Commission Delegated Regulation (EU) 2018/968 of 30 April 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

COMMISSION DELEGATED REGULATION (EU) 2018/968

of 30 April 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[(1)], 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').

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(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.

(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

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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 April 2018.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

Detailed description of the common elements

The common elements	Detailed description
Art 5(1)(a) — a description of the species with its taxonomic identity, its history, and its natural and potential range	(1) The description of the species shall provide sufficient information to ensure that the identity of the species can be understood without reference to additional documentation. (2) The scope of the risk assessment shall be clearly delineated. While, as a general rule, one risk assessment should be developed for each single species, there may be cases where it may be justified to develop one risk assessment covering more than one species (e.g. species belonging to the same genus with comparable or identical features and impact). It shall be clearly stated if the risk assessment covers more than one species, or if it excludes or only includes certain subspecies, lower taxa, hybrids, varieties or breeds (and if so, which subspecies, lower taxa, hybrids, varieties or breeds). Any such choice must be properly justified. (3) The description of the taxonomic identity of the species shall include all of the following elements: — the taxonomic family, order and class to which the species belongs, — the current scientific name of the species and author of that name, — a list of the most common synonyms of the current scientific name, — names used in commerce, — a list of the most common subspecies, lower taxa, hybrids, varieties or breeds, — information on the existence of other species that look very similar: — other alien species with similar invasive characteristics, to be

a UNEP/CBD/SBSTTA/18/9/Add.1. — References to the classification of pathways developed by the Convention on Biological Diversity shall be construed as references to the latest amended version of that classification.

b 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).

c 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).

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	avoided as substitute species (in this case preparing a risk assessment for more than one species together may be considered, cf. point (2); — other alien species without similar invasive characteristics, that could be used as potential substitute species; — native species, to avoid potential misidentification and mis-targeting. (4) The description of the history of the species shall include the invasion history of the species, including information on countries invaded (in the risk assessment area and elsewhere, if relevant) and an indication of the timeline of the first observations, establishment and spread. (5) The description of the natural and potential range of the species shall include an indication of the continent or part of a continent, climatic zone and habitat where the species is naturally occurring. If applicable, it should be indicated whether the species could naturally spread into the risk assessment area.
Art 5(1)(b) — a description of its reproduction and spread patterns and dynamics including an assessment of whether the environmental conditions necessary for its reproduction and spread exist	(1) The descriptions of reproduction and spread patterns shall include elements of the species life history and behavioural traits, which can explain its ability to establish and spread, such as reproduction or growth strategy, dispersal capacity, longevity, environmental and climatic requirements, specialist or generalist characteristics and other relevant available information. (2) The description of the reproduction patterns and dynamics shall include all of the following elements:

a UNEP/CBD/SBSTTA/18/9/Add.1. — References to the classification of pathways developed by the Convention on Biological Diversity shall be construed as references to the latest amended version of that classification.

b 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).

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