

Department for Environment, Food and Rural Affairs

Notes for Guidance: Export Health Certificate for entry into the European Union or Northern Ireland of live bivalve molluscs, echinoderms, tunicates and marine gastropods, and products from these animals intended for human consumption 8364

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No: 8364

Export health certificate for entry into the European Union or Northern Ireland of live bivalve molluscs, echinoderms, tunicates and marine gastropods and products of animal origin from these animals intended for human consumption.

**NOTES FOR GUIDANCE (NFG) FOR THE CERTIFYING OFFICERS AND EXPORTERS
IMPORTANT**

These notes provide guidance for exporters and Certifying Officers (COs). For the purpose of signing Export Health Certificates (EHCs) to the European Union, COs are also 'Official Inspectors' as indicated on the EU certificates. 'Certifying Officers' are persons who have been specifically designated (authorised) for this purpose by the Central Competent Authorities. For additional details please see note three 'CERTIFICATION BY A CERTIFYING OFFICER', below.

This NFG should be read in conjunction with the health certificate and not be read as a standalone document. This NFG should have been issued to the Certifying Officer together with the relevant export certificate(s) for export to the EU of fishery products intended for human consumption.

We strongly advise that exporters obtain full details of the importing country's requirements via their importer from the Border Inspection post of entry to the EU and/or from the veterinary authorities in the country concerned, or their representatives in the UK, in advance of each consignment.

[Please note, NFGs will be further amended as the need arises. Certifying Officers and exporters should use the latest version available.]

1. APPLICABLE LEGISLATION

[Regulations \(EC\) No. 178/2002](#)

[Regulation \(EC\) No. 852/2004](#)

[Regulation \(EC\) No. 853/2004](#)

[Regulation \(EC\) No 2073/2005](#)

[Regulation \(EC\) 396/2005](#)

[Commission Regulation \(EC\) 1881/2006](#)

[Commission Decision 2011/163/EU](#)

[Commission Delegated Regulation \(EU\) 2020/692](#)

[Regulation \(EU\) No 2016/429](#)

[Regulation \(EU\) No 2017/625](#)

[Regulation \(EU\) No 2018/1882](#)

[Regulation \(EU\) No 2019/624](#)

[Commission Implementing Regulation \(EU\) 2019/627](#)

[Commission Delegated Regulation \(EU\) 2020/689](#)

[Commission Delegated Regulation \(EU\) 2020/691](#)

[Commission Implementing Regulation \(EU\) 2020/2235](#)

Please note that Official Control Regulations 2017/625 repeal Regulation (EC) No 854/2004 and Directive No 96/23/EC

EU legislation can be accessed via the following link. Please ensure you use the latest and/or consolidated versions and take into account any recent amendments not yet available in consolidated versions: <https://eur-lex.europa.eu/homepage.html>

Consolidated legislation

Consolidated texts, which integrate the basic instruments of European Union legislation with their amendments and corrections in a single, non-official document, are available. Each consolidated text contains a list of all legal documents taken into account for its construction.

You can search for consolidated texts by using the 'find results by document number' option on the European Commission website. Once you have selected the relevant legislation, click 'document information', and then scroll down to 'all consolidated versions' and select the most recent version.

<https://eur-lex.europa.eu/homepage.html>

Please note that the consolidated text may not contain the latest amendment to the legislation, as it takes several weeks for this to be updated.

Texts provided in this section are intended for information only. Please note that these texts have no legal value. For legal purposes please refer to the texts published in the 'Official Journal of the European Union'.

The Official Control Regulations and the Hygiene Regulations package

Certifying Officers must be aware of the provisions of [Regulations \(EC\) No 178/2002](#) of the European Parliament and of the Council, laying down the general principles and requirements of food law, and procedures in the matters of food safety. Additionally OV's must ensure they are aware of Regulation (EC) Nos [852/2004](#), [853/2004](#) and [2017/625](#), which lay out the requirements surrounding the establishment in which the fishery products for human consumption were produced, the implementation of HACCP principles, and the requirements surrounding the hygienic preparation processes.

[Regulation \(EU\) 2017/625](#) of the European parliament and of the council and [Commission Implementing Regulation \(EU\) 2019/628](#)

The sourcing, processing, handling and packaging of goods for export, must comply with all requirements in order to certify the goods for entry into and placing onto the European

Market. Specific attention is required for compliance with the sub-paragraph points listed in the EHC under Part II. 1.

The [Official Control Regulations 2017/625 \(OCR\)](#) have replaced and repealed Regulations (EC) No 854/2004, 882/2004 and Directive No 96/23/EC. Similar requirements are now contained in the OCR Regulations and legislation made under it.

The hygiene¹ Regulations referenced in the Certificate, have been made into UK law. They are primarily implemented and enforced according to the Food Law Code of Practice as published by the FSA and FSS.

UK legislation will no longer automatically be updated by changes in EU legislation. Where a discrepancy may arise in the requirements of the EU's Hygiene Regulations and similar regulations as implemented in the UK, the requirements of the EU text apply for EU certification purposes.

In relation to animal disease biosecurity, [Regulation \(EU\) 2016/429](#) and its supplementing [Regulation \(EU\) 2020/689](#) list requirements that are relevant to the certificate. Notes in the EHC indicate when these requirements apply.

2. SCOPE OF THE CERTIFICATE

This certificate may be used for entry into the European Union or Northern Ireland of live bivalve molluscs, echinoderms, tunicates and marine gastropods and products of animal origin from these animals intended for human consumption. Shucked oysters and processed molluscs where only the muscle remains, should also use this certificate. **Cephalopods are not in the scope of this certificate**; please refer to 8361EHC for this.

Please note that an additional health attestation must be completed for consignments containing processed bivalve molluscs belonging to the species *Acanthocardia tuberculatum*. This attestation and its relevant legislation can be found in Annex III, Chapter 32 of [Regulation \(EU\) 2020/2235](#) (However, this species is not known to be farmed in the UK.)

