for the placing on the market of pollen produced from maize MON 810, as or in foods and food ingredients ('the application').

(2) On 19 December 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Article 6 of Regulation (EC) No 1829/2003. It concluded that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen were to replace pollen from non-GM maize in or as food.

(3) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities.

(4) Taking into account those considerations, authorisation should be granted to pollen produced from maize MON 810, as or in foods and food ingredients.

(5) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms [2].

(6) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) of Regulation (EC) No 1829/2003, appear to be necessary for foods and food ingredients produced from maize MON 810 pollen.

(7) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [3], lays down in Article 5 traceability requirements for products for foods produced from GMOs. All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(8) The applicant has been consulted on the measures provided for in this Decision.

(9) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified maize (*Zea mays* L.) MON 810, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ81Ø-6, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

Pollen produced from maize MON 810, as or in foods and food ingredients, is authorised for the purposes of Article 4(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision.

[1] OJ L 268, 18.10.2003, p. 1.
[2] OJ L 10, 16.1.2004, p. 5.
[3] OJ L 268, 18.10.2003, p. 24.

*Article 3*

**Labelling**

For the purposes of the labelling requirements laid down in Article 13(1) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'maize'.

*Article 4*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 5*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States.

*Article 6*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 7*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 6 November 2013.

*For the Commission*

Tonio BORG

*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels, Belgium

On behalf of Monsanto Company, United States.

(b) **Designation and specification of the products**

Pollen produced from MON-ØØ81Ø-6 maize, as or in foods and food ingredients.

The genetically modified MON-ØØ81Ø-6 maize, as described in the application, expresses the Cry1Ab protein which confers protection against certain lepidopteran pests.

(c) **Labelling**

For the purposes of the specific labelling requirements laid down in Article 13(1) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'maize'.

(d) **Method for detection**

— Event specific real-time PCR based method for the quantification of MON-ØØ81Ø-6 maize.

— Validated on ground maize seeds (certified reference materials [CRM IRMM-413]), containing mixtures of genetically modified MON 810 and conventional maize, by the Federal Institute for Risk Assessment (BfR) in collaboration with the American Association of Cereal Chemists (AACC), Joint Research Centre (JRC) of the European Commission (EC) (Institute for Reference Material and Measurement (IRMM), Institute for Health and Consumer Protection (IHCP)), and GeneScan, Berlin, published at

http://gmo-crl.jrc.ec.europa.eu/summaries/Mon810_validation_report.pdf

Reference Material: ERM-BF413k accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at

http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

(e) **Unique identifier**

MON-ØØ81Ø-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Not required.

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Not required.

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

*Note*: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION

## of 6 November 2013

**authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3), MON89034 × 1507 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89Ø34-3 × DAS-Ø15Ø7-1), MON89034 × 59122 (MON-89Ø34-3 × DAS-59122-7), 1507 × MON88017 (DAS-Ø15Ø7-1 × MON-88Ø17-3), MON 88017 × 59122 (MON-88Ø17-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

*(notified under document C(2013) 4755)*

**(Only the Dutch, English and French texts are authentic)**

**(Text with EEA relevance)**

(2013/650/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1], and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 24 October 2008, Dow AgroSciences Ltd on behalf of Dow AgroSciences LLC and Monsanto Europe S.A. on behalf of Monsanto Company submitted to the competent authority of the Czech Republic an application, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON89034 × 1507 × MON88017 × 59122 maize ('the application'). The application also covers all possible combinations of the single GM events constituting MON89034 × 1507 × MON88017 × 59122 maize.

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of these GM maizes for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, it includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2] and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) GM crop plants which contain two or more different single GM events are called GM stacks. The harvest from maize GM stacks has specific features due to the reproductive biology of maize. When for example seeds of a maize GM stack with four different single GM events are cultivated, the resulting harvest contains not just grains with all four different GM events, but also grains containing only one, two or three different single GM events, and grains that do not contain any of the four single GM events (negative segregants).

