

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

on the prevention and management of the introduction and spread of invasive alien species

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee¹

After consulting ■ the Committee of the Regions ■ ,

Acting in accordance with the ordinary legislative procedure²,

¹ *OJ C...*

² *Position of the European Parliament of ... (not yet published in the Official Journal) and decision of the Council of ...*

Whereas:

- (1) The appearance of alien species, whether animals, plants, fungi or micro-organisms, in new locations is not always a cause for concern. However, a significant subset of alien species can become invasive and have serious adverse impacts on biodiversity, *the related* ecosystem services, as well as other economic and social impacts, which should be prevented. Some 12 000 species in the environment in the Union and other European countries are alien, of which roughly 10 to 15 % are estimated to be invasive.
- (2) Invasive alien species represent one of the primary threats to biodiversity and ecosystem services, especially in geographically and evolutionary isolated ecosystems, such as small islands, and the risks such species pose may be greater due to increased global trade, transport, tourism and climate change.
- (3) The threat to biodiversity and ecosystem services that invasive alien species pose can take different forms such as impacting severely on native species and ecosystem structure and function through alteration of habitat, predation, competition, transmission of diseases, replacement of native species throughout a significant proportion of range and genetic effects by hybridisation. Furthermore, invasive alien species can also have a significant *adverse* impact on human health and the economy. It is only live specimens, or parts that can reproduce, that represent a threat to biodiversity and ecosystem services, human health or the economy *and should therefore be subject to the restrictions under this Regulation.*

- (4) The Union, as a party to the Convention on Biological Diversity, approved by Council Decision 93/626/EEC¹, is bound by the provisions of Article 8(h) *of that Convention*, according to which the Parties shall, as far as possible and as appropriate, 'prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species'.
- (5) The Union, as a *Party* to the Convention on the Conservation of European Wildlife and Natural Habitats (the Bern Convention), approved by Council Decision 82/72/EEC², has undertaken to take all appropriate measures to ensure the conservation of the habitats of the wild flora and fauna species.
- (6) To support the achievement of the objectives of *Directives* of the European Parliament and of the Council 2000/60/EC³, 2008/56/EC⁴ and 2009/147/EC⁵, and Council Directive 92/43/EEC⁶, the primary objective of this Regulation should be to prevent, minimise and mitigate the adverse effects of invasive alien species on biodiversity, *the related* ecosystem services, *human health and safety* as well as to reduce their economic and social impact.

¹ Council Decision of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity (OJ L 309, 13.12.1993, p. 1).

² Council Decision 82/72/EEC of 3 December 1981 concerning the conclusion of the Convention on the conservation of European wildlife and natural habitats (OJ L 38, 10.2.1982, p. 1).

³ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁴ Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

⁵ 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)

⁶ 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).

- (7) Some species migrate naturally in response to environmental changes. Therefore they should not be considered as alien species in their new environment and are thus excluded from the scope of the new rules on invasive alien species. ***This Regulation should focus only on species introduced in the Union as a consequence of human intervention.***
- (8) At Union level, ***there are currently over 40 animal health directives and regulations which*** include provisions on animal diseases. ***Moreover, Council Directive 2000/29/EC¹*** provides rules for ***organisms which are harmful to plants or plant products***, and Directive 2001/18/EC of the European Parliament and of the Council² **■** sets out the regime applicable to genetically modified organisms. Therefore, ***any*** new rules on invasive alien species should ***be aligned to*** and not overlap with, those ***legislative acts of the*** Union **■** and ***should*** not apply to the organisms targeted by those ***legislative*** acts.
- (9) ***Regulations*** of the European Parliament and of the Council ***(EC) No 1107/2009³ and (EU) No 528/2012⁴ and Council Regulation (EC) No 708/2007⁵*** provide for rules concerning the authorisation for the use of certain alien species for particular purposes. The use of certain species has already been authorised under those regimes at the time of entry into force of ***this Regulation***. In order to ensure a coherent legal framework, those species should thus be excluded from the ***scope of this Regulation***.

¹ ***Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 106, 10.7.2000, p. 1).***

² ***Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).***

³ ***Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).***

⁴ ***Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).***

⁵ ***Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture (OJ L 168, 28.6.2007, p.1).***

- (10) As invasive alien species are numerous, it is important to ensure that priority is afforded to addressing the subset of invasive alien species considered to be of Union concern. A list of such invasive alien species considered to be of Union concern should therefore be drawn up ***and regularly updated***. An invasive alien species should be considered of Union concern if the damage it is causing in the affected Member States is so significant that it justifies the adoption of dedicated measures the scope of which extends across the Union, including in the Member States that are not yet affected or even unlikely to be affected. In order to ensure that the subset of invasive alien species of Union concern remains proportionate, the list should be developed ***and updated*** in line with a gradual and phased-in approach ***and be focused on species whose inclusion in the list would effectively prevent, minimise or mitigate their adverse impacts in a cost efficient manner. As species within the same taxonomic group often have similar ecological requirements and may pose similar risk, the inclusion of taxonomic groups of species into the list of invasive alien species of Union concern should be allowed, where appropriate.***

