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COMMISSION IMPLEMENTING DECISION (EU) 2018/320

of 28 February 2018

on certain animal health protection measures for intra-Union trade in salamanders and the introduction into the Union of such animals in relation to the fungus *Batrachochytrium salamandrivorans*

(notified under document C(2018) 1208)

(Text with EEA relevance)

(OJ L 62, 5.3.2018, p. 18)

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Article 1

Subject and scope

This Decision lays down the animal health protection measures for intra-Union trade in consignments of salamanders and the introduction of such consignments into the Union.

Article 2

Definitions

For the purposes of this Decision, the following definitions shall apply:

(a) ‘salamanders’ means all amphibians of the order *Caudata*;

(b) ‘Bsal’ means the fungus *Batrachochytrium salamandrivorans* (kingdom fungi, *Phylum Chytridiomycota,* order *Rhizophydiales*);

(c) ‘epidemiological unit’ means a group of salamanders with the same likelihood of exposure to Bsal;

(d) ‘quarantine’ means the keeping of salamanders in isolation with no direct or indirect contact with salamanders outside their epidemiological unit, for the purposes of ensuring that there is no spread of Bsal while the animals in isolation are undergoing observation for a specified length of time and testing and, if appropriate, treatment;

(e) ‘operator’ means any natural or legal person having salamanders under its responsibility, including for a limited duration of time, but excluding pet keepers;

(f) ‘appropriate establishment’ means premises:

(i) where salamanders are kept in quarantine before being dispatched to another Member State or after their introduction into the Union; and

(ii) which are registered by the competent authority prior to the date of commencement of any quarantine;

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(g) ‘appropriate diagnostic test’ means a real-time quantitative polymerase chain reaction (qPCR) assay containing species-specific STerF and STerR primers amplifying a 119 nucleotide long fragment of Bsal DNA;

(h) ‘common veterinary entry document’ or ‘CVED’ means the document notifying the arrival of animals into the Union as provided for in Article 1 of Regulation (EC) No 282/2004 and drawn up in accordance with the model set out in Annex I thereto and managed by the integrated computerised veterinary system known as Traces;

(i) ‘confirmed case of Bsal’ means the confirmation of the presence of Bsal or its genetic material on or in the tissues of salamanders by the appropriate diagnostic test;

Article 3

Animal health conditions for intra-Union trade in salamanders

1. Member States shall prohibit the dispatch of consignments of salamanders to another Member State, except where such consignments comply with the following animal health conditions:

(a) they are accompanied by an animal health certificate which complies with the model animal health certificate set out in Part A of Annex I;

(b) the salamanders must not show clinical signs of Bsal, in particular they must show no skin lesions and ulcers at the time of examination by the official veterinarian; that examination must be carried out within a period of 24 hours prior to the time of dispatch of the consignment to the Member State of destination;

(c) the salamanders must come from a population where there have been no mortalities due to Bsal and no clinical signs of Bsal, in particular skin lesions and ulcers must not have been observed by the operator;

(d) the consignment must consist of:

(i) at least 62 salamanders which have undergone quarantine as one epidemiological unit in an appropriate establishment which complies with the minimum conditions set out in Annex II for a period of at least 6 weeks immediately prior to the date of the issuing of the animal health certificate set out in Part A of Annex I and skin swab samples from the salamanders in the consignment must have been tested for Bsal with negative results during the fifth week of the period of quarantine with the appropriate diagnostic test, in accordance with the sample sizes set out in point 1(a) of Annex III; or

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(ii) salamanders which have been treated to the satisfaction of the competent authority against Bsal in accordance with point 1(b) of Annex III.

2. Where consignments of salamanders have been introduced into the Union from a third country and they have already undergone quarantine in an appropriate establishment of destination in accordance with Article 6, Member States shall only authorise their dispatch to another Member State where such consignments comply with the following conditions:

(a) the animal health conditions laid down in paragraph 1(a), (b) and (c);

(b) the salamanders have been kept in quarantine in the appropriate establishment which complies with the minimum conditions set out in Annex II, between the end of the period of quarantine following their introduction into the Union and the issuing of the animal health certificate set out in Part A of Annex I.

