

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)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ⁽¹⁾, and in particular Article 10(4) thereof,Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC ⁽²⁾, and in particular Article 18(1) thereof,

Whereas:

- (1) Since 2013, *Batrachochytrium salamandrivorans* (Bsal), which is an emerging pathogen fungus of salamanders, has been occurring in Belgium, Germany, the Netherlands and the United Kingdom. It affects kept and wild salamander populations, and it can cause significant morbidity and mortality in those populations. Bsal is lethal to certain species of salamanders, while other species are fully or partly resistant to it, but may carry Bsal on their skin and therefore act as a reservoir and source of infection or contamination for other species of salamanders.
- (2) According to current scientific knowledge concerning Bsal, compiled by a scientific opinion ⁽³⁾ of the European Food Safety Authority (EFSA) about Bsal within its Assessment of listing and categorisation of animal diseases in the framework of Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽⁴⁾, Bsal seems to be endemic at least in Japan, Thailand and Vietnam with around a 3 % prevalence rate in wild salamander populations. It is generally thought to have originated in East Asia and to be widespread and endemic there. At the same time, there is a lack of information on how widespread it is in other parts of the world. It is also generally thought that trade in infected or carrier salamanders contributes to the spread of Bsal.
- (3) According to available data, both resistant and susceptible salamander species are traded. Council Directive 92/65/EEC ⁽⁵⁾ lays down the animal health requirements governing trade in and imports into the Union of animals not subject to the animal health requirements laid down in the specific Union acts listed in Annex F thereto. Union animal health legislation, including Directive 92/65/EEC, currently lays down no specific animal health requirements for trade in salamanders or for their imports into the Union that would be effective in protecting animal health against the spread of Bsal in the Union.
- (4) The EFSA, in its scientific and technical assistance concerning the survival, establishment and spread of *Batrachochytrium salamandrivorans* (Bsal) in the EU ⁽⁶⁾ (the EFSA Assistance), assessed the potential of Bsal to affect the health of wild and kept salamanders in the Union, the effectiveness and feasibility of a movement ban on traded salamanders, the validity, reliability and robustness of available diagnostic methods for Bsal detection and possible alternative methods and feasible risk mitigation measures to ensure safe international and intra-Union trade in salamanders.

⁽¹⁾ OJ L 224, 18.8.1990, p. 29.⁽²⁾ OJ L 268, 24.9.1991, p. 56.⁽³⁾ *EFSA Journal* 2017;15(11):5071⁽⁴⁾ 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).⁽⁵⁾ Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).⁽⁶⁾ *EFSA Journal* 2017;15(2):4739.

- (5) According to the EFSA Assistance, quarantining salamanders, the testing of salamanders to demonstrate that they are free of infection from Bsal, restricting movements of salamanders, hygienic procedures and biosecurity measures or treating salamanders against Bsal are important risk mitigation measures in preventing the spread of that disease.
- (6) The EFSA Assistance also highlighted many gaps and uncertainties in the current state of knowledge as regards Bsal. In particular, it concluded, that due to the complexity of the taxonomy as well as the lack of current evidence concerning which species are susceptible to Bsal, rules at the level of the taxonomic order are likely to be both more effective and more feasible than species-specific rules.
- (7) It is therefore appropriate to lay down animal health protection measures for intra-Union trade in consignments of salamanders and the introduction of such consignments into the Union on the taxonomic order of Caudata, in order to ensure that Bsal is not spread by intra-Union trade in those animals and the introduction of such animals into the Union. These measures should take into account the risk mitigation measures referred to in the EFSA Assistance and in particular provide for the appropriate quarantine, diagnostic testing and treatment of salamanders as well as for certification of their health status for their trade in and introduction into the Union. These measures are of an emergency nature and are not deemed specific measures within the meaning of Article 18(2) of Council Directive 92/65/EEC.
- (8) Regulation (EU) No 576/2013 of the European Parliament and of the Council ⁽¹⁾ lays down the animal health requirements applicable to the non-commercial movements of pet animals listed in Annex I thereto, and amphibia are included in the animals listed in that Annex. The animal health protection measures laid down in this Decision should not apply to the non-commercial movements of pet salamanders which fall within the scope of Regulation (EU) No 576/2013, due the specificities of those movements and given the lack of information concerning such movements.
- (9) These measures should apply regardless of other Union rules potentially relevant for trade in and introduction of salamanders, in particular Council Regulation (EC) No 338/97 ⁽²⁾.
- (10) The World Organisation for Animal Health (OIE) listed infection with Bsal in its Aquatic Animal Health Code during its 85th General Session on 21-26 May 2017. But detailed international standards are not yet available and there is a lack of information on the technical capabilities of veterinary services and laboratories around the world to test for Bsal, while various concerned stakeholders in the European Union are in the forefront of progress on the diagnosis and treatment of Bsal and the safe handling of traded salamanders. It is therefore appropriate that most risk-mitigating measures, in particular the quarantining in an appropriate establishment, testing and treatment of traded and introduced salamanders are to be done by competent veterinary authorities, operators and laboratories located within the Union.
- (11) According to the EFSA Assistance, it is possible that Bsal is transmitted between salamander species native to different areas and cross-contamination may take place in various establishments breeding, collecting or distributing salamanders. This makes the risk of Bsal occurring in traded salamanders independent from their place of origin and from the situation in the wild. Therefore all consignments of salamanders destined for intra-Union trade or introduced into the Union should be subject to risk mitigation measures.
- (12) Minimum conditions for appropriate establishments to be used for quarantining salamanders should be laid down to ensure their biosecurity, while the handling of salamanders which die in those establishments should be done according to existing specific rules laid down in the Animal by-products Regulation ⁽³⁾.
- (13) As regards the size of the quarantined epidemiological units, a minimum size eligible for certification for negative diagnostic test results should be specified due to the limited sensitivity of the best available real-time quantitative polymerase chain reaction (qPCR) assay which is sufficiently reliable to be used only if the epidemiological units comprise at least 62 salamanders.