(4) Each of the GM maizes with a single GM event, and each of the combinations of the single GM events, are to be considered as being a specific GMO in the meaning of Article 3(1) and Article 15(1) of Regulation (EC) No 1829/2003. According to Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003, no GMO for food use or food referred in Article 3(1) or for feed use or feed referred in Article 15(1) can be placed on the market unless it is covered by an authorisation granted in accordance with the Regulation. It should therefore be ensured that all possible combinations of the single GM events constituting it are authorised when the GM stack is authorised.

(5) A prerequisite for the risk assessment of a GM stack is the risk assessment of the single GM events constituting

[1] OJ L 268, 18.10.2003, p. 1.

[2] OJ L 106, 17.4.2001, p. 1.

it. The four single GM events that constitute MON89034 × 1507 × MON88017 × 59122 maize have already been authorised ([1]).

(6) On 27 September 2010, the European Food Safety Authority (EFSA) published a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ([2]). This opinion covers MON89034 × 1507 × MON88017 × 59122 maize and only the combinations of the individual GM events as present in its segregating progeny. EFSA considered that (i) MON89034 × 1507 × MON88017 × 59122 maize is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment, and (ii) there is no biological reason to expect that any of the sub-combinations originating from this GM stack in its segregating progeny would raise a safety concern in the context of its intended uses.

(7) On 10 November 2011, following a request of the Commission, EFSA complemented its previous opinion to cover all combinations of the single GM events independently of their origin. The EFSA GMO panel considered it unlikely that any combination of the single maize GM events MON89034, 1507, MON88017 and 59122 have an adverse effect on human and animal health and the environment, in the context of their intended uses ([3]).

(8) In its opinions, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of that Regulation.

(9) EFSA also concluded that the environmental monitoring plan submitted by the applicants, consisting of a general surveillance plan, is in line with the intended uses covered by this decision.

(10) The GM stacks MON89034 × MON88017 maize and 1507 × 59122 maize combine two specific single GM events constituting MON89034 × 1507 × MON88017 × 59122 maize. These GM stacks have already been authorised ([4]). By letter of 13 March 2013, the applicants clarified that the application no longer covers these GM maizes.

(11) Taking into account those considerations, authorisation should be granted.

(12) A unique identifier should be assigned to each GMO as provided for in Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms ([5]).

(13) On the basis of the EFSA opinions, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MON89034 × 1507 × MON88017 × 59122 maize, including all possible combinations of the single GM events. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMOs and products other than food and feed containing or consisting of the GMOs for which authorisation is requested, should be complemented by a clear indication that the products in question must not be used for cultivation.

([1]) Commission Decision 2009/813/EC of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 289, 5.11.2009, p. 21); Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea Mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium (OJ L 291, 5.11.2005, p. 42); Commission Decision 2006/197/EC of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) and renewing the authorisation to place on the market feed produced from such maize, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 70, 9.3.2006, p. 82); Commission Decision 2011/365/EU of 17 June 2011 amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 163, 23.6.2011, p. 52); Commission Decision 2009/814/EC of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 289, 5.11.2009, p. 25); Commission Decision 2007/702/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 42).

([2]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2008-764

([3]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-01132

([4]) Commission Decision 2011/366/EU of 17 June 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 × MON 88017 (MON-89Ø34-3 × MON-88Ø17-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 163, 23.6.2011, p. 55); Commission Decision 2010/432/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 (DAS-Ø15Ø7-1 × DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 202, 4.8.2010, p. 11).

([5]) OJ L 10, 16.1.2004, p. 5.

(14) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1], lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraph (1) to (5) of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(15) The authorisation holders should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council [2].

(16) The EFSA opinions do not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(17) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(18) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms [3].