Article 4

Animal health conditions for the introduction into the Union of consignments of salamanders

Member States shall prohibit the introduction into the Union of consignments of salamanders from a third country, except where such consignments comply with the following conditions:

(a) they come from third countries listed in one of the following:

(i) Annex I to Decision 2004/211/EC;

(ii) Part 2 of Annex II to Decision 2007/777/EC;

(iii) Annex I to Regulation (EC) No 798/2008;

(iv) Part 1 of Annex I to Regulation (EC) No 119/2009;

(v) Part 1 of Annex II to Regulation (EU) No 206/2010;

or

(vi) Annex I to Regulation (EU) No 605/2010;

(b) they are accompanied by an animal health certificate which complies with the model animal health certificate set out in Part B of Annex I;

(c) the salamanders must not show clinical signs of Bsal, in particular there must be no signs of skin lesions and ulcers at the time of examination by the official veterinarian; and that examination must have been carried out within a period of 24 hours prior to the time of dispatch of the consignment to the Union;

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(d) before issuing the animal health certificate referred to in point (b), the epidemiological unit comprising the salamanders in the consignment must have been isolated from other salamanders at the latest at the time of the examination for the purposes of issuing of animal health certificate and they must not have been in contact with other salamanders since that time.

Article 5

Attestation regarding the appropriate establishment of destination

Member States shall ensure that border inspection posts do not accept the entry into the Union of consignments of salamanders unless importers or their agents provide a written attestation, in an official language of the Member State of the border inspection post of entry into the Union, which is signed by the natural or legal person responsible for the appropriate establishment of destination, stating:

(a) the name and address of the appropriate establishment of destination;

(b) that the appropriate establishment of destination complies with the minimum conditions set out in Annex II;

(c) that the consignment of salamanders will be accepted for quarantine.

Article 6

Quarantine rules for consignments of salamanders introduced into the Union

Member States shall ensure that:

1. The official or approved veterinarian responsible for the appropriate establishment of destination records the arrival of the consignment of salamanders introduced into the Union from a third country in Box 45 of Part 3 in the electronic version of the common veterinary entry document.

2. The official or approved veterinarian ensures that the operator keeps the consignment of salamanders in quarantine in the appropriate establishment of destination as one epidemiological unit.

3. The official or approved veterinarian inspects the conditions of quarantine for each consignment of salamanders, including an examination of the mortality records and a clinical inspection of the salamanders in the appropriate establishment of destination, checking in particular for skin lesions and ulcers.

4. Where a consignment comprises 62 or more salamanders, the official or approved veterinarian carries out the examination, sampling, testing and treatment procedures for Bsal in accordance with the procedures referred to in points 1 and 2 of Annex III, following the arrival of the consignment of salamanders at the appropriate establishment of destination.

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5. Where the consignment comprises less than 62 salamanders, the official or approved veterinarian ensures that the consignment is treated to the satisfaction of the competent authority against Bsal in accordance with point 3 of Annex III.

6. The official or approved veterinarian releases the consignment of salamanders from the appropriate establishment of destination by a written authorisation:

(a) in case of testing as referred to in point 1(a) of Annex III, provided that at least 6 weeks has elapsed since the date of the the commencement of the period of quarantine and not before the receipt of the negative test results, whichever is later; or

(b) in the case of treatment as referred to in point 1(b) of Annex III, only after satisfactory completion of the treatment.

Article 7

Measures to be taken in the event of a confirmed case of Bsal in an appropriate establishment of destination

1. Member States shall ensure that where during quarantine it is confirmed that at least one salamander of an epidemiological unit is infected with Bsal, the following measures are taken by the appropriate establishment of destination:

(a) all salamanders in the same epidemiological unit are either:

(i) treated to the satisfaction of the competent authority against Bsal in accordance with point 3 of Annex III; or

(ii) killed and disposed of as animal by-products in accordance with Article 12 of Regulation (EC) No 1069/2009.

