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Contents

[1] Text with EEA relevance.

EN

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

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

DECISIONS

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/1374

of 12 April 2021

amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin

(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 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([1]), and in particular Article 10(1) thereof,

Whereas:

(1) Annex III to Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators.

(2) Rennet is a complex of enzymes used for the production of certain cheeses. It is collected from the stomachs of young ruminants. Based on the experience gained by food business operators, the specific hygiene requirements on stomachs for the production of rennet, laid down in Point 18(a) of Chapter IV to Section I to Annex III of Regulation (EC) No 853/2004, should be amended in order to optimise the collection of rennet from young sheep and goats. In particular, it is appropriate to allow such stomachs to leave the slaughterhouse without being emptied or cleaned.

(3) Technological developments have resulted in a demand for heads and feet of domestic ungulates to be permitted to be skinned or scalded and depilated outside the slaughterhouse in specialised approved establishments for further processing of food. As a practical consequence, heads and feet of domestic ungulates should therefore be allowed to be transported to these establishments under certain conditions that ensure food safety. Point 18(c) of Chapter IV to Section I of Annex III to Regulation (EC) No 853/2004 should therefore be amended.

(4) In accordance with Article 4 of Commission Delegated Regulation (EU) 2019/624 ([2]), the official veterinarian may perform ante-mortem inspection outside a slaughterhouse in the case of emergency slaughter of domestic ungulates. Point 2 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004 requires a veterinarian to carry out ante mortem inspection in the case of emergency slaughter. That requirement should be amended so as to be consistent with that Article 4 of Delegated Regulation (EU) 2019/624 and refer instead to the official veterinarian.

([1]) OJ L 139, 30.4.2004, p. 55.

([2]) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

(5) Improving animal welfare is one of the actions proposed in the Commission's Farm to Fork Strategy ([3]) for a fair, healthy and environmentally-friendly food system, as part of the European Green Deal. There is, in particular, a change in patterns of meat consumption with an increasing demand by the European Parliament, farmers and consumers that slaughter of certain domestic ungulates on the holding of provenance be authorised in order to avoid possible animal welfare concerns during collection and transport thereof.

(6) Apart from emergency slaughter, domestic ungulates are required to be slaughtered in a slaughterhouse approved in accordance with Article 4(2) of Regulation (EC) No 853/2004 to ensure compliance with the hygiene requirements laid down in Chapters II and IV of Section I of Annex III to that Regulation. The competent authorities of Member States can approve mobile slaughterhouses in accordance with that Article. These mobile facilities may be placed in all appropriate locations, including farms, where groups of healthy animals can be slaughtered. In other circumstances, the transport of certain animals may create a risk for the handler or for the welfare of the animals. Slaughter and bleeding should therefore be permitted at the holding of provenance for a limited number of domestic bovine and porcine animals and domestic solipeds. Such practice should be subject to strict conditions to maintain a high level of food safety of the meat derived from such animal.

(7) Domestic bovine and porcine animals and domestic solipeds slaughtered on the holding of provenance, should be accompanied by an official certificate, attesting that the hygiene requirements for slaughter have been complied with. Such an official certificate is provided for in Commission Implementing Regulation (EU) 2020/2235 ([4]).

(8) On 27 September 2018, the European Food Safety Authority (EFSA) adopted a second scientific opinion on hazard analysis approaches for certain small retail establishments and food donations ([5]). That Opinion recommends freezing at retail level as an additional tool for guaranteeing the safe redistribution of food to those in need. The facilitation of safe food donation practices, both prevents food waste and contributes to food security, in line with the objectives laid down in the Commission's Farm to Fork strategy and its overall aim to establish a fair, healthy and environmentally-friendly food system as part of the European Green Deal. The freezing of food can be an important means of ensuring its safe redistribution by food banks and other charities. The freezing of meat is currently not allowed in the case of retail to retail activity since meat intended for freezing is required to be frozen without undue delay after slaughter or cutting in accordance with point 4 of Chapter VII of Section I of Annex III to Regulation (EC) No 853/2004, as regards domestic ungulates and point 5 of Chapter V of Section II of that Annex as regards poultry and lagomorphs. The freezing of meat should therefore be allowed in the case of retail to retail activity under certain conditions to ensure the safe distribution for food donations.

(9) Regulation (EC) No 854/2004 of the European Parliament and of the Council ([6]) defined 'approved veterinarian'. Regulation (EU) 2017/625 of the European Parliament and of the Council ([7]) repealed Regulation (EC) No 854/2004, and defined 'official veterinarian'. As the definition of 'official veterinarian' in Regulation (EU) 2017/625 encompasses 'approved veterinarian', the references to 'approved veterinarian' in Annex III to Regulation (EC) No 853/2004 should be amended to refer instead to 'official veterinarian'

([3]) https://ec.europa.eu/food/sites/food/files/safety/docs/f2f_action-plan_2020_strategy-info_en.pdf

([4]) Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) No 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) No 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

([5]) *EFSA Journal* 2018; 16(11):5432

([6]) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

([7]) 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).

(10) The specific hygiene requirements for the production and placing on the market of meat from even-toed farmed game mammals laid down in Section III of Annex III to Regulation (EC) No 853/2004 only apply to meat from *Cervidae* or *Suidae*. Similar requirements should also apply to meat from other even-toed farmed game mammals such as lamas to avoid a possible food safety risk from changes in consumption patterns due to an increased consumption of such meat.

(11) The bodies and viscera of hunted wild game may be transported to and stored in a collection centre before transport to a game-handling establishment. Specific hygiene rules on the handling and storage of these bodies and viscera in such collection centres should be introduced to ensure the food safety of that meat by amending the hygiene requirements for wild game laid down in Section IV of Annex III to Regulation (EC) No 853/2004.

(12) Wild game is required to be transported as soon as possible to a game handling establishment after examination by a trained person in accordance with point 3 of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004 as regards large wild game and point 3 of Chapter III of that Section as regards small wild game in order to allow chilling to take place within a reasonable time after killing. That requirement should also apply to wild game where no examination took place.

(13) Point 3 of Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, provides that whenever a food business operator moves a batch of live bivalve molluscs between establishments, the batch is required to be accompanied by a registration document. In order to harmonise the information required by point 4 of Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, a common model of the registration document for the movement of live bivalve molluscs between establishments should be established. Moreover it is a common practice that batches of bivalve molluscs may also be sent to intermediate operators, therefore the registration document should also include this possibility.

(14) In accordance with point 1 of Part A of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004, live bivalve molluscs are to be washed with clean water, free of mud and accumulated debris before purification commences. However, in order to save water, washing of clean bivalve molluscs should not be mandatory. The point 1 of Part A of Chapter IV of Section VII should be modified accordingly.

(15) Live bivalve molluscs placed on the market may not contain marine biotoxins that exceed the limits set out in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004. The EFSA has concluded in its Opinion on Marine biotoxins in shellfish – Pectenotoxin group ([8]) that there are no reports of adverse effects in humans associated with Pectenotoxins (PTX) group toxins. In addition, PTX in shellfish are always accompanied by toxins from the Okadaic acid group. It is therefore appropriate to delete the reference to PTX from point 2(c) of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.

(16) Article 11 of Delegated Regulation 2019/624 provides that the classification of production and relaying areas is not required in relation to the harvesting of holothuroidea when the competent authorities carry out official controls on such animals in fish auctions, dispatch centres and processing establishments. Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 should be amended in order to allow the harvesting of Holothuroidea outside classified production and relaying areas.

(17) Vessels should be designed and constructed so as not to cause contamination of fishery products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Also holds, tanks or containers used for storing, cooling or freezing fishery products should not be used for other purposes than the storage of fishery products. Freezer vessels and reefer vessels should be equipped with freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than – 18 °C. Storage holds should not be used for freezing products. The same requirements for freezing and storage equipment should also apply to cold stores on land. Part I of Chapter I and part B of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.

([8]) https://doi.org/10.2903/j.efsa.2009.1109

(18) Following recent frauds concerning tuna initially frozen in brine at – 9 °C and destined for the canning industry but diverted to be consumed as fresh fishery products, it is appropriate to clarify in point 7 of Part II of Chapter I of Section VIII of Annex III to Regulation (EC) No 853/2004 that whole fishery products initially frozen in brine at – 9 °C and destined for the canning industry even if further frozen at a temperature of – 18 °C must not have a different destination than the canning industry.