⁽¹⁾ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

⁽²⁾ Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 61, 3.3.1997, p. 1).

⁽³⁾ 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 (OJ L 300, 14.11.2009, p. 1).

- (14) Salamanders which have undergone quarantine with testing with negative results or satisfactory treatment in the Union should not be subjected to quarantine or testing again, provided that they have been kept isolated from salamanders of a different health status in an appropriate establishment.
- (15) As regards treatments, these should be specified and be in line with the protocols already described in peer-reviewed scientific literature as highlighted by the EFSA Assistance or with comparable ones.
- (16) A list of third countries approved for issuing animal health certificates for the introduction into the Union of consignments of salamanders should be established and limited to those countries which have already provided sufficient guarantees for issuing certificates to prevent misleading and fraudulent certification, at least equivalent to Council Directive 96/93/EC ⁽¹⁾. Therefore, it is appropriate to refer to already available lists existing in the context of introduction into the Union of other commodities. Such third countries are listed in Annex I to Commission Decision 2004/211/EC ⁽²⁾, Part 2 of Annex II to Commission Decision 2007/777/EC ⁽³⁾, Annex I to Commission Regulation (EC) No 798/2008 ⁽⁴⁾, Part 1 of Annex I to Commission Regulation (EC) No 119/2009 ⁽⁵⁾, Part 1 of Annex II to Commission Regulation (EU) No 206/2010 ⁽⁶⁾, or Annex I to Commission Regulation (EU) No 605/2010 ⁽⁷⁾, respectively.
- (17) Consignments of salamanders should be introduced in the Union only if they comply with all the requirements and the competent veterinary authority of the border inspection post of entry can also ascertain that the consignments will be accepted by an operator responsible for an appropriate establishment of destination to be duly quarantined.
- (18) The actual arrival of consignments of salamanders introduced into the Union from third countries at their place of quarantine in the Union should be recorded in the electronic version of the common veterinary entry document set out in Annex I to Commission Regulation (EC) No 282/2004 ⁽⁸⁾ and managed by the integrated computerised veterinary system known as Traces, so that the competent veterinary authority of the border inspection post of entry can be reliably informed of their arrival.
- (19) This Decision should provide for a transitional period in order to give the Member States, the competent authorities and economic operators time to put in place the necessary procedures so that they are in a position to comply with the rules laid down in this Decision. The length of this period should be limited to a few months. At the same time, risk mitigation measures based on the required level of protection by the Member States of destination should already apply.
- (20) It is expected that more information will be available in the coming years about Bsal from scientific sources and from results of official controls carried out by the Member States, supplementing the current knowledge concerning that disease. Therefore, the animal health protection measures laid down in this Decision should be of a temporary nature. Nevertheless, they should apply at least until 31 December 2019 to allow for 1 year of implementation by the Member States and subsequent annual reporting and consideration thereof, while permanent EU animal health rules may be laid down under the new Regulation (EU) 2016/429 on transmissible animal diseases to apply from the date of application of that Regulation.

⁽¹⁾ Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products, (OJ L 13, 16.1.1997, p. 28).

⁽²⁾ Commission Decision 2004/211/EC of 6 January 2004 establishing the list of third countries and parts of territory thereof from which Member States authorise imports of live equidae and semen, ova and embryos of the equine species, and amending Decisions 93/195/EEC and 94/63/EC (OJ L 73, 11.3.2004, p. 1).

⁽³⁾ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

⁽⁴⁾ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

⁽⁵⁾ Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12).

⁽⁶⁾ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

⁽⁷⁾ Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

⁽⁸⁾ Commission Regulation (EC) No 282/2004 of 18 February 2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community (OJ L 49, 19.2.2004, p. 11).

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

HAS ADOPTED THIS DECISION:

Article 1

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;
- (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
 - (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;

- (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.
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 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.

*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.

*Article 11***Applicability**

This Decision shall apply until 31 December 2019.

*Article 12***Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 28 February 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

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) <input type="checkbox"/> Name Registration number Address Postal code		I.13. Place of destination Holding <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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		

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

European Union

Salamanders

II. Health information

II.a. Certificate reference number

II.b. Local reference number

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:

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
							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 <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification Document:		I.16. Entry BIP in EU					
		I.17. No.(s) of CITES (!)					
I.18. Description of commodity				I.19. Commodity code (01069000)			
				I.20. Quantity			
I.21.				I.22. Number of packages			

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

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:	
	<p>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.</p> <p>II.2. The salamanders have been examined and do not show clinical signs of infection with the fungus <i>Batrachochytrium salamandrivorans</i> (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.</p> <p>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.</p> <p>Notes:</p> <p>Part I:</p> <p>(¹) complete or cross out as appropriate: CITES authorisation number is relevant only for animals listed in the Washington Convention on protected species.</p> <p>Part II:</p> <p>(²) 'salamanders' means all amphibians of the order <i>Caudata</i>.</p> <p>— The colour of the stamp and the signature must be different from that of the other particulars in this certificate.</p> <p>— This certificate is valid for a period of 10 days from the date of examination in the third country of origin.</p>	
Official veterinarian		
Name (in capital letters):	Qualification and title:	
Date:	Signature:	
Stamp:		

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) carcasses 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.