(b) following completion of the measures referred to in point (a), the area of the appropriate establishment of destination where the epidemiological unit had been kept is cleaned and disinfected to the satisfaction of the competent authority.

2. The competent authority may require testing of the treated salamanders to verify the effectiveness of the treatment referred to in point 1(a)(i) and may require repeated treatments, as appropriate, to prevent the spread of Bsal.

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Article 8

Costs

Member States shall ensure that all quarantine costs, testing costs and, where necessary, the costs of risk mitigation measures and treatments are borne by the operator or the importer.

Article 9

Annual reporting requirements

At the latest by 30 June each year, starting from 2019, those Member States which have handled salamander consignments in the previous year, shall submit to the Commission the following information concerning the previous year, differentiating between information related to the intra-Union trade or to introductions of salamander consignments into the Union:

(a) the number of epidemiological units with at least one confirmed case of Bsal;

(b) the number of epidemiological units treated without a confirmed case;

(c) any further information they deem relevant on testing, treating or handling the consignments and on the implementation of this Decision.

Article 10

Transitional measures

1. For a transitional period until 6 September 2018, the Member States of destination may accept on their territory consignments of salamanders from other Member States which do not comply with the animal health conditions laid down in Article 3, under appropriate risk mitigation conditions to be determined by the competent authority after consulting the operators and, if necessary, the Member State of origin.

2. For a transitional period until 6 September 2018, the Member States of destination may accept on their territory consignments of salamanders introduced into the Union from a third country which do not comply with the animal health conditions laid down in Article 4, provided that they are handled in accordance with Articles 5 to 7.

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Article 11

Applicability

This Decision shall apply until 20 April 2021.

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Article 12

Addressees

This Decision is addressed to the Member States.

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ANNEX I

PART A

ANIMAL HEALTH CERTIFICATE

for intra-Union trade in salamanders

EUROPEAN UNION **Intra-Union trade certificate**

Part I: Details of consignment presented

I.1. Consignor Name Address Postal code	I.2. Certificate reference No	I.2.a. Local reference No
	I.3. Central competent authority	
	I.4. Local competent authority	
I.5. Consignee Name Address Postal code	I.6.	
	I.7.	
I.8. Country of origin ISO code I.9.	I.10. Country of destination ISO code I.11.	
I.12. Place of origin Other (registered quarantine) ☐ Name Registration number Address Postal code	I.13. Place of destination Holding ☐ Other ☐ Name Approval number Address Postal code	
I.14. Place of loading Postal code	I.15. Date and time of departure	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification	I.17. Transporter Name Approval number Address Postal code Member State	
I.18. Animal species	I.19. Commodity code (HS code) 01069000	
	I.20. Quantity	
I.21.	I.22. Number of packages	

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I.23. Seal/Container No			I.24. Type of packaging
I.25. Animals certified for: Breeding ☐ Other ☐			
I.26. Transit through third country ☐ Third country	ISO code	I.27. Transit through Member States ☐ Member State	ISO code
Exit point	Code	Member State	ISO code
Entry point	BIP No	Member State	ISO code
I.28. Export ☐ Third country	ISO code	I.29.	
Exit point	Code		
I.30.			
I.31. Identification of the animals Species (Scientific name)		Quantity	

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European Union **Salamanders**

II. Health information	II.a. Certificate reference number	II.b. Local reference number

Part II: Certification

I, the undersigned official veterinarian, hereby certify that the animals described in Part I meet the following requirements:

II.1. The salamanders ([1]) have been examined and do not show clinical signs of infection with the fungus *Batrachochytrium salamandrivorans* (Bsal), and in particular skin lesions and ulcers at the time of the examination which took place within a period of 24 hours prior to the planned time of dispatch of the consignment;