(19) This Decision grants authorisation for placing on the market of the products within the scope of the application. This Decision, however, does not cover the single GM events and those combinations of the single GM events which are already authorised by Decisions 2005/772/EC, 2006/197/EC, 2007/702/EC, 2009/813/EC, 2009/814/EC, 2010/432/EU, 2011/365/EU and 2011/366/EU. Operators should therefore pay attention to the fact that, in accordance with Articles 4(2) and/or 16(2) of Regulation (EC) No 1829/2003, all the GMOs (single GM events and the combinations of the single GM events) composing the harvest of MON89034 × 1507 × MON88017 × 59122 maize or the harvest of one of the other GM stacks covered by this Decision need to be authorised in order to be placed on the market. In the case where the authorisation of one of the GMOs composing the harvest of MON89034 × 1507 × MON88017 × 59122 maize or the harvest of one of the other GM stacks covered by this Decision expires without application for renewal or the authorisation is suspended or revoked, the products of this harvest cannot be placed on the market.

(20) The applicants have been consulted on the measures provided for in this Decision.

(21) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifiers**

As provided for in Regulation (EC) No 65/2004, the following unique identifiers are assigned:

(a) for genetically modified maize (*Zea mays* L.) MON89034 × 1507 × MON 88017 × 59122:

unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

(b) for genetically modified maize (*Zea mays* L.) MON89034 × 1507 × MON 88017:

unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3;

(c) for genetically modified maize (*Zea mays* L.) MON 89034 × 1507 × 59122:

unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7;

(d) for genetically modified maize (*Zea mays* L.) MON 89034 × MON88017 × 59122:

unique identifier MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7;

(e) for genetically modified maize (*Zea mays* L.) 1507 × MON 88017 × 59122:

unique identifier DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 275, 21.10.2009, p. 9.
[3] OJ L 287, 5.11.2003, p. 1.

(f) for genetically modified maize (*Zea mays* L.) MON 89034 × 1507:

unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1;

(g) for genetically modified maize (*Zea mays* L.) MON 89034 × 59122:

unique identifier MON-89Ø34-3 × DAS-59122-7;

(h) for genetically modified maize (*Zea mays* L.) MON 1507 × MON 88017:

unique identifier DAS-Ø15Ø7-1 × MON-88Ø17-3;

(i) for genetically modified maize (*Zea mays* L.) MON 88017 × 59122:

unique identifier MON-88Ø17-3 × DAS-59122-7.

These genetically modified maizes (*Zea mays* L.) are specified in point (b) of the Annex to this Decision.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from the GMOs specified by their unique identifiers in Article 1;

(b) feed containing, consisting of, or produced from the GMOs specified by their unique identifiers in Article 1;

(c) the GMOs specified by their unique identifiers in Article 1 in products containing them or consisting of them for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of the GMOs specified by their unique identifiers in Article 1 with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holders shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holders**

1. The authorisation holders shall be:

(a) Dow AgroSciences Ltd, United Kingdom, representing Dow AgroSciences LLC, United States; and

(b) Monsanto Europe S.A., Belgium, representing Monsanto Company, United States.

2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressees**

This Decision is addressed to:

(a) Dow AgroSciences Ltd, European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom; and

(b) Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 6 November 2013.

*For the Commission*

Tonio BORG

*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holders**

Name: Dow AgroSciences Ltd

Address: European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom

on behalf of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States;

and

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels, Belgium

on behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.

(b) **Designation and specification of the products**

(1) foods and food ingredients containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);

(2) feed containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);

(3) the genetically modified maizes (*Zea mays* L.) as specified in (e) in products containing it or consisting of it for any other uses than (1) and (2), with the exception of cultivation.

MON-89Ø34-3 maize expresses the Cry1A.105 and Cry2Ab2 proteins which confer protection against certain lepidopteran pests.

DAS-Ø15Ø7-1 maize, expresses the Cry1F protein which confers protection against certain lepidopteran pests and the PAT protein, which confers tolerance to the herbicide glufosinate-ammonium.

MON-88Ø17-3 maize expresses a modified Cry3Bb1 protein which provides protection to certain coleopteran pests and the CP4 EPSPS protein which confers tolerance to the herbicide glyphosate.