3. CERTIFICATION BY AN OFFICIAL VETERINARIAN (OV) or FOOD COMPETENT CERTIFYING OFFICER (FCCO)

In **England, Scotland and Wales**, this certificate can be signed by a Government Veterinary Officer (e.g., APHA, FSA or FSS employed veterinary officers) or by an Official Veterinarian (OV) appointed by the Animal and Plant Health Agency on behalf of Ministers in Defra, the Scottish Government or the Welsh Government and who hold the appropriate Official Controls Qualification (Veterinary) (OCQ (V)) authorisation.

In England, Scotland, and Wales this certificate may also be signed by a Food Competent Certifying Officer (FCCO) who is authorised by APHA. **An FCCO can only sign this EHC when the animal health attestation (II.2) can be deleted.**

The FCCO or OV must sign and stamp, with their Official stamp, the health certificate in ink of a different colour to that of the printing of the Export Health Certificate (EHC). There is no requirement to sign and stamp in a specific colour.

The FCCO or OV should keep a copy of the signed certificate and any supporting documents for at least two years after signature or receipt/dispatch of the consignment, whichever is later. These can be electronic copies.

EHC in foreign language/s of the EU Member States (MSs).

EHC should be in English and the foreign language of the Border Control Post (BCP) of entry in the EU. The original copy of the required EHC must accompany the consignment to the BCP of entry.

Listing of the EU MS BCPs can be found here: https://ec.europa.eu/food/animals/vet-border-control/bip-contacts_en

The foreign language certificate as received from the APHA Centre for International Trade at Carlisle or via the Export Health Certificates Online system (EHCO) and bearing the same unique reference number as the English certificate, should be considered an official and accurate translations of the English, as published in EU legislation.

The (sub-) paragraphs / options and how they are numbered and formatted is identical in the English and foreign language editions and to the legislation published by the European Commission. Therefore, the same phrases/sentences in the foreign language versions as in the English version should be struck through and these deletions should be stamped and initialled in both versions. Both versions must also be signed (as opposed to being initialled) and stamped by the OV, the foreign language certificate is deemed to be a genuine and properly authorised translation of the English version.

This also applies to any instructions in the guidance notes to strike out certain paragraphs or to certify statements that the country is free of certain notifiable diseases etc.

Additional information can be found in APHA Vet Gateway:

http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/index.htm

SIGNING AND STAMPING

When signing a certificate, the CO should ensure that the certificate contains no deletions or alterations, other than those which are indicated on the certificate to be permissible and any corrections to permitted entries, subject to such changes being initialled and stamped (in the margin) by the CO. Permissible deletions are normally indicated in the 'Notes' section at the end of the certificate, with the instruction 'Keep as appropriate' or 'delete if not applicable'.

- Where the certificate contains optional or contextual statements, the statements which are not relevant shall be crossed out, individually initialled, and stamped by the CO, or completely removed from the certificate.
- Permitted paragraphs and sections may be crossed out by applying a 'Z' across the section or paragraph rather than crossing out line by line.
- There is no requirement for a date and time to accompany each stamp. The date is only entered at the required entry field in Part I of the certificate, and at the end where the CO signs, stamps, and dates that action.
- We are aware of some BCPs demanding that all handwritten information in Part 1 of the EHC is initialled and stamped, including handwritten scoring out of otherwise blank boxes. There is no legal requirement in EU legislation that all the hand-written information entered in the certificate must be signed and stamped. It is only in the case of correction, in any part of the certificate, or in the case of statements to be crossed out, that the certifier must add signature (or initials) and stamp. This has been confirmed by the European Commission. The Commission noted however, in the case of a hand-written certificate, it is expected that the same one person completes the document. If not, the BCP might suspect that empty boxes were completed by another person after the certificate has been signed by the official

You should consider checking with the specific BCP regarding their preference when it comes to the stamping and initialling of handwritten scoring out of otherwise blank boxes in Part I of the EHC.

- **Clarification from the European Commission means that all pages (as opposed to sheets of paper) are signed and stamped once individually in place of fan stamping and in addition to any permitted alterations. There is no requirement to fan stamp.**
- COs are reminded to consult the Notes for Guidance prior to the certification of each EHC. NFG will be updated with this new information in due course.
- Further Information COs should make sure they are familiar with all relevant guidance and other documents relating to EHCs and that they discuss requirements with exporters in advance.
- See: <http://apha.defra.gov.uk/official-vets/Guidance/exports/ehc-online.htm>

You can also contact the Animal and Plant Health Agency's Centre for International Trade (CIT) on 03000 200 301.

PART I: DETAILS OF THE CONSIGNMENT

All boxes in Part I of the certificate must be completed. When a box is not applicable/optional, and not filled, please score it through.

Please use schedule to be attached to the certificate if there is not enough space to fill the information. See section '[Addition of Schedules](#)' for further information.

Please complete all the boxes in Part I of the certificate in accordance with the notes for the completion of certificates provided for in [Chapter 4 of Annex I to the Implementing Regulation \(EU\) 2020/2235](#).

Box I.8 - Region of origin:

In the free text box indicate the production area or “n/a” as appropriate.

Live bivalve molluscs (LBM), and products from these animals require Part I.8 ‘Region of origin’ on this certificate to be completed with the classified harvesting area entered by name and the associated approval code under ‘Code’.

BCPs will check these details against the EU TRACES list of approved premises, which holds a reference list of the classified harvesting areas in GB.

Classified harvesting area listing is only applicable for live bivalve molluscs and their products. No region is needed for tunicates, echinoderms or gastropods which are not filter feeders; scallops also do not require a region to be given if they have not been harvested from an area classified for pectinidae; instead “n/a” should be inserted into box I.8. See guidance below on II.1.h for details on scallops not from classified harvesting areas. For Live bivalve molluscs which do require Part I.8 Region of origin to be completed, the harvesting area code to be entered can be found at:

- [Live bivalve mollusc production areas \(seabed locations\) in Great Britain and the Crown Dependencies approved for export to the EU](#)
- [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/966945/Great Britain and Crown Dependencies Production Areas for Live Bivalve Molluscs.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/966945/Great_Britain_and_Crown_Dependencies_Production_Areas_for_Live_Bivalve_Molluscs.pdf)

Under the heading “SIN (Scotland)/RMP (England and Wales)/Unique Identifier (Crown Dependencies)”. A GBR prefix is not required.

