II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/586

of 12 April 2021

amending Decision 2007/330/EC lifting prohibitions on the movement of certain animal products on the island of Cyprus under Council Regulation (EC) No 866/2004 and laying down conditions for the movement of those products with regard to 'Χαλλούμι' (Halloumi)/'Hellim' (PDO)

(notified under document C(2021) 2386)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 866/2004 of 29 April 2004 on a regime under Article 2 of Protocol 10 to the Act of Accession ([1]), and in particular Article 4(9) thereof,

Whereas:

(1) Pending the reunification of Cyprus, Article 1(1) of Protocol 10 to the Act of Accession suspends the application of the *acquis* in the areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control.

(2) For public health and animal health reasons, Regulation (EC) No 866/2004 prohibits the movement of live animals and animal products subject to Union veterinary requirements across the line between those areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control and the areas in which it does.

(3) Article 4(9) of Regulation (EC) No 866/2004 specifies that prohibitions in respect of live animals or animal products subject to Union veterinary requirements may be lifted by Commission decisions laying down the conditions applicable for trade adopted in accordance with the procedure referred to in Article 58(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([2]).

(4) Commission Decision 2007/330/EC ([3]) lifts the prohibitions on the movement of animal products for fresh fish and for honey for human consumption, subject to those products fulfilling the conditions set out in Annexes I and II to that Decision, respectively.

([1]) OJ L 161, 30.4.2004, p. 128.

([2]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([3]) Commission Decision 2007/330/EC of 4 May 2007 lifting prohibitions on the movement of certain animal products on the island of Cyprus under Council Regulation (EC) No 866/2004 and laying down conditions for the movement of those products (OJ L 123, 12.5.2007, p. 30).

(5) Commission Implementing Regulation (EU) 2021/591 ([4]) entered a name in the register of protected designations of origin and protected geographical indications in respect of 'Χαλλούμι' (Halloumi)/'Hellim' (PDO) ('the product').

(6) This protected designation of origin covers the whole island of Cyprus including those areas in which the Government of the Republic of Cyprus does not exercise effective control. Pending the reunification of Cyprus, it is therefore appropriate to lift the prohibition under Article 4(9) of Regulation (EC) No 866/2004 and allow the movement of the product across the line between the areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control and the areas in which it does and to lay down the conditions for trade in the product.

(7) It is necessary to ensure that public health and animal health are not compromised by the lifting of the prohibition of the product and it is also necessary to guarantee food safety in accordance with Commission Regulation (EC) No 1480/2004 ([5]) which lays down specific rules concerning goods arriving from the areas of the Republic of Cyprus not under the effective control of the Government of the Republic of Cyprus in the areas of the Republic of Cyprus in which the Government of the Republic of Cyprus exercises effective control. Accordingly, trade in the product should be subject to certain conditions.

(8) Since the *acquis* is suspended in certain areas of the eligible geographical area of production of 'Χαλλούμι' (Halloumi)/'Hellim' PDO and pending the reunification of Cyprus a temporary workable arrangement should be established in order to guarantee that Union animal health and public health controls are efficiently performed throughout the island of Cyprus.

(9) To that effect, it is appropriate that the Republic of Cyprus, applying procedures analogous to those in Chapter III of Title II of Regulation (EU) 2017/625 of the European Parliament and of the Council ([6]), delegates to a delegated body the powers necessary to conduct all inspections and controls with regard to the movement of the product across the line. The controls performed by this delegated body should be restricted to the verification that Union public health and animal health requirements applicable to the product are met.

(10) The delegated body should report to the Government of the Republic of Cyprus. The Turkish Cypriot Chamber of Commerce should receive a copy of reports issued by the delegated body.

(11) A dedicated Annex for the product should be added to Decision 2007/330/EC, specifying the relevant conditions necessary to ensure that the product complies with all requirements of Union law on the protection of public health and animal health.

(12) The first of these conditions that should be fulfilled is that the animal health status has been established favourably according to internationally agreed standards of the World Organisation for Animal Health for all the diseases potentially transmissible through trade in the product. Where no such internationally agreed standards exist, the determination should be made in accordance with relevant criteria applicable under Union law. It is envisaged that the animal health status of the areas of the Republic of Cyprus not under the effective control of the Government of

([4]) Commission Implementing Regulation (EU) 2021/591 of 12 April 2021 entering a name in the register of protected designations of origin and protected geographical indications ('Χαλλούμι' (Halloumi)/'Hellim' (PDO)) (OJ L 125, 13.4.2021, p. 42).

([5]) Commission Regulation (EC) No 1480/2004 of 10 August 2004 laying down specific rules concerning goods arriving from the areas not under the effective control of the Government of Cyprus in the areas in which the Government exercises effective control (OJ L 272, 20.8.2004, p. 3).

([6]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

the Republic of Cyprus is established through a Commission Decision. In line with the animal health situation, alternative treatments in the animal health attestation in the Annex will be considered including the treatment referred to in Commission Implementing Regulation. Once the animal health status has been established favourably, a further condition to be fulfilled should be that there is an annual programme for the monitoring of residues which should be prepared by the delegated body. It is envisaged that the Commission approves that programme every year through a Decision.