(19) Livers and roes of fishery products intended for human consumption are to be preserved under ice, at a temperature approaching that of melting ice, or are to be frozen. It is appropriate to allow that livers and roes be also refrigerated under different conditions than under ice, at a temperature approaching that of melting ice. Accordingly, point 6 of Part II of Chapter I of Section VIII of Annex III to Regulation (EC) No 853/2004 should be amended in order to allow that livers and roes of fishery products intended for human consumption may also be refrigerated not only under ice but under different conditions of refrigeration.

(20) It is appropriate that in containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice, the melting water should not remain in contact with any fishery products. It is important, for hygiene reasons, to clarify that melt water not only should not remain in contact with fishery products but should be drained away. Accordingly, point 4 of part A of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 should be amended in order to clarify that melted water not only should not remain in contact with fishery products but should be drained away.

(21) Specific hygiene rules on frogs' legs laid down in Section XI of Annex III to Regulation (EC) No 853/2004 only apply to frogs' legs of the species RNA (family Ranidae) in accordance with the definition of frogs' legs laid down in point 6.1 of Annex I to that Regulation. Specific hygiene rules for snails in that Section only apply to terrestrial gastropods of the species *Helix pomatia Linné, Helix aspersa Muller, Helix lucorum* and species of the family Achatinidae in accordance with the definition of snails laid down in point 6.2 of Annex I to Regulation (EC) No 853/2004. Due to changes in eating habits, frogs' legs and snails of other species are also produced and placed on the market for human consumption. The specific hygiene rules should therefore be extended to cover those species to ensure the safety of food derived from these species.

(22) Section XII of Annex III to Regulation (EC) No 853/2004 lays down specific temperature requirements for the storage of greaves intended for human consumption. Technological developments have allowed certain packaging techniques, such as vacuum-packaging for which the specific temperature requirements are not needed to ensure the safety of food derived from greaves. Those temperature conditions should therefore be deleted while the food business operator should ensure the safety of food derived from the greaves by good hygiene practices and procedures based on Hazard Analysis and Critical Control Point (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council ([9]).

(23) Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III of Regulation (EC) No 853/2004 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*.

([9]) 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).

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

Done at Brussels, 12 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex III to Regulation (EC) No 853/2004 is amended as follows:

(1) Section I is amended as follows:

(a) Chapter IV is amended as follows:

(i) point 2(b)(ii) is replaced by the following:

'(ii) animals slaughtered at the holding of provenance in accordance with Chapter VIa of this Section or in accordance with point 3 of Section III;'

(ii) point 18 is replaced by the following:

'18. Unless intended for use as animal by-product in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council *:

(a) stomachs must be scalded or cleaned; however, when intended for rennet production, the stomachs:

(i) are only required to be emptied in the case of young bovine animals

(ii) are not required to be emptied, scalded or cleaned in the case of young ovine and caprine animals;

(b) intestines must be emptied and cleaned;

(c) heads and feet must be skinned or scalded and depilated; however, when authorised by the competent authority, visibly clean heads, not containing specified risk materials in accordance with Article 8 of Regulation (EC) No 999/2001 of the European Parliament and of the Council **, and visibly clean feet, intended for processing into food, may be transported to and skinned or scalded and depilated in an approved establishment.

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* Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

** Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).'

(b) Chapter VI is amended as follows:

(i) points 2 and 3 are replaced by the following:

'2. The official veterinarian must carry out an ante-mortem inspection of the animal.

3. The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the official veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.'

(ii) point 6 is replaced by the following:

'The official certificate set out in Chapter 5 of Annex IV to Commission Implementing Regulation (EU) 2020/2235 * shall accompany the slaughtered animal to the slaughterhouse or be sent in advance in any format.

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* Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).'

(c) The following Chapter VIa is inserted after Chapter VI:

'CHAPTER VIa: SLAUGHTER AT THE HOLDING OF PROVENANCE OF DOMESTIC BOVINE, OTHERS THAN BISONS, AND PORCINE ANIMALS AND DOMESTIC SOLIPEDS OTHER THAN EMERGENCY SLAUGHTER

Up to three domestic bovine, others than bisons, or up to six domestic porcine animals or up to three domestic solipeds may be slaughtered at the same occasion at the holding of provenance, when authorised by the competent authority in accordance with the following requirements:

(a) the animals cannot be transported to the slaughterhouse, to avoid any risk for the handler and to prevent any injuries to the animals during transport;

(b) there is an agreement between the slaughterhouse and the owner of the animal intended for slaughter; the owner must inform the competent authority in writing of such an agreement;

(c) the slaughterhouse or the owner of the animals intended for slaughter must inform the official veterinarian at least three days in advance of the date and time of intended slaughter of the animals;

(d) the official veterinarian who carries out the ante-mortem inspection of the animal intended for slaughter must be present at the time of slaughter;

(e) the mobile unit to be used for the bleeding and transport of the slaughtered animals to the slaughterhouse must allow their hygienic handling and bleeding, and the proper disposal of their blood and must be part of a slaughterhouse approved by the competent authority in accordance with Article 4(2); however the competent authority may allow bleeding outside the mobile unit if the blood is not intended for human consumption and the slaughter does not take place in restricted zones as defined in Article 4(41) of Regulation (EU) 2016/429 of the European Parliament and of the Council * or establishments in which animal health restrictions are applied in accordance with Regulation (EU) 2016/429 and any acts adopted on its basis;

(f) the slaughtered and bled animals must be transported directly to the slaughterhouse hygienically and without undue delay; removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the official veterinarian; any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to each individual animal;

(g) if more than two hours elapse between the time of slaughter of the first animal and the time of arrival at the slaughterhouse of the slaughtered animals, the slaughtered animals must be refrigerated; where climatic conditions so permit, active chilling is not necessary;

(h) the owner of the animal must inform the slaughterhouse in advance of the intended time of arrival of the slaughtered animals, which must be handled without undue delay after arrival at the slaughterhouse;

(i) in addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the official certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animals to the slaughterhouse or be sent in advance in any format.

* Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).'

(d) In Chapter VII, point 4 is replaced by the following:

'4. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.

However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:

(i) in the case of meat for which a 'use by' date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council *, before the expiry of that date;

(ii) without undue delay to a temperature of – 18 °C or lower;

(iii) ensuring that the date of freezing is documented and provided either on the label or by other means;

(iv) excluding meat that has been frozen before (defrosted meat); and,

(v) in accordance with any condition laid down by the competent authorities for freezing and further use as food.

* Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).'

(2) Section II is amended as follows:

(a) In Chapter V, point 5 is replaced by the following:

'5. Meat intended for freezing must be frozen without undue delay.

However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:

(i) in the case of meat for which a 'use by' date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011, before the expiry of that date;

(ii) without undue delay to a temperature of – 18 °C or lower;

(iii) ensuring that the date of freezing is documented and provided either on the label or by other means;

(iv) excluding meat that has been frozen before (defrosted meat); and,

(v) in accordance with any condition laid down by the competent authorities for freezing and further use as food.'

(b) Chapter VI is amended as follows:

(i) point 6 is deleted;

(ii) point 7 is replaced by the following:

'7. In addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the official certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animal to the slaughterhouse or cutting plant, or be sent in advance in any format.'

(3) Section III is amended as follows:

(a) point 1 is replaced by the following:

'1. The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals, unless the competent authority considers them inappropriate.'

(b) point 3(j) is replaced by the following:

'(j) the official certificate set out in Chapter 3 of Annex IV to Commission Implementing Regulation (EU) 2020/2235, issued and signed by the official veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, accompanies the slaughtered animal to the slaughterhouse or was sent in advance in any format.'

(4) Section IV is amended as follows:

(a) the following introductory sentence is added:

'For the purpose of this Section, 'collection centre' means an establishment used to store the bodies and viscera of wild game before their transport to a game handling establishment.'

(b) Chapter II is amended as follows:

(i) point 4(c) is replaced by the following:

'(c) If no trained person is available to carry out the examination referred to in point 2 in a particular case, the head, except for tusks, antlers and horns, and all the viscera, except for the stomach and the intestines, must accompany the body which must be transported to a game handling-establishment as soon as possible after killing.'

(ii) in point 8(b), the first subparagraph is replaced by the following:

'(b) may be sent to a game handling establishment in another Member State only if, during transport to that game-handling establishment, it is accompanied by an official certificate set out in Chapter 2 of Annex II to Implementing Regulation (EU) 2020/2235 issued and signed by an official veterinarian, attesting that the requirements set out in point 4 of this Chapter as regards the availability of a declaration, when relevant, and the accompaniment of relevant parts of the body, have been complied with.'

