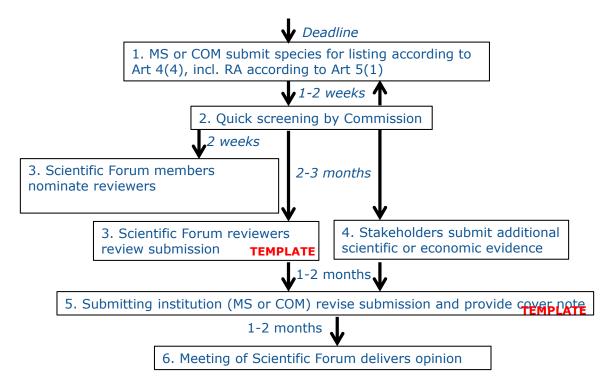


EUROPEAN COMMISSION

DIRECTORATE-GENERAL ENVIRONMENT Directorate D – Natural Capital ENV.D.2 - Biodiversity

Ref: SF3-item4-doc1 – Version 1.0 (finalised following the 3rd meeting on 21 June 2016)

WORKING METHOD SCIENTIFIC FORUM DELIVERY OF OPINION ON SUBMISSIONS



1. A Member State or Commission proposes a species for listing

MS propose species for listing according to Regulation 1143/2014, Article 4(4). They need to submit a risk assessment complying with Article 5(1), as well as evidence that all criteria of Article 4(3) are met. The latter includes information on risk management (Article 4(3)(e)), including any available information on costs and benefits in order to allow the Commission to apply the criteria with due consideration to the cost elements indicated in Article 4(6). All information should be peer reviewed.

The elements to be included in the risk assessment when proposing IAS to be listed on the Union list are described in Article 5(1) of the Regulation. MS may use any protocol or method e.g. GBNNRA (NAPRA), Harmonia+, as long as information to comply with all elements set out in Article 5(1) is covered or added to the existing methods if absent or not sufficiently covered. MS should also make sure the risk management information is added, in order to include evidence that the criterion in Article 4(3)(e) is met and allow for the cost considerations under Article 4(6).

MS are advised to use a prioritisation scheme, in order to select priority species for risk assessment.

Requests by Member States in accordance to Article 4(4) shall be submitted by the member of the Committee on Invasive Alien Species to the email address <u>ENV-IAS@ec.europa.eu</u>.

The Commission sets a <u>deadline (one per year)</u> by when the proposals for species for an update of the list of IAS of Union concern need to be submitted.

2. Quick screening by the Commission

Within 1-2 weeks, the Commission performs a quick screening to check whether all elements required through Article 5(1), as well as evidence on the compliance with all criteria in Article 4(3), are included and whether there are no conflicts with the basic requirements for listing (alien to the Union, capable of establishing and spreading under current and foreseeable climate change conditions and likely to have adverse impact on biodiversity or ecosystem services). The check on the presence of the elements would be a simple present/absent check and would not examine the quality or completeness of the information provided.

In case some elements are missing, the Commission sends the submission back to the submitting MS. The MS can only proceed within this batch of proposals if it is able to add the missing elements within 1 week, otherwise it will need to wait for the next batch. In order to avoid this postponement, MS are advised to submit their risk assessments well before the deadline.

3. Review by the Scientific Forum

The Commission shares the submission with the members of the Scientific Forum.

The Scientific Forum will have <u>2-3 months</u>, depending on the number of submissions, to review the risk assessment and express an opinion about whether the information is robust and fit-for-purpose, i.e. whether it is complete and represents sound science on which to base decision making. The Scientific Forum may deliver a positive opinion on a risk assessment, require a minor or major revision, or deliver a negative opinion on it.

The Commission provides a <u>review template</u> (Annex 1) to document the review and to facilitate and guide the work of the reviewers. Members of the Scientific Forum should, where appropriate, seek the advice of additional experts within their Member State to input into the review.

While every member of the Scientific Forum is welcome to review every submission, it will not be necessary for every single member to examine all of the submissions. However, every member will be called upon expressing the opinion of the scientific community of the Member State he or she represents on each submission, and will thus have to endorse the work of others. During the <u>first 2 weeks</u>, members of the Scientific Forum inform the Commission about which submissions they will review. The Commission ascertains that every submission is reviewed by at least 5 members of the Scientific Forum.

While performing its review, the Scientific Forum should focus on the scientific evidence presented in the submission and the evidence potentially available elsewhere, and avoid subjective views and political comments (for example whether a species should be listed).

The Scientific Forum members should consider the following questions:

- 1. Are all relevant questions answered and correctly interpreted?
- 2. Are all scores/decisions well-reasoned and fully justified?
- 3. Is the confidence level correctly reflected and documented?
- 4. Are there factual inaccuracies?
- 5. Is literature correctly utilised, interpreted and referenced?
- 6. Is the information presented sufficiently detailed to support conclusions?

These questions should be considered in turn for each section of a risk assessment, including: preliminary parts (i.e. taxonomy, invasion history, etc.), entry, establishment, spread, impacts and conclusions, as well as for the risk management information. The reviewer should document the comments in the review template.

The review should be submitted by the member of the Scientific Forum to **ENV-** IAS@ec.europa.eu.

4. Consultation of stakeholders

At the same time the Commission shares the submissions with the Scientific Forum, the Commission also makes them publicly available through:

http://ec.europa.eu/environment/nature/invasivealien/index_en.htm

Stakeholders will have the same 2-3 months, depending on the number of submissions, to provide additional information that could strengthen the evidence underpinning decision making. Only referenced scientific information and data on socio-economic benefits and on risk management will be considered. Opinions on whether a species need to be listed will not be taken into consideration.