DAS-59122-7 maize expresses Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests and the PAT protein, which confers tolerance to the herbicide glufonisate-ammonium.

(c) **Labelling**

(1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of the maizes specified in (e) with the exception of products referred to in point (a) of Article 2.

(d) **Methods for detection**

— Event specific real-time PCR based methods for quantitative detection of genetically modified maize MON-89Ø34-3, DAS-Ø15Ø7-1, MON-88Ø17-3 and DAS-59122-7 maize; the detection methods validated on the single-trait events and verified on MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 would function with a comparable efficacy for the individual GMOs as specified in (e);

— DNA extraction method validated on ground maize seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

— Reference Material: ERM®-BF424 (for DAS-59122-7) and ERM®-BF418 (for DAS-Ø15Ø7-1) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at https://irmm.jrc.ec.europa.eu/rmcatalogue and AOCS 0906-E and AOCS 0406-A (for MON-89Ø34-3) and AOCS 0406-D and AOCS 0406-A (for MON-88Ø17-3) accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifiers**

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3;

MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

MON-89Ø34-3 × DAS-Ø15Ø7-1;

MON-89Ø34-3 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-88Ø17-3;

MON-88Ø17-3 × DAS-59122-7.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII of Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION

## of 8 November 2013

## approving a preventive vaccination plan against low pathogenic avian influenza in a holding keeping mallard ducks in Portugal and certain provisions for their movements and products thereof

*(notified under document C(2013) 7310)*

**(Only the Portuguese text is authentic)**

(2013/651/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC [1], and in particular Article 57(2) thereof,

Whereas:

(1) Directive 2005/94/EC provides that Member States are to ensure that vaccination against avian influenza is prohibited on their territory, except where emergency vaccination or preventive vaccination is carried out pursuant to the conditions laid down in the relevant Sections of Chapter IX of that Directive.

(2) Section 3 of Chapter IX of Directive 2005/94/EC provides that Member States may introduce preventive vaccination in poultry as a long term measure to control that disease, where they deem that on the basis of a risk assessment certain areas of their territory, types of poultry husbandry or certain poultry categories are exposed to the risk of avian influenza.

(3) Article 52(1)(c) further requires that Member States must ensure that vaccines to be used for vaccination of poultry or other captive birds against avian influenza should be authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council [2] or Regulation (EC) No 726/2004 of the European Parliament and of the Council [3].

(4) Following outbreaks of low pathogenic avian influenza in 2007 and 2008 in certain poultry holdings in central and western Portugal, in particular in holdings that keep poultry intended for restocking supplies of game, an emergency vaccination plan was carried out pursuant to Commission Decision 2008/285/EC [4] and the disease was eradicated.

(5) However, according to the results of a risk assessment, high value mallard breeding ducks kept on one holding located in Vila Nova da Barquinha in the region of Lisboa e Vale do Tejo, Ribatejo Norte, are still exposed to the potential risk of avian influenza infection, due to possible indirect contact with wild birds.

(6) Portugal therefore submitted to the Commission for approval a preventive vaccination plan against avian influenza to be carried out as a long term measure until 31 July 2009. That plan was approved by Commission Decision 2008/838/EC [5]. Further preventive vaccination plans against low pathogenic avian influenza submitted by Portugal were approved by Commission Decision 2010/189/EU [6] and Commission Implementing Decision 2012/110/EU [7].

(7) The plan for preventive vaccination against low pathogenic avian influenza approved by Implementing Decision 2012/110/EU was implemented by Portugal until 31 July 2013. As provided for in Article 8 of that Decision, Portugal submitted a report on the implementation of that plan to the Standing Committee on the Food Chain and Animal Health. That report demonstrated that virus circulation was successfully prevented in the vaccinated mallard flocks as well as in poultry holdings located in the surrounding area.

[1] OJ L 10, 14.1.2006, p. 16.