(iii) the following point 10 is added:

'10. The bodies and viscera of large wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:

(a) the collection centre is either:

(1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or

(2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;

(b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;

(c) killed animals are transported to the collection centre hygienically and without delay;

(d) the temperature conditions laid down in point 5 are complied with;

(e) storage time is kept to the minimum possible;

(f) no other handling takes place on the bodies and viscera of the large wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 2, 3 and 4.'

(c) Chapter III is amended as follows:

(i) point 3 is replaced by the following:

'3 Meat of small wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 1 or, if no trained person is available to carry out that examination in a particular case, as soon as possible after killing'.

(ii) the following point 8 is added:

'8. The bodies, including viscera, of small wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:

(a) the collection centre is either:

(1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or

(2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;

(b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;

(c) killed animals are transported to the collection centre hygienically and without delay;

(d) the temperature conditions laid down in point 4 are complied with;

(e) storage time is kept to the minimum possible;

(f) no other handling takes place on the bodies, including viscera, of the small wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 1 and 2.'

(5) Section VII is amended as follows:

(a) In the introductory part, the following point 1a is inserted:

'1a. For the purpose of this Section, 'intermediary operator' means a food business operator, including traders, other than the first supplier, with or without premises, who carries out its activities between production areas, relaying areas or any establishments.'

(b) Chapter I is amended as follows:

(i) point 3 is replaced by the following:

'3. Whenever a food business operator moves a batch of live bivalve molluscs between production areas, relaying areas or any establishments, a registration document must accompany the batch.'

(ii) in point 4, the following point (d) is added:

'(d) Where a batch of live bivalve molluscs is sent by an intermediary operator, a new registration document, filled-in by the intermediary operator, must accompany the batch. The registration document must contain at least the information referred to in points (a), (b) and (c) and the following information:

(i) the name and address of the intermediary operator;

(ii) in the case of conditioning or in the case of re-immersion for storing purpose, the date of starting, the date of end and the place of the conditioning or the re-immersion;

(iii) if a conditioning in a natural site was carried out, the intermediary operator must confirm that the natural site where the conditioning took place was classified at the time of conditioning as an class A production area open for harvest;

(iv) if a re-immersion in natural site was carried out, the intermediary operator must confirm that the natural site where the re-immersion took place was classified at the time of re-immersion with the same classification of the production area where the live bivalve molluscs were harvested.

(v) if a re-immersion was carried out in an establishment, the intermediary operator must confirm that the establishment was approved at the time of the re-immersion. The re-immersion shall not cause additional contamination to the live bivalve molluscs.

(vi) in the case of grouping, the species, the date when the grouping started, the date of the end of the grouping, the status of the area where the live bivalve molluscs were harvested, and the batch of the grouping, that always consists of the same species, captured on the same date, and in the same production area.'

(iii) the following points 8 and 9 are added:

'8. Intermediary operators must be:

(a) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) if they do not have premises or if they have premises where they only handle, wash and store at ambient temperature live bivalve molluscs, without grouping nor conditioning, or

(b) approved by the competent authority as a food business operator in accordance with Article 4(2) if, in addition to carrying out the activities referred to in point (a), they have a cold store or they group or split batches of live bivalve molluscs or they carry out conditioning or re-immersion.

9. Intermediary operators may receive live bivalve molluscs from production areas classified as A, B or C, from relaying areas or from other intermediary operators. Intermediary operators can send live bivalve molluscs:

(a) from class A production areas to dispatch centres or another intermediary operator;

(b) from class B production areas only to purification centres, processing establishments or to another intermediary operator;

(c) from class C production areas to processing establishments or to another intermediary operator with premises.'

(c) In Chapter IV point 1 of Part A is replaced by the following:

'1. Before purification commences, live bivalve molluscs must be free of mud and accumulated debris and washed if necessary, using clean water.'

(d) In Chapter V, point 2:

a) point (a) is replaced by: '(a) for paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalents diHCl per kilogram;'

(b) point (c) is replaced by: '(c) for okadaic acid and dinophysistoxins together 160 micrograms of okadaic acid equivalents per kilogram;'

(e) Chapter IX is replaced by the following:

'CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE, MARINE GASTROPODS AND HOLOTHUROIDEA WHICH ARE NOT FILTER FEEDERS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae, marine gastropods and holothuroidea which are not filter feeders, outside classified production areas or handling such pectinidae, and/or such marine gastropods and/or holothuroidea must comply with the following requirements:

1. Pectinidae, marine gastropods and holothuroidea which are not filter feeders, must not be placed on the market unless they are harvested and handled in accordance with Part B of Chapter II and meet the standards laid down in Chapter V, as demonstrated by a system of own-checks by the food business operators operating a fish auction, a dispatch centre or a processing establishment;

2. In addition to point 1, where data from official monitoring programmes enable the competent authority to classify fishing grounds – where appropriate, in cooperation with food business operators – the provisions of Part A of Chapter II apply by analogy to pectinidae;

3. Pectinidae, marine gastropods and holothuroidea which are not filter feeders, must not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae and/or such marine gastropods, and/or holothuroidea food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV;

4. Food business operators handling pectinidae, marine gastropods and holothuroidea which are not filter feeders, must comply with the following requirements:

(a) with the documentary requirements of points 3 to 7 of Chapter I, where applicable. In this case, the registration document must clearly indicate the location of the area, indicating the system used to describe the coordinates, where the live pectinidae and/or live marine gastropods and/or live holothuroidea were harvested; or

(b) with the requirements of point 2 of Chapter VI concerning the closing of all packages of live pectinidae, live marine gastropods and live holothuroidea dispatched for retail sale and Chapter VII concerning identification marking and labelling.'

(f) The following Chapter X is added:

'CHAPTER X MODEL OF REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS

REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS

Part I – Supplier

I.1 IMSOC Reference number	**I.2 Internal reference number**
I.3 Supplier Name Address Registration or Approval No Country ISO Country code Activity	**I.4 Receiving food business operator** Name Address Registration or Approval No Country ISO Country code Activity
I.5 Description of goods **Aquaculture** ☐ Natural Banks ☐ • CN code or FAO 3-Alpha code | species | quantity | package | batch | date of harvesting| date of starting of conditioning | date of end of conditioning | place of conditioning| date of starting of re-immersion | date of end of re-immersion |place of re-immersion| date of starting of grouping | date of end of grouping | production area | health status including, if applicable, harvested in accordance with Article 62(2) of Implementing Regulation (EU) 2019/627	
I.6 From relaying area Yes☐ No☐ Relaying area Duration of relaying Date of starting Date of end	**I.7 From purification/dispatch centre** **Auction hall Yes ☐ No☐** **Purification/dispatch centre/auction hall approval number** **Date of entry** **Date of exit** **Duration of purification**
I.8 From Intermediary operator **Yes ☐ No ☐** **Name** **Address** **Registration or Approval No** **Country** **ISO Country code** **Activity** **Date of arrival** **Date of exit**	
I.9 Declaration of the supplier I, the undersigned food business operator responsible for dispatching the consignment declare that, to the best of my knowledge and belief, the information provided in Part I of this document is true and complete.	
Date Name of signatory Signature	

Part II – Receiving operator

II.1 Internal reference number (receiving)
II.2 Declaration of the receiving food business operator I, the undersigned food business operator responsible for receiving the consignment declare that the consignment has arrived on [DATE] in my premises. Name of signatory Signature