European stakeholder organisations and third countries are invited to submit this information to ENV-IAS@ec.europa.eu. National or local organisations, as well as citizens, are invited to submit their information through a European stakeholder organisation or through their MS competent authorities. The Commission and the MS will screen the material. If necessary the MS will summarise it in English. The MS may therefore set its own deadlines. The member of the Committee on IAS will submit the material to ENV-IAS@ec.europa.eu by the deadline.

5. Revision by the submitting MS or Commission

The Commission collects the reviews from the Scientific Forum and the inputs by stakeholders and sends them per species to the Committee member of the submitting MS.

The submitting MS receive <u>1 to 2 months</u> for processing the inputs. The MS decide on how to deal with conflicting material and explain their decision in a cover note.

When resubmitting the revised risk assessment, the MS provide a cover note explaining how the received comments have been processed. In particular it should be explained which MS and stakeholders provided input, the substantial comments and inputs that

were processed, as well as the substantial comments and inputs that were not processed, including a motivation for not processing them.

The Commission provides a <u>revision template</u> (Annex 2) to support MS in preparing the cover note documenting the revision.

The revised submission with the cover note should be submitted by the member of the Committee on IAS to <u>ENV-IAS@ec.europa.eu</u>.

6. Opinion of the Scientific Forum

The Commission shares the revised risk assessment and the cover notes with the members of the Scientific Forum.

The members of the Scientific Forum receive 1 to 2 months to examine these before a meeting of the Scientific Forum is convened. At the meeting the Scientific Forum delivers its opinion on each of the submissions or resubmissions. The opinion will be considered final. The Scientific Forum endeavours to find consensus on its opinion. If such consensus is not possible, it will establish its opinion by a simple majority of its members. Therefore each member of the Scientific Forum should have an opinion also on the submissions not directly reviewed by him/her.

The species for which the submissions were deemed by the Scientific Forum as robust and fit-for-purpose are brought for discussion to the IAS Committee with a view to be screened against the criteria of Article 4(3), with due consideration to Article 4(6), and possible inclusion on the Union list.

ANNEX 1

<u>Draft Template for Review by the Scientific Forum of Risk Assessments</u>

Name of reviewer:	[Member State]	
Species assessed:		
Date:		
Summary of expert judgement (based	Is the risk assessment robust and fit-for-purpose on the basis of the scientific evidence presented?	Yes
on the tables below)	Scientific evidence presented:	Requires minor revision
		Requires major revision
Additional information sources	Is there any additional information available that would improve the quality of the risk assessment?	Provide documents or links

Is the risk asse	s the risk assessment fit-for-purpose?	
Risk assessment Section*	Criteria to consider when commenting	Reviewers comments (where possible specify which question in the risk assessment your comment relates to)
Information on the organism	Is the organism clearly a single taxonomic entity and can it be adequately distinguished from other entities of the same rank? Are all relevant questions answered and correctly interpreted? Are all scores/decisions well-reasoned and fully justified?	
	Is uncertainty correctly reflected and documented? Are there factual inaccuracies?	
	Is literature correctly utilised, interpreted and referenced? Is the information presented sufficiently detailed to support conclusions?	
Probability of entry	Are all relevant pathways assessed?	

	Are all relevant questions answered and correctly interpreted?	
	Are all scores/decisions well-reasoned and fully justified?	
	Is uncertainty correctly reflected and documented?	
	Are there factual inaccuracies?	
	Is literature correctly utilised, interpreted and referenced?	
	Is the information presented sufficiently detailed to support conclusions?	
Probability of	Are all relevant questions answered and correctly interpreted?	
establishment	Are all scores/decisions well-reasoned and fully justified?	
	Is uncertainty correctly reflected and documented?	
	Are there factual inaccuracies?	
	Is literature correctly utilised, interpreted and referenced?	
	Is the information presented sufficiently detailed to support conclusions?	

Probability of spread	Are all relevant questions answered and correctly interpreted?	
	Are all scores/decisions well-reasoned and fully justified?	
	Is uncertainty correctly reflected and documented?	
	Are there factual inaccuracies?	
	Is literature correctly utilised, interpreted and referenced?	
	Is the information presented sufficiently detailed to support conclusions?	
Probability of impact	Are all relevant questions answered and correctly interpreted?	
Impact	Are all scores/decisions well-reasoned and fully justified?	
	Is uncertainty correctly reflected and documented?	
	Are there factual inaccuracies?	
	Is literature correctly utilised, interpreted and referenced?	
	Is the information presented sufficiently detailed to support conclusions?	

Conclusion	Is the assessment clearly written?	
	Are all relevant questions answered and correctly interpreted?	
	Are the conclusions well-reasoned and fully justified?	
	Is overall uncertainty scored correctly and fully justified?	
	Is literature correctly utilised, interpreted and referenced?	
	Is literature up-to-date and comprehensively searched?	
	Is the information presented sufficiently detailed to support the overall conclusions?	

^{*} note that these headings can be altered to fit the headings of the risk assessment if different

ANNEX 2

Revision template

This is to be used as cover note explaining how the received comments have been processed when a RA is resubmitted following the review by the Scientific Forum and the consultation of stakeholders.

Name of species assessed:
Date of completion of this document:
Member States/stakeholders that provided comments:
Substantial comments processed in the revised risk assessment:
•
•
Substantial comments that were not processed in the revised risk assessment and motivation
for not processing them:
•
•