

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 to 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.
- (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.

⁽¹⁾ OJ L 317, 4.11.2014, p. 35.

*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 April 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Detailed description of the common elements

The common elements	Detailed description
<p>Art 5(1)(a) — a description of the species with its taxonomic identity, its history, and its natural and potential range</p>	<p>(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.</p> <p>(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.</p> <p>(3) The description of the taxonomic identity of the species shall include all of the following elements:</p> <ul style="list-style-type: none"> — 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: <ul style="list-style-type: none"> — other alien species with similar invasive characteristics, to be 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. <p>(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.</p> <p>(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.</p>
<p>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</p>	<p>(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.</p> <p>(2) The description of the reproduction patterns and dynamics shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list and description of the reproduction mechanisms of the species,

The common elements	Detailed description
	<ul style="list-style-type: none"> — an assessment of whether suitable environmental conditions for the species' reproduction exist in the risk assessment area, — an indication of the propagule pressure of the species (e.g. number of gametes, seeds, eggs or propagules, number of reproductive cycles per year) for each of those reproduction mechanisms in relation to the environmental conditions in the risk assessment area. <p>(3) The description of the spread patterns and dynamics shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list and description of the spread mechanisms of the species, — an assessment of whether suitable environmental conditions for the species' spread exist in the risk assessment area, — an indication of the rate of each of those spread mechanisms in relation to the environmental conditions in the risk assessment area.
<p><i>Art 5(1)(c) — a description of the potential pathways of introduction and spread of the species, both intentional and unintentional, including where relevant the commodities with which the species is generally associated</i></p>	<p>(1) All relevant pathways for introduction as well as for spread shall be considered. The classification of pathways developed by the Convention on Biological Diversity ⁽¹⁾ shall be used as a basis.</p> <p>(2) The description of intentional pathways of introduction shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list and description of pathways with an indication of their importance and associated risks (e.g. the likelihood of introduction into the risk assessment area, based on those pathways; the likelihood of survival, reproduction or increase during transport and storage; the ability and likelihood of transfer from those pathways to a suitable habitat or host), including, where possible, details about the specific origins and end points of the pathways, — an indication of the propagule pressure (e.g. the estimated volume or number of specimens, or the frequency of passage through those pathways), including the likelihood of reinvasion after eradication. <p>(3) The description of unintentional pathways of introduction shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list and description of pathways with an indication of their importance and associated risks (e.g. the likelihood of introduction into the risk assessment area, based on those pathways; the likelihood of survival, reproduction or increase during transport and storage; the likelihood of non-detection at the entry point; the ability and likelihood of transfer from those pathways to a suitable habitat or host), including, where possible, details about the specific origins and end points of the pathways, — an indication of the propagule pressure (e.g. the estimated volume or number of specimens, or the frequency of passage through those pathways), including the likelihood of reinvasion after eradication. <p>(4) The description of commodities with which the introduction of the species is generally associated shall include a list and description of commodities with an indication of associated risks (e.g. the volume of trade flow; the likelihood of the commodity being contaminated or acting as a vector).</p>

⁽¹⁾ 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.

The common elements	Detailed description
	<p>(5) The description of intentional pathways of spread shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list and description of pathways with an indication of their importance and associated risks (e.g. the likelihood of spread within the risk assessment area, based on those pathways; the likelihood of survival, reproduction or increase during transport and storage; the ability and likelihood of transfer from those pathways to a suitable habitat or host), including, where possible, details about the specific origins and end points of the pathways, — an indication of the propagule pressure (e.g. the estimated volume or number of specimens, or the frequency of passage through those pathways), including the likelihood of reinvasion after eradication. <p>(6) The description of unintentional pathways of spread shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list and description of pathways with an indication of their importance and associated risks (e.g. the likelihood of spread within the risk assessment area, based on those pathways; the likelihood of survival, reproduction or increase during transport and storage; the ease of detection; the ability and likelihood of transfer from those pathways to a suitable habitat or host), including, where possible, details about the specific origins and end points of the pathways, — an indication of the propagule pressure (e.g. the estimated volume or number of specimens, or the frequency of passage through those pathways), including the likelihood of reinvasion after eradication. <p>(7) The description of commodities with which the spread of the species is generally associated shall include a list and description of commodities with an indication of associated risks (e.g. the volume of trade; the likelihood of a commodity being contaminated or acting as vector).</p>
<p><i>Art 5(1)(d) — a thorough assessment of the risk of introduction, establishment and spread in relevant biogeographical regions in current conditions and in foreseeable climate change conditions</i></p>	<p>(1) The thorough assessment shall provide insights into the risks of a species' introduction into, establishment in and spread within relevant biogeographical regions in the risk assessment area, explaining how foreseeable climate change conditions will influence those risks.</p> <p>(2) The thorough assessment of those risks does not have to include a full range of simulations on the basis of different climate change scenarios, as long as an assessment of likely introduction, establishment and spread within a medium timeframe scenario (e.g. 30-50 years) with a clear explanation of the assumptions is provided.</p> <p>(3) The risks referred to in point (1) may, for example, be described in terms of 'likelihood' or 'rate'.</p>
<p><i>Art 5(1)(e) — a description of the current distribution of the species, including whether the species is already present in the Union or in neighbouring countries, and a projection of its likely future distribution</i></p>	<p>(1) The description of the current distribution in the risk assessment area or in neighbouring countries shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list of biogeographic region(s) or marine subregion(s) in the risk assessment area, where the species is present and where it has established, — the current establishment status of the species in each Member State and, where relevant, in neighbouring countries.