Explanatory notes

Box	Description
	Part I – Supplier This part of the document shall be filled by the food business operator dispatching a batch of live bivalve molluscs.
I.1	**IMSOC reference number** This is the unique alpha-numeric code assigned by the IMSOC
I.2	**Internal reference number** This box may be used by the **dispatching** food business operator to indicate an internal reference number.
I.3	**Supplier** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of origin. In the case of production areas, please indicate the area as authorised by the competent authorities (CAs). In the case of live pectinidae, marine gastropods or holothuroidea, indicate the location of the harvesting area. Where applicable, indicate the registration or approval number of the establishment. Indicate the activity (gatherer, purification centre, dispatch centre, auction hall or intermediary activities). Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and Holothuroidea which are not filter feeders harvested outside classified production areas, from a fish auction, indicate the approval number and the address of the purification centre/dispatch centre or fish auction.
I.4	**Receiving food business operator** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. In the case of production or relaying areas please indicate the area as authorised by the CAs. Where applicable, indicate the registration or approval number of the establishment Indicate the activity (gatherer, purification centre, dispatch centre, processing establishment or intermediary activities).
I.5	**Description of goods** Indicate as required, the Combined Nomenclature code or FAO 3-Alpha code, species, quantity, type of packaging (bags, bulk, etc.), batch, date of harvesting, date of starting and end of conditioning (when applicable), place of conditioning (indicate the classification of the production area and its location or the approval number of the establishment, when applicable), date of starting and end of re-immersion (when applicable), place of re-immersion (indicate the classification of the production area and its location or the approval number of the establishment when applicable), date of starting and end of grouping (when applicable), production area and its health status (classification of the production area when applicable). When LBMs have been harvested in accordance with Article 62(2) of the Implementing Regulation 2019/627 then this should be explicitly stated. When grouping of live bivalve molluscs is performed, the batch must refer to bivalves of the same species, harvested on the same day and coming from the same production area. Delete as appropriate
I.6	**From relaying area** Where the batch of live bivalve molluscs is sent from a relaying area, indicate the relaying area, as authorised by the CAs, and the duration of the relaying (date of starting and end).
I.7	**From purification centre/dispatch centre or fish auction** Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and holothuroidea which are not filter feeders harvested outside classified production areas, from an auction hall, indicate the approval number and the address of the purification centre/dispatch centre or auction hall. If sent from a purification centre the duration of the purification and the dates on which the batch entered and left the purification centre. Delete as appropriate

I.8	**From intermediary operator** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the intermediary operator. Where applicable, indicate the registration or approval number and the activity.
1.9	**Declaration of the supplier** Include the date, name of the signatory and the signature.

Part II – Receiving food business operator

This part of the document shall be filled by the food business operator receiving a batch of live bivalve molluscs.

II.1	**Internal reference number (receiving)** This box may be used by the food business operator receiving the batch to indicate an internal reference number.
II.2	**Declaration of the receiving food business operator** Indicate the date of arrival of the batch of live bivalve molluscs at the premises of the receiving food business operator. In the case of an intermediary operator without premises indicate the date of purchase of the batch. Include the name of the signatory and the signature.'

(6) Section VIII is amended as follows:

(a) Chapter I is amended as follows:

(i) Point 1 is replaced by the following:

'1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, and reefer vessels comply with the structural and equipment requirements laid down in Part I; and'

(ii) In Part I.A, the following point 5 is added:

'5. Vessels must be designed and constructed so as not to cause contamination of the fishery products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Holds, tanks, or containers used for storing, cooling or freezing unprotected fishery products including those destined for the production of feed, shall not be used for other purposes than the storing, cooling or freezing those products, as well as ice or brine used for such purposes. In the case of reefer vessels, the provisions applicable to unprotected fishery products apply to all the products transported.'

(iii) In Part I.C, points 1 and 2 are replaced by the following:

'1. have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than – 18 °C;

2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than – 18 °C. Storage holds must not be used for freezing unless they fulfil the conditions laid down in point 1, and must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest;'

(iv) In Part I, the following point E is added:

'E. Requirements for reefer vessels

Reefer vessels transporting and/or storing frozen fishery products in bulk must have equipment meeting the requirements for freezer vessels laid down in point 2 of part C concerning their capacity to maintain the temperature.'

(v) In Part II, point 6 is replaced by the following

'6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the fishery products must be washed immediately. The viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from fishery products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or preserved under ice, at a temperature approaching that of melting ice, or be frozen.'

(vi) in Part II, point 7 is replaced by the following:

'7. Where freezing in brine of the whole fish intended for canning is practiced, a temperature of not more than – 9 °C must be achieved for the fishery product. Even if it is subsequently frozen at a temperature of – 18 °C, the whole fish initially frozen in brine at a temperature of not more than – 9 °C must be destined for canning. The brine must not be a source of contamination for the fish.'

(b) Chapter III is amended as follows:

(i) In Part A, point 4.is replaced by the following:

'4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water is drained away and does not remain in contact with any fishery products.'

(ii) Part B is replaced by the following:

'B. REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze or store frozen fishery products must have equipment, adapted to the activity carried out, that satisfies the requirements for freezer vessels laid down in Section VIII, Chapter I part I.C, points 1 and 2 and.'

(7) In Section XI, the following points 7 and 8 are added:

'7. The requirements laid down in points 1, 3, 4 and 6, also apply to any other snails of the Family of *Helicidae, Hygromiidae* or *Sphincterochilidae*, when intended for human consumption.

8. The requirements laid down in points 1 to 5 also apply to frogs' legs of the genus *Pelophylax* from the Family of *Ranidae*, and the genus *Fejervarya, Limnonectes* and *Hoplobatrachus* from the Family of *Dicroglossidae*, when intended for human consumption.'

(8) In Section XII, in Chapter II, point 5 is deleted.

COMMISSION DELEGATED REGULATION (EU) 2021/1375

of 11 June 2021

amending Delegated Regulation (EU) 2019/33 as regards the modification of traditional terms in the wine sector

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 114 thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2019/33 ([2]), which replaced and repealed Commission Regulation (EC) No 607/2009 ([3]), lays down rules supplementing Regulation (EU) No 1308/2013 as regards protection, cancellation and modification of traditional terms.

(2) Article 34 of Delegated Regulation (EU) 2019/33 lays down that the modification of a registered traditional term may only concern the elements referred to in points (b), (c) and (d) of Article 26(1), of that Regulation, which refer respectively to the type of the traditional term, the language in which the traditional term is expressed and the grapevine product category concerned by its use.

(3) However, Article 42a of Regulation (EC) No 607/2009 provided for a longer list of possible modifications. In particular, it included the possibility to modify the traditional term itself, the language in which the traditional term is indicated, the wine or wines concerned and the summary of the definition or conditions of use of the traditional term. The modification possibilities under Regulation (EC) No 607/2009 were therefore broader and allowed wine producers to extend or limit, for example, the list of wines with protected designations of origin or protected geographical indications authorised to use a traditional term or to amend the conditions for the use of a traditional term, including the production methods of the concerned wines.

(4) The provisions of Delegated Regulation (EU) 2019/33 concerning traditional terms were drafted with the intention of ensuring continuity of the common framework related to traditional terms established under Regulation (EC) No 607/2009, while completing and clarifying the existing procedures whenever necessary. Article 34 of Delegated Regulation (EU) 2019/33 makes direct references to the elements of a duly completed application form, as set out in Article 26(1) of that Regulation. However, due to an involuntary omission, point (a) of Article 26(1), referring to the name of the concerned traditional term, point (e) of Article 26(1), referring to the summary of the definition and conditions of use and point (f) of Article 26(1), referring to the protected designations of origin or protected geographical indications concerned, were not mentioned in the list set out in Article 34, even though these elements were included in Article 42a of Regulation (EC) No 607/2009. This has the unintended consequence that the possibilities for modifying a traditional term are restricted to modifying the type of traditional term, the language and the grapevine product category concerned.

([1]) OJ L 347, 20.12.2013, p. 671.

([2]) Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation (OJ L 9, 11.1.2019, p. 2).

([3]) Commission Regulation (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (OJ L 193, 24.7.2009, p. 60).

(5) In practical terms, the current wording of the first paragraph of Article 34 hinders the possibility to extend the use of a traditional term to new protected designations of origin or geographical indications or to exclude from the list of wines authorised to use a traditional term those that no longer comply with its conditions of use. Moreover, it does not allow, for example, to adapt the production methods mentioned in the specifications of a traditional term in case those methods evolve due to the changing environmental or climate conditions.

(6) To correct this unintended omission and restore the flexibility granted to holders of traditional terms under Regulation (EC) No 607/2009, the list of possible modifications of a registered traditional term referred to in the first paragraph of Article 34 of Delegated Regulation (EU) 2019/33 should be extended to include the elements referred to in points (a), (e) and (f) of Article 26(1) of that Regulation.

(7) Delegated Regulation (EU) 2019/33 should therefore be amended accordingly.

(8) For reasons of legal clarity and in order to ensure equal treatment of all applications for modification of a registered traditional term, this Regulation should apply retroactively from 14 January 2019,

HAS ADOPTED THIS REGULATION:

Article 1

Article 34 of Delegated Regulation (EU) 2019/33 is replaced by the following:

'*Article 34*

Modification of a traditional term

An applicant satisfying the conditions of Article 25 may apply for approval of a modification of a registered traditional term concerning the elements referred to in points (a) to (f) of Article 26(1).

Articles 26 to 31 shall apply mutatis mutandis to applications for modification.'.

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*.

It shall apply from 14 January 2019.

