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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 30.4.2018 supplementing Regulation (EU) No 1143/2014 of the European Parliament and of the Council with regard to risk assessments in relation to invasive alien species

Delegations will find attached document C(2018) 2526 final.

Encl.: C(2018) 2526 final

EUROPEAN
COMMISSION

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COMMISSION DELEGATED REGULATION (EU) …/...

of 30.4.2018

supplementing Regulation (EU) No 1143/2014 of the European Parliament and of the Council with regard to risk assessments in relation to invasive alien species

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 1143/2014 on invasive alien species (hereafter the IAS Regulation) sets out the framework to address the impact of invasive alien species on biodiversity and related ecosystem services and empowers the Commission to adopt, update and review a list of invasive alien species of Union concern. The Commission is assisted by a Committee consisting of Member States' representatives (hereafter the IAS Committee).

A precondition for considering the inclusion of a species on the list of invasive alien species of Union concern is the existence of a thorough risk assessment for that species backed by robust science addressing all the elements set out by Article 5(1) of the IAS Regulation.

Article 5(1) of the IAS Regulation sets out all the elements needed to produce a risk assessment capable of underpinning decision-making. The IAS Regulation recognises that it may be useful to specify further those elements, including by providing a methodology for the risk assessment. Furthermore, scientific practices in the domain of risk assessments may evolve and such developments would need to be integrated in the practice of developing risk assessments for the purpose of the IAS Regulation.

Article 5(3) of the IAS Regulation empowers the Commission to adopt delegated acts to further specify the type of evidence acceptable regarding the capability of establishing and spreading of invasive alien species and provide a detailed description of the elements of risk assessments, including the methodology to be applied in the risk assessments, taking into account relevant national and international standards and the need to prioritise action against invasive alien species associated with, or that have the potential to cause, a significant adverse impact on biodiversity or related ecosystem services, as well as on human health or the economy, such adverse impact being considered as an aggravating factor.

The following considerations need to be taken into account.

A methodology is a system of methods used in a particular area of study or activity. This Delegated Regulation does not intend to develop a new risk assessment method, protocol or template, replacing existing and valid scientific exercises in this area. On the contrary, any method, protocol or template used to perform a risk assessment should be considered acceptable as a valid tool for the purpose of the IAS Regulation, as long as the common elements, as further specified by this Delegated Regulation, are properly addressed.

Risk assessment and risk management should be clearly distinguished: a risk assessment is the evaluation of the probability of the introduction and spread of an organism and an assessment of its potential consequences, i.e. it evaluates the risks involved. Risk management instead is the evaluation and selection of options and measures to reduce or avoid such risks. Together, risk assessment and risk management, constitute the process known as risk analysis. Therefore, the risk assessment is considered, alongside the evaluation and selection of management options, a part of the tool that informs and enables the IAS Committee to perform its duties related to risk management.

As such, a risk assessment needs to be evidence based, rigorous and robust, and it should present facts and scientific evidence. It should thus be based on the best available information, if possible from peer reviewed scientific sources. If such scientific sources are lacking, or to complement those scientific sources, grey literature, expert opinions and other sources could also be used, if properly referenced and accompanied by an assessment of the uncertainty. This Delegated Regulation provides guidance on the development and the evaluation of risk

assessments and sets the level of details and quality that a risk assessment should achieve. It aims at facilitating the work of the Commission, the Member States and the Scientific Forum, and at supporting the Commission and the IAS Committee in better decision making.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

This Delegated Regulation has been developed on the basis of a number of studies and on the best available scientific literature.

Furthermore, the Scientific Forum[1], the expert group established by the IAS Regulation with the mandate to provide scientific advice in relation to its implementation, has been closely involved in its preparation. The Scientific Forum is composed of representatives from the scientific community, nominated by the Member States, as mandated by Article 28 of the IAS Regulation. This Forum had discussions to help prepare this Delegated Regulation in four meetings: on 4 April 2016 and 21 June 2016, discussion on the risk assessment methodology; and on 6 October 2016 and 9 February 2017, discussion on a draft text of this Delegated Regulation.

The draft Delegated Regulation was open for public feedback between 27/11/2017 and 25/12/2017. In total 69 contributions were received[2]. The contributions, and how they were taken into consideration, are summarised in the following paragraphs.

Some respondents praised the approach set out. Others were more critical, but while some relevant points were raised, other comments did not relate to the Delegated Regulation, instead referring more broadly to various aspects of the EU policy on IAS, and were thus not considered further. These comments referred *inter alia* to risk management, the process leading to the compilation of the list of species of Union concern, the decision making process of the IAS Committee, the composition of the Scientific Forum, the quality of the existing risk assessments and the cost effectiveness of including species on the Union list.

The IAS Regulation requires a risk assessment to describe the known uses and benefits of a species. This provides the context in which to assess the risks posed by a species. For example, it is useful to know if a species is traded and to have an indication of the volume of trade in order to understand the likelihood of introduction, the importance of certain pathways and the propagule pressure. However, a full economic analysis of the benefits of a species, or of the direct and indirect economic costs and financial consequences for companies, including the number of related jobs, of listing a species, as suggested by some stakeholders, are not necessary to assess the risk of introduction, establishment and spread of a species.

Some proposed to assess the likelihood of introduction and spread and the distribution of species specifically for sites of Community importance and special protection areas, established by virtue of the Nature Directives[3]. This is not necessary as the scope of the IAS Regulation includes, but is not limited to, supporting those Directives. It follows that the risk assessments should describe the impacts on all habitats impacted, as suggested by some stakeholders, rather than limiting the description to endangered habitats. The Delegated Act has been adjusted to reflect this suggestion. Regarding the ability of a species to reproduce and spread, some proposed that a minimum viable population assessment or a population viability analysis should be part of the risk assessment. These are methods used in

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1 Published in the Register of Commission Expert Groups and Other Similar Entities, code number E03276

2 https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5777844/feedback_en

3 Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7) and Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

conservation biology, to determine the chances of survival of a threatened and fragile species. They are not particularly relevant to assess the risk of a species becoming invasive, as some invasive alien species are capable of establishing and cause damage well below such thresholds.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

As mentioned in the introductory section, Article 5(3) of the IAS Regulation provides the legal basis for the development of this Delegated Regulation. In particular, Article 5(3) empowers the Commission to: 1) further specify the type of evidence acceptable for the purposes of point (b) of Article 4(3) – i.e. capability of establishment and spread; 2) provide a detailed description of the application of points (a) to (h) of Article 5(1); and 3) set out the methodology to be applied when preparing a risk assessment, taking into account relevant national and international standards.

This Delegated Regulation sets out to achieve these objectives:

Article 1 sets out the application of the common elements to be considered in a risk assessment; while Article 2 lays out a methodology, which sets out also the specification of the type of evidence that should underpin a risk assessment, including when the evidence relates to Article 4(3)(b) of the IAS Regulation. Finally, the Annex to this Regulation provides a detailed description of the application of points (a) to (h) of Article 5(1), the elements that need to be considered when preparing a risk assessment.

COMMISSION DELEGATED REGULATION (EU) …/...

of 30.4.2018

supplementing Regulation (EU) No 1143/2014 of the European Parliament and of the Council with regard to risk assessments in relation to invasive alien species

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species[4], and in particular Article 5(3) thereof,

Whereas:

(1) The Commission has, in accordance with Article 4 of Regulation (EU) No 1143/2014, adopted a list of invasive alien species of Union concern ('the Union list'), which is to be updated regularly. A precondition for including new species on the Union list is that a risk assessment as referred to in Article 5 of that Regulation ('the risk assessment') has been carried out. Article 5(1) of Regulation (EU) No 1143/2014 sets out, in points (a) to (h), the common elements that are to be considered in the risk assessment ('the common elements').

(2) Member States may, in accordance with Article 4(4) of Regulation (EU) No 1143/2014, submit requests for the inclusion of invasive alien species on the Union list. Those requests are to be accompanied by the risk assessment. Several methods and protocols to carry out the risk assessment are already in existence and are used and respected within the scientific community in the area of biological invasions. The value and scientific robustness of such methods and protocols should be recognised. In the interest of efficiently using existing knowledge, any method or protocol which includes the common elements should be accepted for the preparation of the risk assessment. However, in order to ensure that all decisions on listing species are based on risk assessments of similar high quality and robustness and to provide guidance to the risk assessors on how the ensure that the common elements are appropriately considered, it is necessary to set out a detailed description of the common elements, as well as a methodology to be applied in the risk assessment to which the existing methods and protocol should adhere.

(3) In order for the risk assessment to help underpin decision-making at the Union level, it should be of relevance to the Union as a whole, excluding the outermost regions ('the risk assessment area').

(4) In order for the risk assessment to provide a robust scientific basis and solid evidence to underpin decision-making, all information in it, including in relation to the ability of a species to establish and spread in the environment as per Article 4(3)(b) of Regulation (EU) No 1143/2014, should be supported by the best available scientific evidence. This aspect should be addressed in the methodology to be applied in the risk assessment.

[4] OJ L 317, 04.11.2014, p. 35.

(5) Invasive alien species are a serious environmental threat, but not every species is equally well studied. In cases where a species is not present in the risk assessment area or is only present in low numbers, there may be no knowledge or incomplete knowledge about that species. By the time full knowledge is acquired, the species may have already been introduced into or spread within the risk assessment area. Thus, the risk assessment should be able to account for such lack of knowledge and information and address the high degree of uncertainty as regards the consequences of an introduction or spread of the relevant species.

(6) In order for the risk assessment to provide a sound basis to underpin decision-making, it should be subject to rigorous quality control,

HAS ADOPTED THIS REGULATION:

Article 1
Application of the common elements

A detailed description of the application of the common elements laid down in points (a) to (h) of Article 5(1) of Regulation (EU) No 1143/2014 ('the common elements') is set out in the Annex to this Regulation.

Article 2
Methodology to be applied in the risk assessment

1. The risk assessment shall include the common elements, as specified in the Annex to this Regulation, and shall comply with the methodology set out in this Article. The risk assessment may be based on any protocol or method, provided that all requirements set out in this Regulation and in Regulation (EU) No 1143/2014 are fulfilled.

2. The risk assessment shall cover the territory of the Union, excluding the outermost regions ('the risk assessment area').

3. The risk assessment shall be based on the most reliable scientific information available, including the most recent results of international research, supported by references to peer reviewed scientific publications. In cases where there are no peer reviewed scientific publications or where the information provided by such publications is insufficient, or to supplement the information collected, the scientific evidence may also include other publications, expert opinions, information collected by Member States' authorities, official notifications and information from databases, including information collected through citizen science. All sources shall be acknowledged and referenced.

4. The method or protocol used shall allow for completion of the risk assessment to take place even where there is no information about a certain species or when the information about a species is insufficient. Where there is such a lack of information, the risk assessment shall state that fact explicitly so that no question in the risk assessment is left unanswered.

5. Each answer provided in the risk assessment shall include an assessment of the level of uncertainty or confidence attached to that answer, reflecting the possibility that information needed for the answer is not available or is insufficient or the fact that the available evidence is conflicting. The assessment of the level of uncertainty or confidence attached to an answer shall be based on a documented method or

protocol. The risk assessment shall include a reference to that documented method or protocol.

6. The risk assessment shall include a summary of its different components, as well as an overall conclusion, in a clear and consistent form.

7. A quality control process shall be an integral part of the risk assessment and shall include at least a review of the risk assessment by two peer reviewers. The risk assessment shall include a description of the quality control process.

8. The author(s) of the risk assessment and the peer reviewers shall be independent and have relevant scientific expertise.

9. The author(s) of the risk assessment and the peer reviewers shall not be affiliated to the same institution.

Article 3
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30.4.2018

For the Commission
The President
Jean-Claude JUNCKER