II.2. According to the operator, they come from a population where no mortalities due to Bsal or signs of Bsal, in particular skin lesions and ulcers have been observed by the operator;

II.3. The consignment consists of:

([2]) *either* [(i) one epidemiological unit of at least 62 specimens of salamanders which has been quarantined from other salamanders in an appropriate establishment for a period of at least 6 weeks immediately prior to the date of the issuing of this certificate; and

(ii) skin swab samples from the salamanders taken during the fifth week of the quarantine have been tested for Bsal with negative results with the appropriate diagnostic test, in accordance with the sample sizes laid down in point 1(a) of Annex III to Commission Implementing Decision (EU) 2018/320;]

([2]) *or* [salamanders which have been treated to the satisfaction of the competent authority against Bsal in accordance with point 1(b) of Annex III to Commission Implementing Decision (EU) 2018/320;]

([2]) *or* [salamanders which have been introduced into the European Union and have undergone quarantine or treatment and have been kept in the appropriate establishment of destination isolated from other salamanders between the end of the quarantine period following their introduction into the European Union and the issuing of this certificate;]

Notes

([1]) 'salamanders' means all amphibians of the order *Caudata.*

([2]) Delete as applicable.

— The required details of this certificate must be entered into Traces on the date of issuing of this certificate and at the latest within a period of 24 hours thereof.

— The colour of the stamp and the signature must be different from that of the other particulars in this certificate.

— This certificate is valid for a period of 10 days from the date of issue.

Official veterinarian

Name (in capital letters): Qualification and title:

Local Veterinary Unit (LVU): LVU No:

Date: Signature:

Stamp:

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PART B

ANIMAL HEALTH CERTIFICATE

for the introduction of consignments of salamanders into the European Union

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Country Tel.		I.2. Certificate reference number	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent authority	
I.5. Consignee Name Address Country Tel.		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10.
I.11. Place of origin Name Address Name Address Name Address		I.12.	
I.13. Place of loading Address		I.14. Date of departure	Time of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Document:		I.16. Entry BIP in EU	
		I.17. No.(s) of CITES ([1])	
I.18. Description of commodity		I.19. Commodity code (01069000)	
			I.20. Quantity
I.21.			I.22. Number of packages

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I.23. Seal/Container No	I.24.
I.25. Commodities certified for: Other ☐ Breeding ☐ Approved bodies ☐	
I.26.	I.27. For import or admission into EU ☐
I.28. Identification of the commodity Species (scientific name) Quantity	

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COUNTRY **Salamanders**

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

I, the undersigned official veterinarian, hereby certify that the animals described in Part I meet the following requirements:

II.1. The consignment of salamanders ([2]) comes from a third country of origin which is listed in Annex I to Commission Decision 2004/211/EC, in Part 2 of Annex II to Commission Decision 2007/777/EC, in Annex I to Commission Regulation (EC) No 798/2008, in Part 1 of Annex I to Commission Regulation (EC) No 119/2009, in Part 1 of Annex II to Commission Regulation (EU) No 206/2010 or in Annex I to Commission Regulation (EU) No 605/2010.

II.2. The salamanders have been examined and do not show clinical signs of infection with the fungus *Batrachochytrium salamandrivorans* (Bsal), and in particular skin lesions and ulcers, at the time of the examination which took place within a period of 24 hours prior to the planned time of dispatch of the consignment to the European Union.

II.3. The consignment of salamanders has been isolated from other salamanders at the latest at the time of the examination referred to in point II.2 and the consignment has not been in contact with other salamanders since that time.

Notes:

Part I:

([1]) complete or cross out as appropriate: CITES authorisation number is relevant only for animals listed in the Washington Convention on protected species.

Part II:

([2]) 'salamanders' means all amphibians of the order *Caudata.*

— The colour of the stamp and the signature must be different from that of the other particulars in this certificate.