(13) Pending the reunification of Cyprus, a Working Group may be established, with the assistance of the Commission, composed of equal numbers of representatives of the Greek Cypriot community and the Turkish Cypriot community, and chaired by a representative of the Commission to hold regular meetings to review the functioning of the inspection system for the product established by this Decision.

(14) Decision 2007/330/EC should therefore be amended accordingly.

(15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2007/330/EC is amended as follows:

(1) in Article 1, the first subparagraph is replaced by the following:

'The prohibitions under Article 4(9) of Regulation (EC) No 866/2004 on the movement of animal products across the line between the areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control and the areas in which it does, shall no longer apply in respect of the animal products referred to in Annexes I, II and III to this Decision.';

(2) the text set out in the Annex to this Decision is added as Annex III.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 12 April 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

'ANNEX III

"Χαλλούμι" (Halloumi)/"Hellim" (PDO)

A. **Animal Product: "Χαλλούμι" (Halloumi)/"Hellim" (PDO)**

B. **Conditions to be met before trade can take place**

1. Animal health status

The animal health status in the areas of the Republic of Cyprus not under the effective control of the Government of the Republic of Cyprus must in a first step be established favourably according to internationally agreed standards of the World Organisation for Animal Health for all the diseases referred to in points 5 and 6(a) of Part C allowing the trade of "Χαλλούμι" (Halloumi)/"Hellim" (PDO) under the conditions as referred to in Commission Implementing Regulation (EU) 2021/591 [1]. Where international standards do not exist, the determination must be made in accordance with other relevant criteria applied by the Commission concerning animal health status. The necessary investigations and collection of evidence must be carried out by the delegated body referred to in Part D. Once the animal health status can be established on the basis of scientific evidence provided by the delegated body referred to in Part D, it is envisaged that the Commission adopts a Decision recognising this status in accordance with applicable procedures. The status must be notified to the World Organisation for Animal Health.

2. Monitoring of residues

Once the animal health status has been established favourably in accordance with point 1 of this Part, the delegated body referred to in Part D must prepare an annual programme for the monitoring of residues that is based on data of milk production. It is envisaged that the Commission approves that programme every year through a Decision. Criteria analogous to those applied by the Commission for the evaluation of the annual programmes for the monitoring of residues must be used.

3. Approval of eligible dairies

The delegated body referred to in Part D must inspect the milk processing establishments for compliance with Annex II to Regulation (EC) No 852/2004 and Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004. It must approve those establishments eligible for the movement of the product across the line between the areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control and the areas in which it does.

4. Experts of the delegated body referred to in Part D must establish that the conditions under points 1 to 3 of this Part are met.

C. **General conditions applicable to trade**

1. The product must be wholly produced by a producer residing in those areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control.

2. The product has been certified as compliant with the requirements of Implementing Regulation (EU) 2021/591

3. All stages of the production process for the product have been inspected by the delegated body referred to in Part D.

4. Experts of the delegated body referred to in Part D have certified that the conditions listed in points 5 to 11 of this Part have been met.

5. The areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control have been free from foot-and-mouth disease for at least 12 months.

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[1] Commission Implementing Regulation (EU) 2021/591 of 12 April 2021 entering a name in the register of protected designations of origin and protected geographical indications ('Χαλλούμι' (Halloumi)/'Hellim' (PDO)) (OJ L 125, 13.4.2021, p. 42).

6. All establishments where cows, sheep or goats are kept in the areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control:

   (a) are not under restrictions due to bovine tuberculosis, bovine brucellosis or ovine and caprine brucellosis;

   (b) satisfy the health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;

   (c) satisfy the animal health conditions laid down in Chapter I of Directive 2002/99/EC ([2]); and

   (d) implement the prohibition to feed ruminants with meat-and-bone meal, greaves and processed animal protein derived from ruminants.

7. From the date of entry into force of this Decision, cows, sheep and goats have been transferred into the areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control only from countries that are authorised to export such animals to the European Union, as listed in Part 1 of Annex I to Commission Regulation (EU) No 206/2010 ([3]) and certified in accordance with Part 2 of Annex I to that Regulation.

8. The milk used to produce the product:

   (a) came from identified animals from registered establishments which keep records on animal movements to ensure traceability;

   (b) was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;

   (c) satisfied the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;

   (d) did not contain residues of antimicrobial compounds at concentrations in excess of the maximum authorised limit laid down in the Annex to Commission Regulation (EU) No 37/2010 ([4]);

   (e) did not contain residues of pesticides at concentrations in excess of the maximum residue levels laid down in Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council ([5]); and

   (f) did not contain contaminants at concentrations in excess of the maximum levels laid down by Commission Regulation (EC) No 1881/2006 ([6]).

9. Dairies producing the product have implemented a programme based on Hazard Analysis and Critical Control Points (HACCP) principles in accordance with Regulation (EC) No 852/2004.

10. The product has been processed, stored, wrapped, packaged and transported in accordance with the relevant conditions laid down in Annex II to Regulation (EC) No 852/2004 and in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004.

11. The product has been produced according to the criteria laid down in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004.

([2]) Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

([3]) Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

([4]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([5]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([6]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

12. Each consignment of the product must be accompanied by a document issued in accordance with Article 2 of Regulation (EC) No 1480/2004. That document must be issued by the Turkish Cypriot Chamber of Commerce, duly authorised for that purpose by the Commission in agreement with the Government of the Republic of Cyprus, or by another body so authorised in agreement with the latter. That document must be issued in accordance with the procedure laid down in Article 4(5) and (6) of Regulation (EC) No 866/2004 and must state that the product meets the conditions set out in this Part.

13. The product must bear a health and identification marking in compliance with Article 5 of Regulation (EC) No 853/2004.

14. Each consignment of the product must be accompanied by the following animal health and public health attestations signed by an expert of the delegated body referred to in Part D:

"**PUBLIC HEALTH AND ANIMAL HEALTH ATTESTATION**

Reference number:

I. **Public health attestation**

I, an expert appointed by the delegated body mentioned in point D of Annex III to Decision 2007/330/EC, declare that I am aware of the relevant provisions of Annex III to Decision 2007/330/EC as well as of those of Regulations (EC) No 178/2002 ([7]), (EC) No 852/2004 ([8]), (EC) No 853/2004 ([9]) and (EU) 2017/625 ([10]) and (EU) 2019/627 ([11]) and hereby certify that the product described above was produced in accordance with those provisions, in particular that:

(a) it was manufactured from raw milk:

(i) which comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Articles 49 and 50 of Implementing Regulation (EU) 2019/627;

(ii) which was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;

(iii) which meets the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;

(iv) which complies with the guarantees on the residues status of raw milk provided by the monitoring plans for the detection of residues or substances submitted in accordance with Article 29 of Council Directive 96/23/EC ([12]);

([7]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([8]) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

([9]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

([10]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

([11]) Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

([12]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

(v) which, pursuant to testing for residues of antibacterial drugs carried out by the food business operator in accordance with the requirements of Annex III, Section IX, Chapter 1, Part III, point 4 of Regulation (EC) No 853/2004, it complies with the maximum residue limits for residues of antibacterial veterinary medicinal products laid down in the Annex to Commission Regulation (EU) No 37/2010 ([13]);

(vi) which has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council ([14]), and the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006 ([15]).

(b) it comes from (an) establishment(s) applying general hygiene requirements and implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the competent authorities;

(c) it has been processed, stored, wrapped, packaged and transported in accordance with the relevant hygiene conditions laid down in Annex II to Regulation (EC) No 852/2004 and Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004;

(d) it meets the relevant criteria laid down in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 and the relevant microbiological criteria in Commission Regulation (EC) No 2073/2005 ([16]) on microbiological criteria for foodstuffs;

(e) it has undergone or been produced from raw milk which has been submitted to a heat treatment referred to in Part II.1.2, and sufficient to ensure, where applicable, a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment;

(f) the product has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005, and the maximum levels for contaminants laid down in Regulation (EC) No 1881/2006.

II. **Animal health attestation**

The **product**:

II.1.1 originates from the those areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control; and

either II.1.2. has been processed from raw milk obtained from **only one species of animals**, in particular from **the species** [*Bos taurus*] ([1]) [*Ovis aries*] ([1]) [*Capra hircus*] ([1]) and the raw milk used for the processing of the dairy product has undergone:

either [a sterilisation process, to achieve an F_0 value equal to or greater than 3.] ([1])

or [a ultra-high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time.] ([1])

or [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds applied twice to milk with a pH equal to or greater than 7,0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment.] ([1])

or [a HTST treatment of milk with a pH below 7,0.] ([1])

or [a HTST treatment combined with another physical treatment by:

either [(i) lowering the pH below 6 for one hour.] ([1])

or [(ii) additional heating equal to or greater than 72 °C, combined with desiccation.] ([1])] ([1])

([13]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([14]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([15]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

([16]) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

or II.1.2. has been processed **mixing** raw milk obtained from **animals of the following species:** [*Bos taurus,*] (1) [*Ovis aries,*] (1) [*Capra hircus,*] (1) and [before] (1) [after] (1) mixing all the raw milk used for the processing of the dairy product has undergone:

either [a sterilisation process, to achieve an F_0 value equal to or greater than 3.] (1)

or [a ultra-high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time.] (1)

or [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds applied twice to milk with a pH equal to or greater than 7,0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment.] (1)

or [a HTST treatment of milk with a pH below 7,0.] (1)

or [a HTST treatment combined with another physical treatment by:

either [(i) lowering the pH below 6 for one hour.] (1)

or [(ii)additional heating equal to or greater than 72 °C, combined with desiccation.] (1)] (1)

or II.1.3. after the completion of the treatment referred to in point II.1.2, has been handled until packaged in a way to prevent any cross contamination that could introduce an animal health risk.

(1) Keep as appropriate.

D. **Controls**

The Republic of Cyprus, applying procedures analogous to those in Chapter III of Title II of Regulation (EU) 2017/625, must delegate to a delegated body the powers necessary to conduct all inspections and controls needed to ensure compliance with Union animal health and food safety requirements in the chain of production of the product.'"