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

Done at Brussels, 11 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION REGULATION (EU) 2021/1376

of 13 August 2021

establishing a fisheries closure for redfishes in NAFO 3M area for vessels flying the flag of a Member State of the European Union

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) 2021/92 [2] lays down quotas for 2021.

(2) According to the information received by the Commission, catches of the stock of redfishes in NAFO 3M area by vessels flying the flag of or registered in a Member State of the European Union have exhausted the quota allocated for 2021.

(3) It is therefore necessary to prohibit directed fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

Article 1

Quota exhaustion

The fishing quota allocated to Member States of the European Union for the stock of redfishes in NAFO 3M area for 2021 referred to in the Annex shall be deemed to be exhausted from the date set out in that Annex.

Article 2

Prohibitions

Directed fishing activities for the stock referred to in Article 1 by vessels flying the flag of or registered in a Member State of the European Union shall be prohibited from the date set out in the Annex.

Article 3

Entry into force

This Regulation shall enter into force on the 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, 13 August 2021.

For the Commission,
On behalf of the President,
John DALLI
Member of the Commission

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

[2] Council Regulation (EU) 2021/92 of 28 January 2021 fixing for 2021 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters (OJ L 31, 29.1.2021, p. 31).

ANNEX

No	14/TQ92
MEMBER STATE	**European Union (All Member States)**
STOCK	**RED/N3M.**
SPECIES	**Redfishes *(Sebastes* spp.)**
ZONE	**NAFO 3M**
CLOSING PERIOD	**24 July 2021 at 24.00 UTC**

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1377

of 19 August 2021

authorising the change of the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) establishing a Union list of authorised novel foods was adopted.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.

(4) The novel food 'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' has been authorised pursuant to Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]) for use in food supplements intended for the general population, as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]). The maximum authorised levels of the astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae for the general population is currently 40-80 mg per day of oleoresin, resulting in ≤ 8,0 mg astaxanthin per day.

(5) At the time of the establishment of the Union list of authorised novel foods in 2017, the Commission considered that, based on previous two opinions ([5]), ([6]) of 2014 of the European Food Safety Authority ('the Authority'), one on the use of astaxanthin in feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and the Council ([7]) on feed additives for animal nutrition, that established an Acceptable Daily Intake ('ADI') of 0,034 mg/kg body weight per day for astaxanthin, and one on the safety of astaxanthin as a novel food ingredient, the intake of astaxanthin from food supplements containing the maximum authorised use levels of up to 8,0 mg per day, may exceed the ADI and may not be in accordance with the conditions set out in Article 7 of Regulation (EU) 2015/2283. The Commission considered that the Union list should be amended to adjust the authorised levels of astaxanthin in light of the 2014 Authority opinions.

([1]) OJ L 327, 11.12.2015, p. 1.
([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).
([3]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).
([4]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
([5]) EFSA Journal 2014;12(6):3724.
([6]) EFSA Journal 2014; 12(7):3757.
([7]) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

(6) The Commission also became aware of new scientific evidence in 2017, submitted by business operators during the public consultation of the draft Implementing Regulation establishing the Union list of authorised novel foods, pointing to a considerably higher ADI for astaxanthin than the one previously established by the Authority. In addition, evidence submitted during the same public consultation demonstrated that there already existed a considerable intake of astaxanthin from the normal diet as it is naturally present in some fish and crustaceans.

(7) On 27 February 2018, the Commission, in accordance with Article 29(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([8]) requested the Authority to deliver an opinion on the safety of astaxanthin when used as a novel food in food supplements at levels of up to 8,0 mg/day, taking into account the overall cumulative intake of astaxanthin from all food sources.

(8) On 18 December 2019, the Authority adopted its scientific opinion 'Safety of astaxanthin for its use as a novel food in food supplements' ([9]).

(9) In its scientific opinion, the Authority concluded that on the basis of the new evidence, the ADI for astaxanthin is 0,2 mg/kg body weight per day. Taking into account the astaxanthin ADI and the intake of astaxanthin from the normal diet, the Authority concluded that the intake of the maximum currently authorised levels of up to 8,0 mg/day astaxanthin from food supplements containing astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae is safe for adults and adolescents above 14 years old.

(10) A clear designation of the novel food and a labelling requirement should be laid down for food supplements containing astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae in order ensure that those food supplements are not consumed by children and adolescents aged less than 14 years of age.

(11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(12) Evidence form the market place seems to indicate that although food supplements containing ≤ 8,0 mg astaxanthin are currently authorised for the general population, in practice they are not used by children and adolsescents but are almost exclusively used by the adult population. In order to limit the administrative burden and to provide business operators with sufficient time to adjust their practices to comply with the requirements of this Regulation, transitional periods should be laid down to cover food supplements containing ≤ 8,0 mg astaxanthin which have been placed on the market or dispatched from third countries for the Union and are intended for the general population, before the date of entry into force of this Regulation. Those transitional measures should take into account the safety of consumers by providing them the information about the appropriate use in line with the requirements of this Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

1. The entry in the Union list of authorised novel foods, as provided for in Article 6 of Regulation (EU) 2015/2283 and included in Implementing Regulation (EU) 2017/2470, referring to the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae, is amended as specified in the Annex to this Regulation.

2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

([8]) 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).

([9]) EFSA Panel on Nutrition, Novel Foods and Food Allergens, Scientific Opinion on the safety of astaxanthin as a novel food in food supplements. EFSA Journal 2020;18(2):5993.

Article 2

1. Food supplements containing ≤ 8,0 mg astaxanthin intended for the general population which were lawfully placed on the market before the date of entry into force of this Regulation, may be marketed until their date of minimum durability or use by date.

2. Foods supplements containing ≤ 8,0 mg astaxanthin intended for the general population imported into the Union may be marketed until their date of minimum durability or use by date where the importer of such food can demonstrate that they were dispatched from the third country concerned and were on their way to the Union before the date of entry into force of this Regulation.

3. The food business operators should provide a notice for the food supplements referred to in paragraph 1 to be displayed at the place of sale informing them that those food supplements should not be consumed by infants, children and adolescents below the age of 14 years.

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, 19 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Astaxanthin-rich oleoresin from Haematococcus pluvialis algae' in Table 1 (Authorised novel foods) is replaced by the following:

'**Authorised novel food**	**Conditions under which the novel food may be used**		**Additional specific labelling requirements**	**Other requirements**
	Specified food category	***Maximum levels***	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae' The labelling of food supplements containing Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae shall bear a statement that they should not be consumed by infants, children, and adolescents younger than 14 years.'	
'Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae'	Food Supplements as defined in Directive 2002/46/EC, excluding infants, young children, children, and adolescents younger than14 years	40-80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day		

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1378

of 19 August 2021

laying down certain rules concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic and in-conversion products into the Union and establishing the list of recognised control authorities and control bodies in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 ([1]), and in particular Articles 45(4) and 46(1) thereof,

Whereas:

(1) In accordance with point (b)(i) of Article 45(1) of Regulation (EU) 2018/848, a product may be imported from a third country for the purpose of placing that product on the market within the Union as an organic product or as in-conversion product, if operators and groups of operators, including exporters in the third country concerned, have been subject to controls by control authorities or control bodies recognised in accordance with Article 46 of that Regulation, and those authorities or bodies have provided all such operators, groups of operators and exporters with a certificate confirming that they comply with Regulation (EU) 2018/848.

(2) In order to give effect to point (b)(i) of Article 45(1) of Regulation (EU) 2018/848, the content of the certificate referred to in that provision should be specified, as well as the technical means by which it is to be issued.

(3) In addition, for the purposes of point (b)(i) of Article 45(1) of Regulation (EU) 2018/848, it is appropriate to establish in this Regulation the list of recognised control authorities and control bodies that are competent to carry out those controls and to issue that certificate in third countries.

(4) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Organic Production Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Certificate for operators, groups of operators and exporters in third countries

Control authorities and control bodies that have been recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 shall provide operators, groups of operators and exporters in third countries that have been subject to the controls referred to in point (b)(i) of Article 45(1) of that Regulation with a certificate confirming that such operators, groups of operators and exporters comply with Regulation (EU) 2018/848 ('the certificate').

([1]) OJ L 150, 14.6.2018, p. 1.