[2] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

[3] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[4] Commission Decision 2008/285/EC of 19 March 2008 concerning emergency vaccination against low pathogenic avian influenza in mallard ducks in Portugal and certain measures restricting the movements of such poultry and their products (OJ L 92, 3.4.2008, p. 37).

[5] Commission Decision 2008/838/EC of 3 November 2008 concerning preventive vaccination against low pathogenic avian influenza in mallard ducks in Portugal and certain measures restricting the movements of such poultry and their products (OJ L 299, 8.11.2008, p. 40).

[6] Commission Decision 2010/189/EU of 29 March 2010 concerning preventive vaccination against low pathogenic avian influenza in mallard ducks in Portugal and certain measures restricting the movements of such poultry and their products (OJ L 83, 30.3.2010, p. 62).

[7] Commission Implementing Decision 2012/110/EU of 10 February 2012 concerning preventive vaccination against low pathogenic avian influenza in mallard ducks in Portugal and certain measures restricting the movements of such poultry and their products (OJ L 50, 23.2.2012, p. 46).

(8) On 26 August 2013, Portugal submitted a new plan for preventive vaccination against low pathogenic avian influenza to the Commission for approval. That plan is to be applied until 31 December 2014 ('the preventive vaccination plan').

(9) Scientific opinions of the European Food Safety Authority in 2005 ([1]), 2007 ([2]) and 2008 ([3]) have confirmed that preventive vaccination is a valuable tool to complement control measures for avian influenza.

(10) In addition in order to detect a potential silent virus circulation in vaccinated birds, surveillance and laboratory testing in the holding keeping the vaccinated mallard ducks and unvaccinated sentinel birds should be carried out as set out in the preventive vaccination plan including individual identification of that poultry.

(11) It is also appropriate to introduce certain restrictions on the movement of vaccinated mallard ducks, their hatching eggs and mallard ducks derived from such ducks in accordance with the preventive vaccination plan. Due to the small number of mallard ducks present on the holding where preventive vaccination is to be carried out, as well as for reasons of traceability and logistics, vaccinated mallard ducks should not be moved from that holding, but killed after the end of their reproductive cycle in accordance with the requirements of Article 18 of Council Regulation (EC) No 1099/2009 ([4]) and safely disposed of in accordance with the requirements set out in Commission Regulation (EU) No 142/2011 ([5]).

(12) Portugal has taken additional measures pursuant to Commission Decision 2006/605/EC ([6]) for trade in poultry intended for restocking supplies of game.

(13) To reduce the economic impact on the holding concerned, certain derogations from movement restrictions for mallard ducks derived from vaccinated mallard ducks should be allowed provided that such movements do not increase the risk for the spread of avian influenza and provided that official surveillance is carried out and that the specific animal health requirements for trade within the Union are complied with.

(14) Considering the epidemiological situation as regards low pathogenic avian influenza in Portugal, the risk associated with the type of holding concerned and the limited scope of the preventive vaccination plan, the plan should be approved and implemented until 31 December 2014.

(15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

*Article 1*

**Subject matter and scope**

1. This Decision lays down certain measures to be applied in Portugal in one holding in the municipality of Vila Nova da Barquinha, region of Lisboa e Vale do Tejo, Ribatejo Norte, where preventive vaccination of mallard ducks (*Anas platyrhynchos*) intended for restocking supplies of game ('mallard ducks') is carried out in a holding, which is exposed to the risk of the introduction of the avian influenza virus.

Those measures include:

(a) certain restrictions on the movement within and dispatch from Portugal of the vaccinated mallard ducks, their hatching eggs and mallard ducks derived therefrom;

(b) the disposal of vaccinated mallard ducks.

2. This Decision shall apply without prejudice to the protection measures to be taken by Portugal in accordance with Directive 2005/94/EC and Decision 2006/605/EC.