I.20 - Commodity Certified for

‘Products for human consumption’: concerns only products of animal origin intended for human consumption for which an animal health, official certificate or animal health/official certificate is required by Union legislation.

‘Live aquatic animals for human consumption’: means animals destined to be prepared with a view to being supplied live to the final consumer.

‘Dispatch centre’: means an on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of molluscs intended for human consumption.

‘Further processing’: concerns products that *have to be further processed before being placed on the market* as well as live aquatic animals and products of animal origin from aquatic animals other than live aquatic animals, which are destined for a disease control aquatic food establishment as defined in Article 4(52) of Regulation (EU) 2016/429 of the European Parliament and of the Council.

“Further processing” means any type of measure or techniques affecting anatomical wholeness (e.g. bleeding, evisceration, heading, slicing, filleting) which produces waste or by-products which could cause risk of disease spread.

Box I.21 - Transits

If a consignment is transiting the EU to a third country, indicate the name and ISO country code of the third country of destination.

Animal health rules apply to consignments transiting the European Union, however public health rules do not apply to consignments of fishery products transiting the European Union.

Box I.27 - CN code

Please insert the **HS Code** and Combined Nomenclature (CN) title as discussed with the exporter.

The **Harmonised System (HS) Code** is a commodity classification system used as a basis for customs tariffs and for international trade statistics. **It is the exporter’s responsibility to ensure that the HS code and CN title is entered correctly and accurately reflects the product(s) being consigned, as defined by the World Customs Organisation and as referred to in [Council Regulation \(EEC\) No 2658/87](#)**

Further information on HS Codes for customs tariffs can be found online at:

<https://www.gov.uk/trade-tariff/sections> and

<http://madb.europa.eu/madb/euTariffs.htm>

Box I.27 - (Date of collection/production)

Guidance in Chapter 4 of Annex I of Regulation 2020/2235 states this should be the “oldest” date of collection/production - we have clarification from the EU Commission that this means the earliest date of final production of items contained in the consignment.

Identify the type of packaging according to the definition given in [Recommendation No 21 \(10\) of UN/CEFACT \(United Nations Centre for Trade Facilitation and Electronic Business\)](#).

PART II: CERTIFICATION

II.1 Public Health attestation for live bivalve molluscs, echinoderms, tunicates and marine gastropods and products of animal origin from these animals.

Products must have satisfactorily undergone the official controls laid down in:

- [Articles 51 to 66 of Commission Implementing Regulation \(EU\) 2019/627](#) (laying down requirements for LBMs from classified production and relaying areas) or

- [Article 11 of Commission Delegated Regulation \(EU\) 2019/624](#) (laying down controls on pectinidae, marine gastropods and Holothuroidea, which are not filter feeders, that are harvested from unclassified production areas) or
- [Articles 69 to 71 of Commission Implementing Regulation \(EU\) 2019/627](#) (laying down official controls on fishery products and approval of factory, freezer or reefer vessels). The CO signing the export health certificate is responsible for checking that the consignment complies with the particular public health attestations as set out in Part II.1 of the export health certificate. Where you as Certifying Officer are not part of the team that implements these food hygiene regulations, you should check with the Local Authority as appropriate that there are no concerns or enforcement issues that may affect the status and certification of the commodity being exported.

The starting point for certification of the consignment is the Food Business Operator's implementation and compliance with the relevant Regulations as indicated by the presence of the oval Identification Mark on, or associated with, the commodity, which indicates that the products have been produced at an approved food establishment in accordance with the requirements of the public health regulations mentioned in the certificate and subject to the Food Law Code of Practice risk based inspection regime of the relevant Competent Authority. Therefore, Certifying Officers (COs) should obtain, as appropriate, confirmation from the relevant professional working for the Competent Authority (a food competent authorised officer) that there are no concerns or investigations relating to the approval and safe production of food at the establishment(s) of production.

For primary production and handling prior to arrival at the approved premises, compliance with the referenced Regulations, the Certifying Officer may rely on the UK's Competent Authorities for the implementation of legislative requirements and controls according to the Food Law Code of Practice (FLCoP) as published by the Food Standards Agency / Food Standards Scotland respectively. The goods must have been produced and be in compliance with the general and specific requirements stated in the EHC, including that any processing was undertaken at approved food establishments. COs should make additional appropriate checks and inspections to satisfy themselves that the standards required for certification of the goods are being met, including the specification, quantity, and packaging of the goods.

For goods that were processed prior to arrival at the approved food establishment, or that were processed elsewhere prior to export, for the avoidance of doubt, COs (including OVs) should accept an official completed EHC or an attestation document on the Local Authority's letterhead, which provides the relevant assurances needed for completion of the official EHC that will accompany the goods for export. Any such supporting document must be appropriately stamped and signed by a CO, to facilitate completion of the final export certificate.

Please note that this EHC (8364) cannot be used to export Live Bivalve Molluscs that have been harvested from Class B areas, unless purified or relayed in the UK to the relevant standard. This statement does not apply to pectinidae (scallops) which have their own specific requirements and must be despatched from an approved food premises, usually a dispatch centre.

Similarly, LBM that require relaying may not be exported with this certificate (8364). LBM that require relaying may still be able to be exported under a 'live animal aquaculture certificate' issued by the relevant competent authority (Cefas, Marine Scotland).

Please note that if products are of aquaculture origin, COs must ensure those fulfil the residues' guarantees. Please see Section 'Residue Check Guarantee' below.