The certificate shall:

(a) be issued in electronic form, in accordance with the model set out in Annex I to this Regulation, and by using the electronic Trade Control and Expert System (TRACES) referred to in point (36) of Article 2 of Commission Implementing Regulation (EU) 2019/1715 ([2]);

(b) allow the identification of:

(i) the operator, group of operators or exporter covered by the certificate, including the list of members of a group of operators;

(ii) the category of products covered by the certificate, classified in the same way as provided for in Article 35(7) of Regulation (EU) 2018/848; and

(iii) its period of validity;

(c) certify that the activity of the operator, group of operators or exporter complies with Regulation (EU) 2018/848; and

(d) be updated whenever changes occur concerning the data included in it.

Article 2

List of recognised control authorities and control bodies

1. The list of control authorities and control bodies recognised in accordance with Article 46(1) of Regulation (EU) 2018/848 is set out in Annex II to this Regulation. The list shall contain the following information on each recognised control authority or control body:

(a) the name and code number of the control authority or control body;

(b) the product categories, as set out in Article 35(7) of Regulation (EU) 2018/848, for each third country;

(c) the third countries in which the product categories have their origin, provided that those third countries are not already covered for the product category or product concerned by an agreement on trade in organic products in accordance with Article 47 of Regulation (EU) 2018/848 or through an equivalence recognition in accordance with Article 48 of that Regulation;

(d) the duration of the recognition; and

(e) the exceptions to the recognition, where appropriate.

2. Detailed information relating to the mailing address, website address and email contact point of the control authority or control body, as well as the name of the accreditation body granting the accreditation in accordance with point (d) of Article 46(2) of Regulation (EU) 2018/848, shall be publicly available via the Commission organic farming website.

Article 3

Entry into force and application

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

It shall apply from 1 January 2022.

([2]) Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation) (OJ L 261, 14.10.2019, p. 37).

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

Done at Brussels, 19 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

MODEL OF THE CERTIFICATE

CERTIFICATE FOR OPERATORS, GROUPS OF OPERATORS AND EXPORTERS IN THIRD COUNTRIES FOR PRODUCTS TO BE IMPORTED INTO THE EUROPEAN UNION AS ORGANIC PRODUCTS OR IN-CONVERSION PRODUCTS

Part I: Mandatory elements

1. Document number	2. (choose as appropriate) • Operator • Group of operators – see point 10 • Exporter
3. Name and address of the operator, group of operators or exporter:	4. Name, address and code number of the control authority or control body of the operator, group of operators or exporter:

5. Activity or activities of the operator, group of operators or exporter (choose as appropriate):

- Production
- Preparation
- Distribution
- Storing
- Import
- Export

6. Category or categories of products as referred to in Article 35(7) of Regulation (EU) 2018/848 of the European Parliament and of the Council [1] and production methods (choose as appropriate):

(a) unprocessed plants and plant products, including seeds and other plant reproductive material
Production method:
☐ organic production excluding during the conversion period
☐ production during the conversion period
☐ organic production with non-organic production

(b) livestock and unprocessed livestock products
Production method:
☐ organic production excluding during the conversion period
☐ production during the conversion period
☐ organic production with non-organic production

(c) algae and unprocessed aquaculture products
Production method:
☐ organic production excluding during the conversion period
☐ production during the conversion period
☐ organic production with non-organic production

[1] Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

(d) processed agricultural products, including aquaculture products, for use as food
Production method:
☐ production of organic products
☐ production of in-conversion products
☐ organic production with non-organic production

(e) feed
Production method:
☐ production of organic products
☐ production of in-conversion products
☐ organic production with non-organic production

(f) wine
Production method:
☐ production of organic products
☐ production of in-conversion products
☐ organic production with non-organic production

(g) other products listed in Annex I to Regulation (EU) 2018/848 or not covered by the previous categories
Production method:
☐ production of organic products
☐ production of in-conversion products
☐ organic production with non-organic production

7. Directory of products:

Name of the product and/or Combined Nomenclature (CN) code as referred to in Council Regulation (EEC) No 2658/87 ([2]) for products within the scope of Regulation (EU) 2018/848	☐ Organic ☐ In-conversion

This document has been issued in accordance with Commission Implementing Regulation (EU) 2021/1378 ([3]) to certify that the operator, group of operators or exporter (choose as appropriate) complies with Regulation (EU) 2018/848.

8. Date, place Name and signature on behalf of the issuing control authority or control body:	9. Certificate valid from……. [insert date] to..……[insert date]

10. List of members of the group of operators as defined in Article 36 of Regulation (EU) 2018/848

Name of member	Address or other form of member identification

([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256 7.9.1987, p. 1).

([3]) Commission Implementing Regulation (EU) 2021/1378 of 19 August 2021 laying down certain rules concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic products into the Union and establishing the list of recognised control authorities and control bodies in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council (OJ L 297, 20.8.2021, p. 24).

Part II: Specific optional elements

One or more elements to be completed if so decided by the control authority or control body that issues the certificate to the operator, group of operators or exporter in accordance with Implementing Regulation (EU) 2021/1378

1. Quantity of products

Name of the product and/or CN code as referred to in Regulation (EEC) No 2658/87 for products within the scope of Regulation (EU) 2018/848.	☐ Organic ☐ In-conversion	Quantity estimated in kilograms, litres or, where relevant, in number of units.

2. Information on the land

Name of the product	☐ Organic ☐ In-conversion ☐ Non-organic	Surface in hectares

3. List of premises or units where the activity is performed by the operator or group of operators

Address or geolocation	Description of the activity or activities as referred to in point 5 of part I

4. Information on the activity or activities carried out by the operator or group of operators and whether the activity is, or the activities are performed for their own purpose or as a subcontractor carrying out the activity or activities for another operator, while the subcontractor remains responsible for the activity or activities performed

Description of the activity or activities as referred to in point 5 of part I	☐ Carrying out activity/activities for own purpose ☐ Carrying out activity/activities as a subcontractor for another operator, while the subcontractor remains responsible for the activity or activities performed

5. Information on the activity or activities carried out by the subcontracted third party

Description of the activity or activities as referred to in point 5 of part I	☐ Operator or group of operators remains responsible ☐ Subcontracted third party is responsible

6. List of subcontractors carrying out an activity or activities for the operator or group of operators for which the operator or group of operators remains responsible as regards organic production and for which it has not transferred that responsibility to the subcontractor

Name and address	Description of the activity or activities as referred to in point 5 of part I

7. Information on the accreditation of the control body in accordance with point (d) of Article 46(2) of Regulation (EU) 2018/848

   (a) name of the accreditation body;

   (b) hyperlink to the accreditation certificate.

8. Other information

ANNEX II

List of control authorities and control bodies recognised in accordance with Article 46 of Regulation (EU) 2018/848

For the purposes of this Annex, the product categories are designated by the following codes:

A: unprocessed plants and plant products, including seeds and other plant reproductive material;

B: livestock and unprocessed livestock products;

C: algae and unprocessed aquaculture products;

D: processed agricultural products, including aquaculture products, for use as food;

E: feed;

F: wine;

G: other products listed in Annex I to Regulation (EU) 2018/848 or not covered by the previous categories.

Information relating to the mailing address, website address and email contact point of the control authority or control body, as well as the name of the accreditation body granting its accreditation, can be found on the Commission organic farming website.

Name of the control authority or control body:

1. Code numbers, third countries and product categories concerned

Code number	Third country	Category of products						
XX-BIO-XXX		A	B	C	D	E	F	G

2. Duration of the recognition:

3. Exceptions:

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1379

of 19 August 2021

concerning the non-renewal of approval of the active substance famoxadone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011

(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 Article 20(1) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2002/64/EC ([2]) included famoxadone as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance famoxadone, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2022.

(4) An application for the renewal of the approval of famoxadone was submitted in accordance with Article 4 of Commission Implementing Regulation (EU) No 1141/2010 ([5]) within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Implementing Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 15 July 2014.

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

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

([2]) Commission Directive 2002/64/EC of 15 July 2002 amending Council Directive 91/414/EEC to include cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M and picolinafen as active substances (OJ L 189, 18.7.2002, p. 31).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) 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).

([5]) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

(8) On 3 July 2015 the Authority communicated to the Commission its conclusion ([6]) on whether famoxadone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that there is a high potential for all the representative uses assessed to exceed the acceptable operator exposure level ('AOEL') for workers during crop hand-harvesting even with the use of personal protective equipment ('PPE'). The Authority further concluded that there is a high long-term risk for mammals and high risk for aquatic organisms from the use of famoxadone. In addition, the Authority stated that the available information is insufficient to conclude on the the long-term risk assessments for birds.

(9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 17(1) of Implementing Regulation (EU) No 1141/2010, on the draft review report. The applicant submitted its comments, which have been carefully examined.