*Article 2*

**Approval of the preventive vaccination plan**

1. The plan for preventive vaccination against low pathogenic avian influenza in Portugal, as submitted by Portugal to the Commission on 26 August 2013, until 31 December 2014 ('the preventive vaccination plan') is approved.

2. The Commission shall publish the preventive vaccination plan on its website.

([1]) Scientific Opinion on Animal health and welfare aspects of Avian Influenza (The EFSA Journal (2005) 266, 1-21).
([2]) Scientific Opinion on Vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds (The EFSA Journal (2007) 489).
([3]) Scientific Opinion on Animal health and welfare aspects of avian influenza and the risks of its introduction into the EU poultry holdings (The EFSA Journal (2008) 715, 1-161).
([4]) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).
([5]) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).
([6]) Commission Decision 2006/605/EC of 6 September 2006 on certain protection measures in relation to intra-Community trade in poultry intended for restocking of wild game supplies (OJ L 246, 8.9.2006, p. 12).

*Article 3*

**Conditions for implementing the preventive vaccination plan**

1. Portugal shall ensure that the preventive vaccination plan is implemented by using a monovalent inactivated vaccine containing the avian influenza subtype H5 authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.

2. Portugal shall ensure that the preventive vaccination plan is implemented as notified.

*Article 4*

**Marking and restrictions on the movement and dispatch and disposal of vaccinated mallard ducks**

Portugal shall ensure that vaccinated mallard ducks on the holding referred to in Article 1(1) are:

(a) marked individually;

(b) not moved to other poultry holdings within Portugal;

(c) not dispatched from Portugal.

After their reproductive period, those mallard ducks shall be killed on the holding referred to in Article 1(1) of this Decision in accordance with the requirements of Article 18 of Regulation (EC) No 1099/2009, and their carcases safely shall be disposed of in accordance with the requirements of Regulation (EU) No 142/2011.

*Article 5*

**Restrictions on the movement and dispatch of hatching eggs derived from mallard ducks on the holding referred to in Article 1(1)**

Portugal shall ensure that hatching eggs derived from mallard ducks on the holding referred to in Article 1(1):

(a) are only moved to a hatchery in Portugal;

(b) are not dispatched from Portugal.

*Article 6*

**Restrictions on the movement and dispatch of mallard ducks derived from vaccinated mallard ducks**

1. Portugal shall ensure that mallard ducks derived from the vaccinated parent mallard ducks are only moved after hatching from the holding referred to in Article 1(1) to a holding located in an area surrounding that holding.

That area shall be established and identified by Portugal as set out in the preventive vaccination plan.

2. By way of derogation from paragraph 1, mallard ducks derived from vaccinated parent mallard ducks and provided they are older than four month may be:

(a) released into the wild in Portugal; or

(b) dispatched from Portugal provided that:

(i) the results of the surveillance and laboratory tests as set out in the preventive vaccination plan, are favourable;

(ii) the conditions for dispatch of poultry for restocking supplies of wild game laid down in Decision 2006/605/EC are met.

*Article 7*

**Health certification for trade within the Union in mallard ducks derived from vaccinated mallard ducks**

Portugal shall ensure that health certificates for intra-Union trade in poultry intended for restocking supplies of game accompanying the mallard ducks dispatched pursuant to Article 6(2)(b) include the following sentence:

'The animal health conditions of this consignment are in accordance with Commission Implementing Decision 2013/651/EU (*).

(*) OJ L 302, 13.11.2013, p. 53.'.

*Article 8*

**Reports**

Portugal shall submit to the Commission a report on the implementation of the preventive vaccination plan within one month from the date of notification of this Decision and report every six months thereafter at the meeting of the Standing Committee on the Food Chain and Animal Health.

*Article 9*

**Applicability**

This Decision shall apply until 31 December 2014.

*Article 10*

**Addressee**

This Decision is addressed to the Portuguese Republic.

Done at Brussels, 8 November 2013.

*For the Commission*

Tonio BORG

*Member of the Commission*

EN

[1] Text with EEA relevance

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN