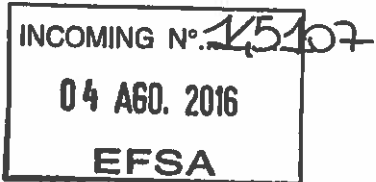




EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director-General for Food Safety



27. 07. 2016

Brussels

SANTE G2/PB/lp (2016) 3977986

Ares (2016) 3961108

Dear Dr Url,

Subject: Request for i) a scientific and technical assistance and ii) a scientific opinion concerning the risk of survival, establishment and spread of *Batrachochytrium salamandrivorans* (Bsal) in the EU

I would like to submit a formal request to the European Food Safety Authority for a scientific and technical assistance and for a scientific opinion concerning the risk of entry, survival, establishment and spread of *Batrachochytrium salamandrivorans* (Bsal) into and in the EU, with particular emphasis on the relatively new European situation of occurrences of this pathogen in several EU Member States (Netherlands, Belgium, Germany, UK) both in kept and wild salamander populations.

EFSA is asked to provide a scientific and technical assistance by the end of 2016 and a scientific opinion by the end of 2017.

My services remain at your disposal for further information. On this matter, you can contact Mr P. Bernorio, who is responsible for the dossier in Unit G2, Animal Health and welfare unit and Ms M. Marini, who is the relevant contact point in the Unit D1 in charge of Science, stakeholders, enforcement. Their respective phones and e-mail addresses are indicated below.

Yours sincerely,

Ladislav Miko

Contact persons:

Ms. M. Marini (02.299.93307)

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Mr. P. Bernorio (02.299.84882)

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Annex: Terms of Reference

C.c.: T. Bregeon, B. Van Goethem, M. Scannell, E. Zamora Escribano, L. Terzi, M. Marini, P. Bernorio, L. Kuster, B. Logar, (DG SANTE), A. Gervelmeyer (EFSA).

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ANNEX TERMS OF REFERENCE

INTRODUCTION - BACKGROUND INFORMATION

Bsal was identified by scientists as recently as in 2013. Over the last couple of years Bsal occurred at least in certain parts of Europe either in wild population of salamanders and newts¹ (e.g. the Netherlands, Belgium in several locations) or in kept population (e.g. Germany, UK) or possibly in both populations. There is no data from other EU countries but similar cases either in wild or in kept salamanders cannot be excluded. In certain areas (e.g. the Netherlands) this fungus is said to have devastated local fire salamander populations. In other places the fungus is apparently present in susceptible species, but without increased mortalities. Many Asian salamander species seem to be immune or tolerant to this pathogen to various extents. Many European species seem to be susceptible.

This situation and state of knowledge is patchy, fragmented and is expected to change as more knowledge about this emerging pathogen and especially surveillance data becomes available, continually and gradually. Overall, scientific data on Bsal is still scarce with significant gaps. Currently the disease is not listed under OIE standards or in the EU rules.

A few affected countries, or those which anticipate that Bsal could affect them, adopted diverse control policies or consider various possible measures against the disease to cope with its feared short- and long-term consequences in wild animals and in kept salamanders and their trade. One of such examples is an import ban of certain salamander species introduced by the USA, where Bsal is either absent or not yet detected. Other measures are of non-legislative nature, such as rising of awareness among stakeholders on risks, guidelines for improved biosecurity or survey salamander populations, changes thereof, with the emphasis on increased mortalities and/or occurrence of Bsal. To date, these have been done under environmental policies.

Some actors have recently called for, *inter alia*, EU animal health policy and legislative measures to be adopted, in particular an immediate ban on import of many species of salamanders from Asia into the EU. It has been shown by phylogenetic analysis that the fungus, indeed, originates in certain parts of Asia. Therefore it has been speculated by some that trade in Asian salamanders may play a role in its spread into and within the EU, although there is no proof that this pathogen entered the EU via this route. And if so, when and under what circumstances. In general, details are missing on its actual spread into or in the EU or between kept and wild animals.

The Commission therefore needs a quick but comprehensive compilation, scrutiny of available data and assessment to determine if Bsal is a disease with the potential to harm kept and wild salamanders in the Union and various risk factors associated with:

- imports of Asian salamanders into the EU and their trade within the EU;
- movements of European salamanders (both caught from the wild or kept ones) within the EU, and

¹ The term "salamanders" is wide. All newts are salamanders but they are usually differentiated. The taxonomical term Salamandroidae does not cover all salamanders however, there are other sub-orders too, also called salamander in common speech. All belong to the Order Urodela. The term Caudata is also often used (amphibians with tails both when larvae and adult). In this mandate salamanders = Urodela = Caudata, for simplification.

- imports and movements of animal by-products obtained from Asian and European salamanders (both caught from the wild or kept ones).

Such assessment would be essential for the consideration of potential safeguard measures in relation to imports from Asia or for movements from infected to non-infected EU areas.

In the past, EFSA has produced scientific opinions dealing with various aspects of emerging pathogens, including those where environmental aspects or wild animals play increased role or are affected (such as e.g. on small hive beetle). Therefore, a similar opinion is necessary to understand better possible scenarios for the evolution of this new disease, the current epidemiological situation, the experience gained so far from the implementation of the various control policies and possible alternative methods to diminish negative effects on wild salamander populations and to ensure safe trade of kept animals and their products. Identification of gaps and uncertainties is also very important for this emerging disease.