(10) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.

(11) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance famoxadone in accordance with Article 20(1)(b) of that Regulation.

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

(13) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing famoxadone.

(14) For plant protection products containing famoxadone, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should be as short as possible and not exceed 12 months from the date of entry into force of this Regulation.

(15) Implementing Regulation (EU) 2021/745 ([7]) extended the approval period of famoxadone to 30 June 2022 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.

(16) This Regulation does not prevent the submission of a further application for the approval of famoxadone pursuant to Article 7 of Regulation (EC) No 1107/2009.

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

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([6]) Conclusion on the peer review of the pesticide risk assessment of the active substance famoxadone. EFSA Journal 2015;13(7):4194, 116 pp. doi:10.2903/j.efsa.2015.4194.

([7]) Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distilation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ L 160, 7.5.2021, p. 89).

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of approval of active substance

The approval of the active substance famoxadone is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 35, on famoxadone, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing famoxadone as active substance by 16 March 2022.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 16 September 2022.

Article 5

Entry into force

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

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

Done at Brussels, 19 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/1380

of 19 August 2021

establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by Ukraine to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic ([1]), and in particular Article 8(2) thereof,

Whereas:

(1) Regulation (EU) 2021/953 lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates ('EU Digital COVID Certificate') for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. It is also to contribute to facilitating the gradual lifting of restrictions to free movement put in place by Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

(2) Regulation (EU) 2021/953 allows for the acceptance of COVID-19 certificates issued by third countries to Union citizens and their family members where the Commission finds that those COVID-19 certificates are issued in accordance with standards that are to be considered as equivalent to those established pursuant to that Regulation. Furthermore, in accordance with Regulation (EU) 2021/954 of the European Parliament and of the Council ([2]), Member States have to apply the rules laid down in Regulation (EU) 2021/953 to third-country nationals who do not fall within the scope of that Regulation, but who are legally staying or residing in their territory and who are entitled to travel to other Member States in accordance with Union law. Therefore, any equivalence findings laid down in this Decision should apply to COVID-19 vaccination certificates issued by Ukraine to Union citizens and their family members. Similarly, on the basis of Regulation (EU) 2021/954, such equivalence findings should also apply to COVID-19 vaccination certificates issued by Ukraine to third-country nationals legally staying or residing in the territory of the Member States under the conditions laid down in that Regulation.

(3) On 16 July 2021, Ukraine provided the Commission with detailed information on the issuance of interoperable COVID-19 vaccination, test and recovery certificates under the system entitled 'Single State portal of electronic services' (Diia portal and mobile application)Ukraine informed the Commission that it considered that its COVID-19 certificates are being issued in accordance with a standard and a technological system that are interoperable with the trust framework established by Regulation (EU) 2021/953 and that allow for the verification of the authenticity, validity and integrity of the certificates. In this regard, Ukraine informed the Commission that COVID-19 certificates issued by Ukraine in accordance with the 'Single State portal of electronic services' (Diia portal and mobile application) system contain the data set out in the Annex of Regulation (EU) 2021/953.

([1]) OJ L 211, 15.6.2021, p. 1.

([2]) Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

(4) On 4 August 2021, following a request by Ukraine, the Commission carried out technical tests that demonstrated that the COVID-19 vaccination, test and recovery certificates are issued by Ukraine in accordance with a system, the 'Single State portal of electronic services' (Diia portal and mobile application), that is interoperable with the trust framework established by Regulation (EU) 2021/953 and allows for the verification of their authenticity, validity and integrity. The Commission also confirmed that the COVID-19 vaccination, test and recovery certificates issued by Ukraine in accordance with the 'Single State portal of electronic services' (Diia portal and mobile application) system contain the necessary data.

(5) In addition, the Ukraine informed the Commission that it will issue interoperable vaccination certificates for COVID-19 vaccines. These currently include Vaxzevria, Comirnaty, Spikevax, COVID-19 Vaccine Janssen, CoronaVac-COVID-19 Vaccine (Vero Cell) Inactivated, Covishield, and NVX-CoV2373.

(6) Ukraine also informed the Commission that it will issue interoperable test certificates only for nucleic acid amplification tests or for rapid antigen tests listed in the common and updated list of COVID-19 rapid antigen tests agreed by the Health Security Committee, established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ([3]), on the basis of the Council Recommendation of 21 January 2021 ([4]).

(7) Furthermore, Ukraine informed the Commission that it issues interoperable certificates of recovery at the earliest 14 days after a positive test. Those certificates are valid for not more than 180 days after the date of the first positive test.

(8) Ukraine also informed the Commission that it accepts vaccination, test and recovery certificates issued by the Member States, EEA countries, and other countries in respect of which an implementing decision is adopted pursuant to Article 8(2) of Regulation (EU) 2021/953. Ukraine also informed the Commission that people with EU Digital COVID Certificate test certificate for negative NAAT test and EU Digital COVID Certificate test certificate for negative RAT test are allowed to enter Ukraine, but like for the Ukrainian citizens, it is required for them to make additional NAAT\RAT test within 72 hours.

(9) In addition, Ukraine informed the Commission that when verifiers in Ukraine verify certificates, the personal data included in them will be processed only to verify and confirm the holder's vaccination, test result or recovery status and will not be retained afterwards.

(10) The necessary elements for establishing that COVID-19 certificates issued by Ukraine in accordance with the 'Single State portal of electronic services' (Diia portal and mobile application) system are to be considered as equivalent to those issued in accordance with Regulation (EU) 2021/953 are thus fulfilled.

(11) Therefore, COVID-19 certificates issued by Ukraine in accordance with the 'Single State portal of electronic services' (Diia portal and mobile application) system should be accepted under the conditions referred to in Article 5(5), Article 6(5), and Article 7(8) of Regulation (EU) 2021/953.

(12) In order for this Decision to be operational, Ukraine should be connected to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953.

(13) In order to protect the Union's interests, in particular in the area of public health, the Commission may use its powers to suspend or terminate this Decision if the conditions of Article 8(2) of Regulation (EU) 2021/953 are no longer met.

(14) In the light of the need to connect Ukraine to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953 as rapidly as possible, this Decision should enter into force on the day of its publication in the *Official Journal of the European Union*.

([3]) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

([4]) Council Recommendation of 21 January 2021 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (OJ C 24, 22.1.2021, p. 1).

(15) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 14 of Regulation (EU) 2021/953,

HAS ADOPTED THIS DECISION:

Article 1

COVID-19 vaccination, test and recovery certificates issued by Ukraine in accordance with the 'Single State portal of electronic services' (Diia portal and mobile application) system shall, for the purpose of facilitating the right of free movement within the Union, be treated as equivalent to those issued in accordance with Regulation (EU) 2021/953.

Article 2

Ukraine shall be connected to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953.

Article 3

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

Done at Brussels, 19 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1381

of 19 August 2021

establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Republic of North Macedonia to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic ([1]), and in particular Article 8(2) thereof,

Whereas:

(1) Regulation (EU) 2021/953 lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates ('EU Digital COVID Certificate') for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. It is also to contribute to facilitating the gradual lifting of restrictions to free movement put in place by Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

(2) Regulation (EU) 2021/953 allows for the acceptance of COVID-19 certificates issued by third countries to Union citizens and their family members where the Commission finds that those COVID-19 certificates are issued in accordance with standards that are to be considered as equivalent to those established pursuant to that Regulation. Furthermore, in accordance with Regulation (EU) 2021/954 of the European Parliament and of the Council ([2]), Member States have to apply the rules laid down in Regulation (EU) 2021/953 to third-country nationals who do not fall within the scope of that Regulation, but who are legally staying or residing in their territory and who are entitled to travel to other Member States in accordance with Union law. Therefore, any equivalence findings laid down in this Decision should apply to COVID-19 vaccination, test and recovery certificates issued by North Macedonia to Union citizens and their family members. Similarly, on the basis of Regulation (EU) 2021/954, such equivalence findings should also apply to COVID-19 vaccination, test and recovery certificates issued by North Macedonia to third-country nationals legally staying or residing on the territory of the Member States under the conditions laid down in that Regulation.

(3) On 8 July 2021, North Macedonia provided the Commission with detailed information on the issuance of interoperable COVID-19 vaccination, test and recovery certificates under the National e-Health System. North Macedonia informed the Commission that it considered that its COVID-19 vaccination, test and recovery certificates are being issued in accordance with a standard and a technological system that are interoperable with the trust framework established by Regulation (EU) 2021/953 and that allow for the verification of the authenticity, validity and integrity of the certificates. In this regard, North Macedonia informed the Commission that COVID-19 vaccination, test and recovery certificates issued by North Macedonia in accordance with the National e-Health System contain the data referred to in the Annex to Regulation (EU) 2021/953.