- (11) The criteria to list invasive alien species considered to be of Union concern *are* the core instrument to apply *this Regulation*. *In order to ensure an effective use of resources, the criteria should also make sure that the invasive alien species having the most significant adverse impact among the potential invasive alien species currently known are those that will be listed. The Commission will* submit a proposal for a list based on those criteria within one year of the entry into force of this legislation to the Committee. *When proposing the list, the Commission should inform the Committee on how it took into account those criteria.* The criteria should include a risk assessment pursuant to the applicable provisions under the *relevant* Agreements of the World Trade Organisation on placing trade *restrictions* on species.
- (12) *In order to avoid disproportionate or excessive costs for any Member State and safeguard the added value of Union action through this Regulation, when proposing the list and consequential measures, the Commission should take into consideration the socio-economic aspects, the implementation cost for Member States and the cost of non-action. In this context, in selecting the invasive alien species to be included in the list of Union concern, special attention should be given to species that are widely used and provide significant social and economic benefits in a Member State, without compromising the objectives of this Regulation.*

- (13) In order to ensure compliance with the rules *under the relevant Agreements* of the World Trade Organisation and ■ the coherent application of *this Regulation*, common criteria should be established to perform the risk assessment. Those criteria should use when appropriate existing national and international standards and should encompass different aspects of the characteristics of the species, the risk and modes of *introduction* into the Union, the *adverse* economic, social and biodiversity impacts of the species, the potential benefits of uses and the costs of mitigation to weight them against the *adverse* impacts, as well as *an assessment* of the *potential costs of* environmental, economic and social damage ■ demonstrating the significance for the Union, so as to further justify action. In order to develop the system progressively and build upon the experience gained, the overall approach should be evaluated *by 2021*.
- (14) Some invasive alien *species* are included in Annex B to Council Regulation (EC) No 338/97¹ ■ , and their import into the Union is prohibited because their invasive character has been recognised and their introduction into the Union has *an adverse* impact on native species. *Those* species are: *Callosciurus erythraeus*, *Sciurus carolinensis*, *Oxyura jamaicensis*, *Lithobates (Rana) catesbeianus*, *Sciurus niger*, *Chrysemys picta*, *Trachemys scripta elegans*. To ensure a coherent legal framework and uniform rules ■ on invasive alien species *at the level of the Union*, those invasive alien animals should be considered as a matter of priority for listing as invasive alien species of Union concern.

¹ *Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein* (OJ L 61, 3.3.1997, p. 1).

- (15) Prevention is generally more environmentally desirable and cost-effective than reaction after the fact and should be prioritised. ***Therefore, priority should be given to the listing of species that are not yet present in the territory of the Union or are at an early stage of invasion as well as to species that are likely to have the most significant adverse impacts.*** As new species can be introduced continuously into the Union and alien species present are spreading and expanding their range, it is necessary to ensure that the list of invasive alien species of Union concern is constantly revised and kept up-to-date.
- (16) ***Regional cooperation should be explored between Member States concerned with the same species that are not able to establish a viable population in a large part of the Union. Where the objectives of this Regulation are better achieved by measures at Union level, these species could also be included in the list of invasive alien species of Union concern.***

- (17) *It is appropriate to take account of the specific situation of the outermost regions as regards the objectives of this Regulation, and in particular their remoteness, insularity and the uniqueness of their respective biodiversities. Therefore, it is justified to adapt the requirements under this Regulation of taking restrictive and preventive measures relating to* ■ *invasive alien species of Union concern to these specificities of the outermost regions, as defined by the Treaty on the Functioning of the European Union (TFEU), taking into account European Council Decisions 2010/718/EU¹ ■ and 2012/419/EU².*
- (18) The risks and concerns associated with invasive alien species represent a cross-border challenge affecting the whole of the Union. It is therefore essential to adopt at Union level a ban on intentionally *or negligently* bringing into the Union, reproducing, growing, transporting, buying, selling, using, exchanging, keeping and releasing invasive alien species of Union concern, to ensure that *early and* consistent action is taken across the Union so as to avoid distortions of the internal market and to prevent situations where action taken in one Member State is undermined by inaction in another Member State.

¹ *European Council Decision 2010/718/EU of 29 October 2010 amending the status with regard to the European Union of the island of Saint-Barthélemy (OJ L 325, 9.12.2010, p. 4).*

² *European Council Decision 2012/419/EU of 11 July 2012 amending the status of Mayotte with regard to the European Union (OJ L 204, 31.7.2012, p. 131).*

- (19) With a view to enabling scientific research and ex-situ conservation activities, it is necessary to provide specific rules for the invasive alien species of Union concern subject to those activities. Those activities should be carried out in closed *establishments* where the organisms are in contained holding and with all the necessary measures taken to avoid the escape or unlawful release of invasive alien species of Union concern. *Where authorised by the Commission in duly motivated exceptional cases of compelling public interest those rules could also apply to certain other activities, including commercial activities. In implementing those rules, particular attention should be paid to avoiding any adverse impacts on protected species and habitats, in line with relevant Union law.*
- (20) There may be cases where alien species not yet recognised as invasive alien species of Union concern appear at the Union borders or are detected in the Union territory. Member States should therefore be granted the possibility to adopt on the basis of available scientific evidence certain emergency measures. Such emergency measures would allow immediate reaction against species which may pose risks related to their introduction, establishment and spread in those countries, while Member States assess the effective risks posed by them, in line with the applicable provisions of the *relevant* Agreements of the World Trade Organisation, in particular with a view to having those species recognised as invasive alien species of Union concern. There is a need to couple national emergency measures with the possibility of adopting emergency measures at Union level in order to comply with the provisions of the *relevant Agreements* of the World Trade Organisation. Furthermore, Union level emergency measures would equip the Union with a mechanism to act swiftly in case of presence or imminent danger of entry of a new invasive alien species in accordance with the precautionary principle.