— This certificate is valid for a period of 10 days from the date of examination in the third country of origin.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

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ANNEX II

MINIMUM CONDITIONS FOR APPROPRIATE ESTABLISHMENTS OF DESTINATION

(1) The appropriate establishment of destination:

(a) has a system that ensures adequate surveillance of the salamanders;

(b) is under the control of an official or approved veterinarian;

(c) is cleaned and disinfected in accordance with instructions by the competent authority.

(2) The operator of the appropriate establishment ensures that:

(a) cleaning and disinfection of the tanks, crates or other fomites used for the transport of the salamanders is carried out unless those are destroyed, in a way to prevent the spread of Bsal.

(b) waste material and waste water is collected regularly, stored and subsequently treated in a way to prevent the spread of Bsal.

(c) carcases of quarantined salamanders are examined in a laboratory indicated by the competent authority.

(d) the necessary tests and treatments of salamanders are carried out in consultation with and under the control of the official or approved veterinarian.

(3) The operator of the appropriate establishments of destination informs the official or approved veterinarian of diseases and deaths of salamanders during the quarantine.

(4) The operator of the appropriate establishments of destination keeps a record of:

(a) the date, number and species of salamanders entering and leaving for each consignment;

(b) copies of the animal health certificates and the common veterinary entry documents accompanying the consignment of salamanders;

(c) cases of illness and the number of deaths on a daily basis;

(d) dates and results of testing;

(e) types and dates of treatment and the number of animals subjected to it.

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ANNEX III

EXAMINATION, SAMPLING, TESTING AND TREATMENT PROCEDURES FOR BSAL

(1) During quarantine, the salamanders are subjected to the following procedures:

(a) If the size of the epidemiological unit is 62 or more, skin swab samples from quarantined salamanders must be examined under the control of the official or approved veterinarian with the appropriate diagnostic test during the fifth week following the date of their entry into the appropriate establishment, in accordance with the sample sizes set out in the reference table, unless the operator opts for treatment in accordance with point (b).

Reference Table ([1]):

Size of the epidemiological unit	62	186	200	250	300	350	400	450
Sample size	62	96	98	102	106	108	110	111

([1]) Assuming 3 % prevalence of Bsal in the epidemiological unit and ensuring its detection with a 95 % confidence rate with the sensitivity of the appropriate diagnostic test calculated to be at 80 %.

(b) If the operator opts for one of the treatments listed in point (3) or in all cases where the size of the epidemiological unit is less than 62, all salamanders in the consignment must be treated by the operator against Bsal under the control of the official or approved veterinarian to the satisfaction of the competent authority.

(c) In cases referred to in point (b) the official or approved veterinarian may require representative testing of the epidemiological unit with the appropriate diagnostic test before the treatment to monitor the presence of Bsal or after treatment to verify the absence of Bsal.

(d) Skin swab samples from all dead or clinically sick salamanders, in particular those with skin lesions, must be examined under the control of the official or approved veterinarian with the appropriate diagnostic test at the time they show lesions or other clinical signs or at the time of death, whichever is sooner.

(e) All salamanders which die in the appropriate establishment must be subjected to a post mortem examination under the control of the official or approved veterinarian, in particular to check for signs of Bsal, to confirm or to exclude Bsal as cause of death, to the extent possible.

(2) All testing of samples taken and post mortem examination during quarantine must be carried out in laboratories indicated by the official or approved veterinarian.

(3) The following treatments are considered to be satisfactory:

(a) keeping salamanders at a temperature of at least 25 °C for at least 12 days;

(b) keeping salamanders at a temperature of at least 20 °C for at least 10 days combined with a treatment with polymyxin E submersion baths (2 000 IU/ml) for 10 minutes twice per day, followed by applying voriconazole spray (12,5 μg/ml);

(c) any other treatment with comparable results in eliminating Bsal as reported in a peer-reviewed article published in a scientific journal.