II.1. Public Health Attestation – [This cannot be deleted as GB does not have equivalence agreements with the EU, nor is it part of the EU.]

II.1 –

(a) Insert the applicable region of origin code, for example for Great Britain: 'GB'. This may be certified based on GB and The Crown Dependencies being listed in Annex VIII of Commission Implementing [Regulation 2021/405](#) (amended by Commission Implementing Regulation 2021/606) for entry into the European Union of consignments of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods, in accordance with [Article 127\(2\) of Regulation \(EU\)2017/625](#).

(b) Can be certified based on the establishment(s) being approved by the relevant competent authority and being listed by the EU. See Section 9 for more information.

(d, e, f and g) Please note that in attestations there are deletion options based on whether the consignment consists of live or processed animals.

(h) To certify in the case of ***Pectinidae, marine gastropods and Holothuroidea*** that are not filter feeders harvested outside classified production areas, COs must ensure that those products comply with the specific requirements laid down in Section VII, Chapter IX of Annex III to Regulation (EC) No 853/2004. This requires standards to be demonstrated by a "system of own-checks", so the CO should be satisfied that these standards have been met – either by results from end-product testing, or evidence that a satisfactory monitoring system is in place based on FSA/FSS guidance:

- <https://www.food.gov.uk/business-guidance/biotoxin-and-phytoplanktonmonitoring#scallop-pectinidae-monitoring>
- https://www.foodstandards.gov.scot/downloads/Managing_Shellfish_Toxin_Risks_in_the_Scallop_Sector_Guidance_-_JULY_2018_PDF.pdf.

Currently no validated testing method is available to verify that the biotoxin levels within consignments of marine gastropods are within acceptable levels for human consumption prior to export. To allow attestations and certification of marine gastropod consignments for export to the EU, FBOs should apply an interim measure based on testing using rapid lateral flow assays to detect all regulated Paralytic Shellfish Poison (PSP), Amnesic Shellfish Poison (ASP) and Lipophilic toxins, including Diarrhetic Shellfish Poison (DSP) toxins. This interim measure only relates to marine biotoxins and therefore does not impact on the E. coli and Salmonella requirements as listed in Regulation (EC) 2073/2005. The interim measure will be in place until a validated testing method for biotoxins in marine gastropod molluscs is available.

(i) Please indicate the classification of the production area [A] [B] or [C] at the moment of harvesting by deleting the ones which do not apply. (except for Pectinidae, marine gastropods and Holothuroidea that are not filter feeders, which are harvested outside classified production areas)

(j) For LBMs from classified shellfish harvesting areas this paragraph may be certified on the basis of official controls carried out by FSA and FSS

(k) This paragraph may be certified on the basis that the national surveillance scheme implements Council Directives 96/22/EC and 96/23/EC, which are transposed into national legislation by The Animals and Animal Products (Examination for Residues and Maximum Limits) Regulations 1997. UK is listed in [Decision 2011/163/EU](#).

II.2 Animal Health attestation

If applicable the Official Veterinarian signing the export health certificate must ensure that the animal health attestations set out in Part II.2 of the health certificate have been complied with.

The whole of Part II.2 can be deleted as per footnote (2) If the consignments consists of:

a) species other than those LBMs listed in the [Annex to Commission Implementing Regulation \(EU\) 2018/1882](#)

i. To note, as per footnote 3, species listed in column 4 of this annex shall only be regarded as vectors under the conditions set out in [Article 171 of Delegated Regulation \(EU\) 2020/692](#):

- POAO from aquatic animals other than live aquatic animals **shall not** be regarded as vectors
- Aquatic animals shall only be regarded as vectors under conditions set out in the [Annex XXX of Regulation \(EU\) 2020/692](#). **LBMs which are listed in Column 4 and are harvested from the sea are considered vectors for this purpose as they are in contact with column 3 listed species.**

OR

b) wild aquatic animals and POAO from those wild aquatic animals which are landed from fishing vessels for human consumption. **Hand-gathered wild molluscs are not exempt from the animal health requirements, and II.2 will need to be certified unless footnote 2a or 2c apply.**

OR

c) products of animal origin from aquatic animals (other than live aquatic animals) which are ready for direct human consumption without undergoing further processing in the Union

This means that II.2 can be deleted for POAO (other than live aquatic animals) which are not known to be going for further processing in the EU.

“Further processing” means any type of measure or techniques affecting anatomical wholeness (e.g. bleeding, evisceration, heading, slicing, filleting) which produces waste or by-products which could cause risk of disease spread. To note this does not include wrapping or packaging.

*II.2 **cannot** be deleted where the consignment consists of any of the following:*

- *Listed live bivalve molluscs from aquaculture or hand caught from the sea*
- *Products of these LBMs which are known to be going for further processing in in the EU.*

For example:

*For live European flat oysters from aquaculture going to any destination in the EU, II.2 **cannot** be deleted, and this will require certification by an OV.*

*For POAO from European flat oysters (which are not live) from aquaculture, which are going to be further processed in the EU (excluding wrapping and packaging), II.2 **cannot** be deleted, and this will require certification by an OV.*

*For POAO from European flat oysters (which are not live) from aquaculture, which are destined for a market, or going for wrapping or packaging without any other processing, in the EU, II.2 **can** be deleted, and this can be certified by a FCCO or an OV.*

*For live hand collected wild cockles, II.2 **cannot** be deleted and will require certification by an OV. However, where their products (other than live animals) are exported, II.2 can be deleted, and these can be certified by a FCCO or an OV.*

See Annex below for further examples.

II.2.1 - The Certifying Officer must ensure that they are aware of the relevant diseases listed in [Part 4 of Annex I to Delegated Regulation \(EU\) 2020/692](#) Certification can be based on Section 4 Notifiable Disease Clearance (see paragraph below), supporting documentation from the establishment vet can also be sought.

Annex I of Commission Decision 2021/260 and Annexes XV, XVI, and XVII of Commission Implementing Regulation 2021/620 also lays down the MS's/territories/zones or compartments declared free from some listed diseases.