([1]) OJ L 211, 15.6.2021, p. 1.

([2]) Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

(4) On 26 July 2021, following a request by North Macedonia, the Commission carried out technical tests that demonstrated that the COVID-19 vaccination, test and recovery certificates are issued by North Macedonia in accordance with a system, the National e-Health System, that is interoperable with the trust framework established by Regulation (EU) 2021/953 and allows for the verification of the authenticity, validity and integrity of the certificates. The Commission also confirmed that the COVID-19 vaccination, test and recovery certificates issued by North Macedonia in accordance with the National e-Health System contain the necessary data.

(5) In addition, North Macedonia informed the Commission that it will issue interoperable vaccination certificates for COVID-19 vaccines Vaxzevria, Comirnaty, Sputnik V, Sinopharm and Sinovac.

(6) Furthermore, North Macedonia informed the Commission that it will issue interoperable test certificates only for nucleic acid amplification tests or for rapid antigen tests listed in the common and updated list of COVID-19 rapid antigen tests agreed by the Health Security Committee, established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ([3]), on the basis of the Council Recommendation of 21 January 2021 ([4]).

(7) North Macedonia also informed the Commission that it accepts vaccination, test and recovery certificates issued by the Member States, EEA countries and other countries in respect of which an implementing decision is adopted pursuant to Article 8(2) of Regulation (EU) 2021/953.

(8) In addition, North Macedonia informed the Commission that when verifiers in North Macedonia verify certificates, the personal data included in them will be processed only to verify and confirm the holder's vaccination, test result or recovery status and will not be retained afterwards.

(9) The necessary elements for establishing that COVID-19 vaccination, test and recovery certificates issued by North Macedonia in accordance with the National e-Health System are to be considered as equivalent to those issued in accordance with Regulation (EU) 2021/953 are thus fulfilled.

(10) Therefore, COVID-19 vaccination, test and recovery certificates issued by North Macedonia in accordance with the National e-Health System should be accepted under the conditions referred to in Article 5(5), Article 6(5), and Article 7(8) of Regulation (EU) 2021/953.

(11) In order for this Decision to be operational, North Macedonia should be connected to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953.

(12) In order to protect the Union's interests, in particular in the area of public health, the Commission may use its powers to suspend or terminate this Decision if the conditions of Article 8(2) of Regulation (EU) 2021/953 are no longer met.

(13) In light of the need to connect North Macedonia to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953 as rapidly as possible, this Decision should enter into force on the day of its publication in the *Official Journal of the European Union*.

(14) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 14 of Regulation (EU) 2021/953,

([3]) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

([4]) Council Recommendation of 21 January 2021 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (OJ C 24, 22.1.2021, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

COVID-19 vaccination, test and recovery certificates issued by North Macedonia in accordance with the National e-Health System shall, for the purpose of facilitating the right of free movement within the Union, be considered as equivalent to those issued in accordance with Regulation (EU) 2021/953.

Article 2

North Macedonia shall be connected to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953.

Article 3

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

Done at Brussels, 19 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1382

of 19 August 2021

establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Republic of Turkey to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic ([1]), and in particular Article 8(2) thereof,

Whereas:

(1) Regulation (EU) 2021/953 lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates ('EU Digital COVID Certificate') for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. It is also to contribute to facilitating the gradual lifting of restrictions to free movement put in place by Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner.

(2) Regulation (EU) 2021/953 allows for the acceptance of COVID-19 certificates issued by third countries to Union citizens and their family members where the Commission finds that those COVID-19 certificates are issued in accordance with standards that are to be considered as equivalent to those established pursuant to that Regulation. Furthermore, in accordance with Regulation (EU) 2021/954 of the European Parliament and of the Council ([2]), Member States have to apply the rules laid down in Regulation (EU) 2021/953 to third-country nationals who do not fall within the scope of that Regulation, but who are legally staying or residing in their territory and who are entitled to travel to other Member States in accordance with Union law. Therefore, any equivalence findings laid down in this Decision should apply to COVID-19 vaccination certificates issued by the Republic of Turkey to Union citizens and their family members. Similarly, on the basis of Regulation (EU) 2021/954, such equivalence findings should also apply to COVID-19 vaccination certificates issued by the Republic of Turkey to third-country nationals legally staying or residing in the territory of the Member States under the conditions laid down in that Regulation.

(3) On 9 July 2021, the Republic of Turkey provided the Commission with detailed information on the issuance of interoperable COVID-19 vaccination, test and recovery certificates under the system entitled 'Health Pass'. The Republic of Turkey informed the Commission that it considered that its COVID-19 certificates are being issued in accordance with a standard and a technological system that are interoperable with the trust framework established by Regulation (EU) 2021/953 and that allow for the verification of the authenticity, validity and integrity of the certificates. In this regard, the Republic of Turkey informed the Commission that COVID-19 certificates issued by the Republic of Turkey in accordance with the 'Health Pass' system contain the data set out in the Annex to Regulation (EU) 2021/953.

([1]) OJ L 211, 15.6.2021, p. 1.

([2]) Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

(4) On 26 July 2021, following a request by the Republic of Turkey, the Commission carried out technical tests that demonstrated that the COVID-19 vaccination, test and recovery certificates are issued by the Republic of Turkey in accordance with a system, the 'Health Pass', that is interoperable with the trust framework established by Regulation (EU) 2021/953, and allows for the verification of the authenticity, validity and integrity of the certificates. The Commission also confirmed that the COVID-19 vaccination, test and recovery certificates issued by the Republic of Turkey in accordance with the 'Health Pass' system contain the necessary data.

(5) In addition, the Republic of Turkey informed the Commission that it will issue interoperable vaccination certificates for COVID-19 vaccines. These currently include Sinovac, Comirnaty and Sputnik V.

(6) The Republic of Turkey also informed the Commission that it will issue interoperable test certificates only for nucleic acid amplification tests or for rapid antigen tests listed in the common and updated list of COVID-19 rapid antigen tests agreed by the Health Security Committee, established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ([3]), on the basis of the Council Recommendation of 21 January 2021 ([4]).

(7) Furthermore, the Republic of Turkey informed the Commission that it issues interoperable certificates of recovery at the earliest 21 days after a positive test. Those certificates are valid for not more than 180 days after the date of the first positive test.

(8) The Republic of Turkey also informed the Commission that it accepts vaccination, test and recovery certificates issued by the Member States, EEA countries and other countries in respect of which an implementing decision is adopted pursuant to Article 8(2) of Regulation (EU) 2021/953.

(9) In addition, the Republic of Turkey informed the Commission that when verifiers in Turkey verify certificates, the personal data included in them will be processed only to verify and confirm the holder's vaccination, test result or recovery status and will not be retained afterwards.

(10) The necessary elements for establishing that COVID-19 certificates issued by the Republic of Turkey in accordance with the 'Health Pass' system are to be considered as equivalent to those issued in accordance with Regulation (EU) 2021/953 are thus fulfilled.

(11) Therefore, COVID-19 certificates issued by the Republic of Turkey in accordance with the 'Health Pass' system should be accepted under the conditions referred to in Article 5(5), Article 6(5), and Article 7(8) of Regulation (EU) 2021/953.

(12) In order for this Decision to be operational, the Republic of Turkey should be connected to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953.

(13) In order to protect the Union's interests, in particular in the area of public health, the Commission may use its powers to suspend or terminate this Decision if the conditions of Article 8(2) of Regulation (EU) 2021/953 are no longer met.

(14) In the light of the need to connect the Republic of Turkey to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953 as rapidly as possible, this Decision should enter into force on the day of its publication in the *Official Journal of the European Union*.

(15) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 14 of Regulation (EU) 2021/953,

([3]) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

([4]) Council Recommendation of 21 January 2021 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (OJ C 24, 22.1.2021, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

COVID-19 vaccination, test and recovery certificates issued by the Republic of Turkey in accordance with the 'Health Pass' system shall, for the purpose of facilitating the right of free movement within the Union, be considered as equivalent to those issued in accordance with Regulation (EU) 2021/953.

Article 2

The Republic of Turkey shall be connected to the EU Digital COVID Certificate trust framework established by Regulation (EU) 2021/953.

Article 3

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

Done at Brussels, 19 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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