The common elements	Detailed description
	<p>(2) The projection of the likely future distribution in the risk assessment area or in neighbouring countries shall include all of the following elements:</p> <ul style="list-style-type: none"> — a list of biogeographic region(s) or marine subregion(s) in the risk assessment area, where the species could establish, in particular under foreseeable climate change conditions, — a list of Member States and, where relevant, neighbouring countries where the species could establish, in particular under foreseeable climate change conditions.
<p>Art 5(1)(f) — a description of the adverse impact on biodiversity and related ecosystem services, including on native species, protected sites, endangered habitats, as well as on human health, safety, and the economy including an assessment of the potential future impact having regard to available scientific knowledge</p>	<p>(1) In the description, a distinction shall be made between the known impact and the potential future impact on biodiversity and related ecosystem services. The known impact shall be described for the risk assessment area, and for third countries if relevant (e.g. with similar eco-climatic conditions). The potential future impact shall be assessed only for the risk assessment area.</p> <p>(2) The description of the known impact and the assessment of the potential future impact shall be based on the best available quantitative or qualitative evidence. The magnitude of the impact shall be scored or otherwise classified. The impact scoring or classification system used shall include a reference to the underlying publication.</p> <p>(3) The description of the known impact and the assessment of the potential future impact on biodiversity shall make reference to all of the following elements:</p> <ul style="list-style-type: none"> — the different biogeographic regions or marine sub-regions where the species could establish, — native species impacted, including red list species and species listed in the annexes of Council Directive 92/43/EEC ⁽²⁾ and species covered by Directive 2009/147/EC of the European Parliament and of the Council ⁽³⁾, — habitats impacted, including red list habitats and habitats listed in the annexes of Directive 92/43/EEC, — protected sites impacted, — impacted chemical, physical or structural characteristics and functioning of ecosystems, — impacted ecological status of aquatic ecosystems or impacted environmental status of marine waters. <p>(4) The description of the known impact and the assessment of the potential future impact on related ecosystem services shall make reference to all of the following elements:</p> <ul style="list-style-type: none"> — provisioning services, — regulating services, — cultural services. <p>(5) The description of the known impact and the assessment of potential future impact on human health, safety and the economy, shall, if relevant, include information on:</p> <ul style="list-style-type: none"> — illnesses, allergies or other affections to humans that may derive directly or indirectly from a species, — damages provoked directly or indirectly by a species with consequences for the safety of people, property or infrastructure, — direct or indirect disruption of, or other consequences for, an economic or social activity due to the presence of a species.

⁽²⁾ 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).

⁽³⁾ 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).

The common elements	Detailed description
<i>Art 5(1)(g) — an assessment of the potential costs of damage</i>	<p>(1) The assessment, in monetary or other terms, of the potential costs of damage on biodiversity and ecosystem services shall describe those costs quantitatively and/or qualitatively depending on what information is available. If the information available is not sufficient to assess the costs for the entire risk assessment area, qualitative data or different case studies from across the Union or third countries shall be used, if available.</p> <p>(2) The assessment of the potential costs of damage on human health, safety, and the economy shall describe those costs quantitatively and/or qualitatively depending on what information is available. If the information available is not sufficient to assess the costs for the entire risk assessment area, qualitative data or different case studies from across the Union or third countries shall be used, if available.</p>
<i>Art 5(1)(h) — a description of the known uses for the species and social and economic benefits deriving from those uses</i>	<p>(1) The description of known uses for the species shall include a list and description of known uses in the Union and elsewhere, if relevant.</p> <p>(2) The description of social and economic benefits deriving from the known uses for the species shall include a description of the environmental, social and economic relevance of each of those uses and an indication of associated beneficiaries, quantitatively and/or qualitatively depending on what information is available. If the information available is not sufficient to provide a description of those benefits for the entire risk assessment area, qualitative data or different case studies from across the Union or third countries shall be used, if available.</p>