II.2.2 - This only applies to aquaculture animals and POAO from aquaculture animals.

II.2.2.1 - This can be certified on the basis the aquaculture premises are authorised by the Fish Health Inspectorate and in compliance with The Aquatic Animal Health (England and Wales) or (Scotland) Regulations 2009.

II.2.2.2 – This can be certified on the basis of history of surveillance by Fish Health Inspectors in accordance with Aquatic Animal Health (England and Wales) Regulations (2009) or Aquatic Animal Health (Scotland) Regulations (2009), and one or more of the following measures:

- The certifying OV's direct knowledge of the site and its disease status.
- Records of a health visit to the site by a veterinarian who has knowledge of the premises and its operation.

General Animal Health Requirements

II.2.3.1 and II.2.3.2 - These attestations can be deleted if consignment contains only the aquatic animals detailed in Footnote 6.

II.2.3.1 - The appropriate code should be entered as per Annex XXI of Implementing Regulation 2021/404 (amended by Implementing Regulation 2021/634). For example, for Great Britain enter: 'GB-0'.

II.2.3.3 - This can be certified based on the OV's knowledge of the dispatching establishment and transport conditions.

II.2.3.4 - This can be certified as GB aquaculture premises which do not meet GB standards will be subject to formal controls preventing them from trading to other areas, and packaging conditions that prevent contamination.

II.2.4 Specific Health Requirements [Either/Or Option]

Either: This section may be deleted if Footnote 6 applies.

As per footnote 4 where statements are not applicable, they should be deleted where indicated.

II.2.4.1. - Requirements for species listed (as per Footnote 3) for infection with

- ***Microcytos Mackini*** (Pacific Oyster, Eastern Oyster, Olympia Flat Oyster and European Flat Oyster **and Vector species as applicable**)
- ***Perkinsus Marinus*** (*Pacific Oyster, Eastern Oyster and Vector species as applicable*)

To note: only live aquatic animals are regarded as vectors

The first paragraph may be completed based on the Notifiable Disease Clearance status of the waters of origin of the consignment. See Section 4 below on notifiable disease clearance.

Freedom from *Perkinsus marinus* and *Microcytos mackini* in GB can be certified by default. Should this change for any reason, e.g., a disease status is being investigated, the Certifying Officer (CO) or organisation holding relevant certificates will be officially notified of suspension to certify for this status.

(i) This may be completed based on the Notifiable Disease Clearance status of origin of the consignment. See Section 4 below on Notifiable Disease Clearance For imported consignments this may be certified based on the accompanying import EHC or attestation of competent authority

(ii) may be certified if of GB origin as vaccination for these diseases is prohibited. If of foreign origin, then it may be certified based on GB's import requirements.

II.2.4.2. - Requirements for species listed (as per Footnote 3) for infection with

This section may be deleted if the Member State of destination of the consignment does not have disease free status, nor is it subject to an optional eradication scheme, for the following diseases as per footnote 7. The relevant member states are listed in the corresponding annexes of [Commission Implementing Regulation\(EU\) 2021/620](#).

Annex XV- *Martelia refringens*

Annex XVI- *Bonamia exitiosa*

Annex XVII- *Bonamia ostreae*

- *Martelia refringens* (Australian Mud Oyster, Chilean Flat Oyster, European Flat Oyster, Argentinian Oyster **and Vector species as applicable**)
- *Bonamia exitiosa* (Australian Mud Oyster, Chilean Flat Oyster, European Flat Oyster **and Vector species as applicable**)
- *Bonamia ostreae* (Australian Mud Oyster, Chilean Flat Oyster, Olympia Flat Oyster, Asian Oyster, European Flat Oyster, Argentinian Oyster **and Vector species as applicable**)

To note: only live aquatic animals are regarded as vectors

The first paragraph may be completed based on the Notifiable Disease Clearance status of the waters of origin of the consignment. See Section 4 on Notifiable disease clearance below.

Freedom from *Bonamia exitiosa* in GB can be certified by default. Should this change for any reason, e.g., a disease status is being investigated, the Certifying Officer (CO) or organisation holding relevant certificates will be officially notified of suspension to certify for this status.

For imported consignments this may be certified based on the accompanying import EHC or an attestation from the competent authority.

Due to the presence of *Marteilia refringens* in certain parts of the UK, species susceptible to *Marteilia refringens* may therefore only be exported to countries/compartments/zones which neither have disease free status nor are subject to an optional eradication programme as per Footnote 7.

(at time of writing, the waters of the Republic of Ireland and part of the waters of Northern Ireland(see [Annex XV 2021/620](#)) alone have disease free status. No member states have optional eradication programmes currently. 27/4/21)

Due to the presence of *Bonamia ostreae* in certain parts of the UK, species susceptible to *Bonamia ostreae* may therefore only be exported to countries/compartments/zones which neither have disease free status nor are subject to an optional eradication programme as per Footnote 7.

(at time of writing the whole territory of Estonia and parts of the waters of both the Republic of Ireland and Northern Ireland (see Annex XVII 2021/620) alone have disease free status. No member states have optional eradication programmes currently. 27/4/21)

The second statement may be certified if of GB origin as vaccination for these diseases is prohibited. If of foreign origin, then it may be certified based on GB import requirements.

II.2.4.3. - Requirements for species listed as per Footnote 9 susceptible to infection with

- Ostreid Herpes Virus 1. (Pacific Oyster)

This section may be deleted if the Member State of destination of the consignment does not have approved national measures in place for Ostreid Herpes Virus 1 as per footnote 8. The relevant member states are listed in Annex I and II of [Commission Implementing Regulation\(EU\) 2021/260](#).

This paragraph may be completed based on the Notifiable Disease Clearance status of the waters of origin of the consignment. See Section 4.

Due to the presence of Ostreid Herpes Virus in certain parts of the UK, species susceptible to Ostreid Herpes Virus cannot be exported from those parts if the Member State of destination of the consignment has approved national measures in place for Ostreid Herpes Virus 1 as per footnote 8.