Furthermore, EFSA has already been made aware of the adoption and publication of the Regulation on transmissible animal diseases (Animal Health Law²), hereinafter referred to as AHL. As Bsal is not included in the list of diseases in Annex II to the AHL (or on the list of any other existing EU animal health legislation), environmental actors asked the Commission to place Bsal onto that list. Therefore, the review of this list will be necessary in accordance with a set of criteria provided for in the AHL before it comes into force, taking into account the transitional periods envisaged for its application (five years starting from April 2016). Hence the Commission needs scientific advice for the assessment of the significance of Bsal within the framework of this already known listing and categorisation according to the AHL, in the same manner it was requested previously, for another two groups of diseases (Ref. SANTE G2/BL/lp (2015) 4940871, SANTE G3/LPA/lp (2016) 3154863, respectively).

The criteria, provided for in Article 7 and 8 and Annex IV of the AHL, shall be used as a basis for this analytical assessment. The risk manager needs a scientific advice in order to:

1. assess if Bsal causes disease for which control measures at the EU level are justified;
2. proceed with the profiling of the disease in view to its categorisation; and
3. assign listed species to Bsal identified as eligible for EU intervention.

The Commission have identified the main issues for which concrete elements of science may provide good basis for formulating policies and/or adapt current approach. These are as follows:

- Provisions for safe trade (entry into the Union and trade within the Union) with Asian and European salamanders and animal by-products obtained therefrom;
- Identifying links between groups of salamanders in trade (i.e. in consignments being moved or in shops etc.) and kept ones (i.e. stationary, whether for hobby or else) and salamanders in wild (i.e. in their natural habitat) and possible routes and risks of spreading Bsal between the specimens belonging to the above three groups and locations;
- Effects of the respective infection of salamanders with Bsal, including aspects stemming from different susceptibility of various species to Bsal;

² <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0429&rid=8>

- Measures to monitor occurrence of Bsal in those groups and mitigate mortality due to Bsal, whether regulatory measures or non-regulatory ones.

TERMS OF REFERENCE

Scientific and technical assistance

I. Scientific and technical assistance in accordance with Article 31 of Regulation (EC) No 178/2002

In view of the above, in accordance with Article 31 of Regulation (EC) No 178/2002, the Commission asks EFSA to provide scientific and technical assistance concerning:

- Assessment of the potential of Bsal to affect the health of wild and kept salamanders in the Union;
- effectiveness and feasibility of a movement (including intra-EU trade and introduction from non-EU countries) ban of traded salamanders, including both Asian and non-Asian species;
- the validity, reliability and robustness of the available diagnostic methods for the detection of Bsal;
- possible alternative methods and feasible risk mitigation measures to ensure safe international and EU trade of salamanders and their products.

II. Scientific opinion in accordance with Article 29 of Regulation (EC) No 178/2002

In accordance with Article 29 of Regulation (EC) No 178/2002, the Commission asks EFSA to provide a scientific opinion on the following:

- 1) **As regards susceptibility, morbidity and mortality, assess:**
 - a) Susceptibility and morbidity of various Asian and European salamanders to Bsal;
 - b) Nature of Bsal as facultative or not pathogen of European salamanders;
 - c) If there are species of salamanders carrying Bsal without clinical symptoms and/or clinical and serological evidence and if so, which ones;
 - d) Mortality rates of native European salamander species due to Bsal;
 - e) Role of other factors (e.g. habitat degradation, etc.) in increased mortalities associated with Bsal.
- 2) **As regards presence, absence, surveillance and eradication, assess:**
 - a) the risk of survival and establishment of Bsal in the environment in the EU under various meteorological conditions;
 - b) possible identification of various areas (e.g. countries, zones, territories etc.) which may be considered infected with Bsal or free from it;
 - c) definition of requirements for reliable detection of Bsal in the wild in affected areas or exclusion of its presence;
 - d) suitability of surveillance methods to ensure reliable and robust demonstration of presence or absence of Bsal.

3) As regards spread of Bsal in and from infected areas or via infected animals or fomites, assess:

- a) the risk of survival, spread and establishment of Bsal within already infected areas and spread from infected areas into other parts of the EU under various scenarios:
 - i) by natural movements of live salamanders taking into account especially relevant geographical, hydrographical and meteorological conditions;
 - ii) by movements of traded live salamanders and their traded products, body parts etc. from infected areas, both under identified risk mitigation measures or without;
- b) risk mitigating factors that could potentially be effective in ensuring safe international or intra-EU trade of live salamanders (both captured in the wild and bred) and their products and by-products as regards the transmission of Bsal, including diagnosis and potential treatment(s);
- c) the role of live, silent carriers of Bsal in spreading it as vectors and those of fomites (e.g. waste water, animal by-products, feed etc.) and risk mitigating measures concerning those;
- d) the possible routes of spread between kept salamanders, originating from international trade and the autochthonous salamanders living in wild, i.e. their natural habitat.

4) As regards on-site protection from Bsal, assess:

- a) Potential and feasible risk mitigating factors and methods in kept salamanders;
- b) Risk mitigating factors and methods for salamanders in their natural habitat.

5) Listing and categorisation of Bsal in the framework of the Animal Health Law.

- a) Assess, following the criteria laid down in Article 7 of the AHL, its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;
- b) If found eligible to be listed for Union intervention, provide:
 - i) an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;
 - ii) a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.