Or: [II.2.4 Specific Health Requirements cont.]

This section may be deleted, if Footnote 6 applies

II.2.4 - This paragraph may be certified if the consignment is destined for an approved disease control aquatic food establishment for processing for human consumption. Otherwise, it should be deleted and the above EITHER option should be certified.

II.2.5 - These points may be certified on the basis of Personal Knowledge of the establishment and a signed declaration by the Operator.

II.2.6 - Transport requirements

Although there is not a (4) by this paragraph to permit its deletion, the EU Commission has confirmed that the whole paragraph II.2.6 can be deleted if the EHC is used to certify POAO. If the EHC is used to export live aquatic animals, this paragraph must be certified.

II.2.6.1 - This can be certified based on the CO's knowledge of the processes and scrutiny of the route plan the exported consignment will take to enter the EU.

II.2.6.2 and II.2.6.3 - A Certifying Officer (CO) or Certification Support Officer (CSO) must be present to confirm that the requirements have been met, as applicable.

The Certifying Officer should ensure that the transport conditions of the live bivalve molluscs do not alter their health status including confirming that they do not come into contact with water that has been in contact with live bivalve molluscs of a lower health status. **II.2.7 -**

Labelling requirements

The stipulations of labelling are detailed as described in [Article 169 of Delegated Regulation \(EU\) 2020/692](#). The legible label must clearly link the consignment/containers to this EHC. Any traceability information which is entered in Part 1 of the EHC which can link the consignment to the certificate may be used.

II.2.7.2 - This can be deleted if the consignment does not contain live animals. c) An estimate number of live aquatic animals is acceptable.

II.2.7.3 - This can be deleted if the consignment does not contain POAO from aquatic animals (other than live animals).

4. NOTIFIABLE DISEASE CLEARANCE

Some export certificates for animals and animal products will include statements that will require the OV to certify that specified zones or the entire country of origin are free from certain diseases.

COs must check the following sources of disease information for the United Kingdom immediately prior to certification, to ensure disease freedom statements can be certified: The disease status of each farm in Great Britain is accessible at:

- <https://www.gov.uk/government/groups/fish-health-inspectorate#disease-status-offishshellfish-and-crustacea-in-england-and-wales>
- <https://www.gov.scot/publications/registers-of-authorised-aquaculture-productionbusinessesand-authorised-processing-establishments/>
- <https://www.gov.scot/publications/health-status-of-fish-and-shellfish-diseases-in-scotland/>.

Note: For aquaculture purposes the CO must treat GB and NI as separate epidemiological areas or zones.

5. RESIDUE CHECK GUARANTEE

The UK has a surveillance programme in place to monitor for residues of authorised veterinary medicines, prohibited substances, and other contaminants in domestically produced foodstuffs of animal origin. Sample collection is conducted at the point of production i.e., at farm and slaughterhouse. The requirement for this monitoring is outlined in The Animal and Animal Products (Examination for Residues and Maximum Residue

Limits) (England and Scotland) Regulations of 2015 and equivalent legislation in Wales (2019) and Northern Ireland (2016). The monitoring conducted in GB is in accordance with the legislative requirements of Directive 96/23 (EC), 96/22 (EC), Decision 97/747 (EC) and 470/2009 (EC) concerning residue testing of products of animal origin. The residues tested in the programme are in accordance with Annex I and II of Directive No 96/23 (EC), specifically, and include veterinary medical products, banned substances and environmental contaminants.

With regards to maximum levels used to determine sample non-compliance, for authorised veterinary medicines GB work to the GB Maximum Residue Limits (MRLs) published [here](#); these MRLs are aligned to the EU veterinary MRLs published under Reg (EU) 37/2010. If a pesticidal compound has an MRL for food-producing species then this MRL is used as the respective non-compliance threshold, but if a pesticide does not have a foodstuff MRL then the MRLs as listed in Regulation (EC) 396/2005 are applied. For contaminants, such as heavy metals and mycotoxins, the limits as set out in Reg (EC) 1881/2006 are used to determine sample non-compliance.

The results of the statutory surveillance programme can be accessed on the link below:

<https://www.gov.uk/government/collections/residues-statutory-and-nonstatutory-surveillance-results>

The EHC residue testing requirements can be certified based on evidence of compliance to the national surveillance programme, which complies with the relevant EU legislation.

The national monitoring programme for pesticide MRLs in food and feed in place under Regulation 396/2005 is underpinned by national legislation, The Pesticides (Maximum Residue Levels) Regulations (England and Wales) 2008 (as amended) and devolved administration equivalents. A national monitoring programme for Maximum Residue Levels is managed by the Health and Safety Executive. This involves testing a selection of produce that has already been placed on the market in Great Britain to provide assurance that only authorised pesticides, within permitted levels, are present. The results are published in an annual report. Annual reports can be found on gov.uk. <https://www.gov.uk/government/publications/expert-committee-on-pesticide-residues-in-food-prif-annual-report>

Any EHC residue pesticide requirements can be certified based on evidence of compliance with the pesticide residue monitoring scheme.

<https://www.gov.uk/government/collections/pesticide-residues-in-food-results-of-monitoring-programme>.

6 COLLECTION OF EVIDENCE

In GB, the Certification Support Officer (CSO) role has been developed by APHA. CSOs can collect evidence, directed by an OV, which may be used to support OV certification of matters which do not require a clinical assessment or judgement e.g., for POAO and ABPs.

In **England, Scotland and Wales**, CSOs can be utilised by OV's for gathering evidence relating to this certificate. The CSOs must be authorised by APHA and they must hold the appropriate Official Controls Qualification (Animal Health Professional) (OCQ (AHP)-CSO) qualification.

The OV must direct the CSO as to how and where any necessary evidence relevant to the requirements of the Export Health Certificate (EHC) should be obtained. CSOs may not carry out any functions that require the exercise of veterinary judgement and are restricted to the execution of administrative checks.

They may only carry out such inspections, factual verification and evidence collection as specified by the directing OV, who remains responsible for the certification of the product. CSOs are not authorised to sign an EHC in their own right or on behalf of an OV.

Any documentary evidence collected by the CSO must be stamped, signed, and dated by the CSO, before being submitted by them as supporting evidence to the OV. It is required that the OV is familiar with the product process and evidence required to start with, before directing the CSO to provide future evidence on an ongoing basis.

Additional guidance and principles of implementation are provided in the [OV Instructions Exports section](#) of the APHA Vet Gateway.

7. Groupage Export Facilitation Scheme (GEFS)

For groupage exports from Great Britain, where certain types of products are produced from a stable supply chain and are fully packaged for the final consumer, exporters who are GEFS members may use 30 day support attestations to provide information to OV's to facilitate completion of this certificate.

For further information including the definition of groupage exports, the template 30-day support attestation which must be used and requirements for exporters, suppliers and vets to use the scheme see:

http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/Products_Exports.html

You can check that exporters are GEFS members by emailing the exporter's name, GEFS membership number and the address of the exporting premises to GEFS@defra.gov.uk

8. CONSIGNMENTS OR PARTS OF THE CONSIGNMENT ORIGINATING FROM NI, EU MEMBER STATES OR FROM A THIRD COUNTRY (TRIANGULAR TRADE)

NI origin:

For Northern Ireland origin raw materials which have then been processed into a final product in GB or are presented in their original state and bearing a UK(NI) identification mark, the CO can certify certain matters relating to EU compliance at a national level.

Where the EHC refers to EU approval status of the premises of origin or manufacture in NI, this can be certified under the terms of the [EU-UK Withdrawal Agreement and the Northern Ireland Protocol \(NIP\)](#). The NIP treats NI as if it is in the EU SPS zone (which includes the EEA/EFTA states). Approved and registered premises in NI continue to implement the full

requirements of Regulation (EC) Nos. [852/2004](#) and [853/2004](#) and Regulation (EU) No. [2017/625](#) and all relevant supporting EU legislation as set out in Annex 2 to the Protocol. This compliance is indicated by the presence of the EU oval health and identification marks applied to the products.

Some examples, but not a complete list, of how assurance can be established at national level are listed below.

Compliance with the microbiological criteria set out in [Regulation \(EC\) No. 2073/2005](#) can be certified if the products originate in an EU approved premises in NI, and bearing the EU oval ID mark.

Public health statements referring to compliance with EU requirements for testing for residues as set out in [Regulation \(EU\) No 2017/625](#), Directive (EC) [Nos 96/22](#) and [470/2009](#) can be certified by the CO on the basis of a national residue surveillance programme implemented in NI under [The Animals and Animal Products \(Examination for residues and maximum Residues Limits\) Regulation \(NI\) 2016](#). This forms part of the UK national surveillance programme.

With regards to controls for Transmissible Spongiform Encephalopathies, guidance provided in this document relating to statements about the method of slaughter of animals in GB also applies to animals slaughtered in NI and can be certified by the CO on that basis.

Disease clearance for animals or products originating in NI can be completed using auto-clearance NDC found here:

<https://www.daera-ni.gov.uk/articles/notifiable-diseases-northern-ireland>

Where regional or local level disease clearance is required, this can be certified upon request on the basis of information from NI in the form of a declaration or a supporting health attestation.

Animal health statements which refer to the prohibition of certain vaccination programmes e.g. against FMD or CSF or ASF can be certified at a national level by the CO on the basis that NI also enforces a ban on such vaccinations in accordance with EU regulations.

Statements relating to implementation of a national system for identification and registration of bovine animals can be certified on the basis of the requirement to register all bovine animal births, moves and deaths on the DAERA database.

Animal welfare statements can be certified by the CO on the basis that relevant inspections, monitoring and controls are implemented in NI through [The Welfare of Animals at the Time of Killing Regulations \(NI\) 2014 as amended](#), in compliance with [Regulation \(EC\) No. 1099/2009](#).

Animal By-Products are handled in accordance with [EU Regulation 1069/2009](#), which is implemented by the [EU Implementing Regulation 142/2011](#), and ABP statements for materials originating in NI, can be certified on that basis.

When the certificate requires specific information to be included, such as the date of slaughter or the date of introduction into NI, the GB exporter/CO must request this

information from the NI exporter. This NI exporter may forward the request to the relevant NI CO to provide this information. This supporting information must be in writing and kept by the GB CO. The GB CO is not required to attach it as a supporting document to the EHC, unless requested by the EU Border Control Post or told otherwise.

EU origin:

It is possible that some consignments may contain animal products that are of EU origin and were imported into GB on a Commercial Document or EU Intra-Trade Animal Health Certificate (ITAHC). The Commercial Document may not contain enough information to allow the CO to sign an EHC.

In such cases, the CO will need further information from the EU member state regarding particular attestations on the EHC that cannot be signed by the CO without support documentation. Thus, the GB exporter must request from the EU exporter an attestation or written declaration from an EU registered vet, The GB exporter may wish to obtain these directly from the EU vet who has inspected the animal products before export from the EU.

When the certificate requires specific information to be included, such as the date of slaughter or the date of introduction into the EU, the GB exporter/CO must request this information from the EU exporter. This EU exporter may forward the request to the relevant EU vet to provide this information. This supporting information must be in writing and kept by the GB CO. The GB CO is not required to attach it as a supporting document to the EHC, unless requested by the EU Border Control Post or told otherwise.

Third country origin:

It is also possible that some consignments may contain POAO that have been imported to GB from non-EU countries and then processed in GB, which GB exporters intend to export to EU (known as Triangular Trade). In these cases, COs may obtain a copy of the EHC for the import of such commodity from the Third Country to the GB.

GB COs are not required to attach a copy of the Third Country EHC as a supporting document to the EHC, unless requested by the EU Border Control Post or specifically instructed in the NFG.

It is the GB exporter's ultimate responsibility to obtain any necessary support documents (from the EU member state exporter/Third Country exporter), to enable GB COs to be able to certify the products in good time before the export to the EU.

9.UK APPROVED ESTABLISHMENTS ELIGIBLE TO EXPORT TO THE EU

The exporting establishment must be listed as a 'UK approved establishment' and a list of UK approved establishments for import of POAO to the EU, can be found on the European Commission's list of approved establishments' link below:

https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en

Please note that the list is updated regularly and ONLY establishments on the list are approved to export to the EU, and this does not include establishments with pending applications for approval.

If the final product contains POAO from other establishments, or products were previously processed in different establishments in the production chain, then these establishments should also be listed as UK and/or EU approved establishments.

There are lists of approved establishments for other commodities, e.g. germinal products on the link above.

10. OVAL MARK ON 'PRODUCTS OF ANIMAL ORIGIN – POAOs'

EU hygiene regulations require that food of animal origin carries an oval health or identification mark and that official controls are carried out by enforcement authorities to ensure the appropriate marking has been applied. Domestic legislation has been introduced to ensure these requirements continue to apply in GB as retained legislation.

The health marks indicate that meat is fit for human consumption and the identification marks show when foods of animal origin have been produced in officially approved establishments which are compliant with retained EU food hygiene Regulations (EC) No [852/2004](#), (EC) No [853/2004](#) and (EU) No [2017/625](#). Also, the primary food legislation in England, Wales and Scotland is [The Food Safety Act 1990 \(as amended\)](#).

<https://www.food.gov.uk/business-guidance/guidance-on-health-and-identification-marksthat-applies-from-1-january-2021>

Relevant text on the EHC can be certified on the basis that carcasses, half carcasses or quarters, or half carcasses cuts into three pieces, of domestic ungulates, farmed game mammals (other than lagomorphs) and large wild game bear the official health mark or that the primary, secondary and/or shipping packaging on food products of animal origin show the identification mark.

11. ADDITION OF SCHEDULES

When the space in Part I or Part II of the certificate is insufficient to accommodate full details of the consignment a schedule may be used. In the relevant section of the certificate the CO should annotate the certificate 'see attached schedule'. A new schedule should be created (typed or clearly written) containing the same information as that required in the certificate. The schedule must include the certificate reference number on each page and must be signed, dated, and stamped by the CO in a colour other than the printed text on each page and under the last entry. The schedule forms part of the certificate. All pages of the certificate, including the schedule, must be sequentially numbered. Any blank spaces in the schedule or the certificate should be struck through with diagonal lines.

Further guidance is available here:

http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/index.htm

12. CERTIFIED COPIES OF EXPORT HEALTH CERTIFICATES

When completing export certificates, the CO and, if applicable, FCCO must make photocopies of, or scan and save all documents they certify. OVs must retain copies of certification documents in accordance with RCVS Certification principles.

<https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professionalconduct-for-veterinary-surgeons/supporting-guidance/certification/>

COs must retain copies of all export documentation for a period of two years. A certified copy of this EHC does not need to be returned to the APHA CITC. For the purposes of completing routine Quality Assurance checks on export certification, CITC may request certified copies of certification from COs.

Further details on Post Certifying Procedures, ‘certified copies’ of certification and the types of documents that should be retained by COs can be found on the [APHA Vet Gateway](#).

13. LEGAL STATEMENT

The existing EU legislation that the UK complied with prior to the end of the Transition Period has been incorporated into our domestic law as “retained EU law” under the [European Union \(Withdrawal\) Act 2018](#). References in our guidance and certification to such EU instruments should be taken to be references to this “retained EU law”. The EU standards that this legislation includes continue to remain in force, without substantive amendment, as part of UK domestic law (apart from corrections to make the EU legislation fully operable

14. DISCLAIMER

This certificate and NFG are provided on the basis of information available at the time and may not necessarily comply fully with the requirements of the importing country. It is the exporter’s responsibility to check the certificate against any relevant import permit or any advice provided by the competent authority in the importing country. If these do not match, the exporter should contact the Animal and Plant Health Agency (APHA) in Carlisle.

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Annex

Please note this is an illustration of common examples of exports and should not be viewed as a definitive table of all possible scenarios. The CO must ensure that all relevant requirements in the EHC are met.

Commodity for export	Who can certify these EHCs?	Is there a requirement for regular health inspection of the aquaculture premises by a vet?	Does the consignment need clinical inspection by an OV?
Any species of wild caught shellfish landed by a fishing vessel	FCCO or OV	No	No
Any species not listed in column 3 or 4 of the Annex to Regulation 2018/1882	FCCO or OV	No	No
Any product (other than live animals) of species only listed in column 4 of Annex to Regulation 2018/1882	FCCO or OV	No	No
Any product (other than live animals) not intended for further processing* in the EU or Northern Ireland	FCCO or OV	No	No
Farmed live Pacific oysters (or their products which are intended for further processing* in the EU or Northern Ireland)	OV	Yes	Not if requirements in footnote 6 of EHC are met
Farmed live European oysters (or their products which are intended for further processing* in the EU or Northern Ireland)	OV	Yes	Not if requirements in footnote 6 of EHC are met
Farmed live blue mussels	OV	Yes	Not if requirements in footnote 6 of EHC are met
Farmed live king scallops (Great Atlantic scallops)	OV	Yes	Not if requirements in footnote 6 of EHC are met
Wild hand collected live cockles	OV	No	Not if requirements in footnote 6 of EHC are met
Products (other than live animals) of blue mussels, king scallops or cockles	FCCO or OV	No	No

Farmed live queen scallops (or their products)	FCCO or OV	No	No
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* "Further processing" means any type of measure or techniques affecting anatomical wholeness (e.g. bleeding, evisceration, heading, slicing, filleting) which produces waste or by-products which could cause risk of disease spread. To note this does not include wrapping or packaging.