- (21) A large proportion of invasive alien species are introduced unintentionally into the Union. It is therefore crucial to manage the pathways of unintentional introduction *more effectively*. Action in this area would need to be gradual, given the relatively limited experience in this field. Action should include voluntary measures, such as the actions proposed by the International Maritime Organisation's Guidelines for the Control and Management of Ships' Biofouling, and mandatory measures and should build on the experience gained in the Union and in Member States in managing certain pathways, including measures established through the International Convention for the Control and Management of Ships Ballast Water and Sediments. ***Accordingly the Commission should take all appropriate steps to encourage Member States to ratify that Convention.***
- (22) In order to develop an adequate knowledge base to address the problems raised by invasive alien species, it is important that Member States undertake research, monitoring and surveillance of such species. As surveillance systems offer the most appropriate means for early detection of new invasive alien species and for the determination of the distribution of already established species, they should include both targeted and general surveys and benefit from the involvement of different sectors and stakeholders, including *regional and local communities*. Surveillance systems should imply paying continuous attention to any new invasive alien species anywhere in *the Union and aim to provide an effective and complete picture at the level of* the Union. In the interest of efficiency and cost-effectiveness, existing systems of *customs* control, surveillance and monitoring already established *by the Union law* should be applied, in particular those set out *in Directives* ■ 92/43/EEC, 2000/60/EC, 2008/56/EC and 2009/147/EC.

- (23) Official controls on animals and plants should be carried out in order to prevent the intentional introduction of invasive alien species. Live animals and plants should enter the Union through border control *entities* in accordance with Regulation (EC) No 882/2004, *Directives 91/496/EEC and 97/78/EC or points of entry in accordance with Directive 2000/29/EC*. In order to ensure efficiency gains and avoid creating parallel systems of *customs* controls, the verification whether these species are invasive alien species of Union concern should also be carried out at the first *border control entity or point of entry of arrival*.
- (24) After the introduction of an invasive alien species, early detection and rapid eradication measures are crucial to prevent their establishment and spread. The most effective and cost efficient response is often to eradicate the population, as soon as possible while the number of specimens is still limited. In the event that eradication is not feasible or the costs of eradication outweigh in the long term the environmental, economic and social benefits, containment and control measures should be applied. *Management measures should be proportional to the impact on the environment and take due consideration of biogeographic or climatic conditions of the Member State concerned.*

- (25) **Management measures should avoid any adverse impacts on the environment as well as on human health.** Eradicating and managing some **animal** invasive alien species, while necessary **in some cases**, may induce pain, distress, fear or other forms of suffering to the animals even when using the best available technical means. For that reason, Member States and any operator involved in the eradication, control or containment of invasive alien species should take the necessary measures to **spare avoidable** pain, distress and suffering of animals during the process, taking into account in so far as possible the best practices in the field, for example the Guiding Principles on Animal Welfare developed by the World Organisation for Animal Health. **Non-lethal methods should be considered and any actions taken should minimise impact on non-target species.**
- (26) Invasive alien species generally cause damage to ecosystems and reduce their resilience. Therefore **proportionate** restoration measures **should be undertaken** to strengthen the ecosystems' resilience towards invasions, to repair the damage caused and to enhance the conservation status of species and their habitats in accordance with **Directives 92/43/EEC and 2009/147/EC** , the ecological status of inland surface waters, transitional waters, coastal waters and groundwater in accordance with **Directive 2000/60/EC**, and the environmental status of marine waters in accordance with **Directive 2008/56/EC**. **Costs of such restoration measures should be recovered in accordance with the polluter pays principle.**

- (27) *Cross-border cooperation, particularly with neighbouring countries, and coordination between Member States, particularly within the same biogeographical region of the Union should be fostered to contribute to the effective application of this Regulation.*
- (28) A system to address invasive alien species should be underpinned by a centralised information system collating the existing information on alien species in the Union and allowing access to information on presence of species, their spread, their ecology, invasion history and all other information necessary to underpin policy and management decisions *and also the exchange of best practices.*
- (29) Directive 2003/35/EC of the European Parliament and of the Council¹ *has established* a framework for public consultation in environment related decisions. In defining action in the field of invasive alien species, effective public participation should enable the public to express, and the decision-maker to take account of, opinions and concerns which may be relevant to those decisions, thereby increasing the accountability and transparency of the decision-making process and contributing to public awareness of environmental issues and support for the decisions taken.

¹ *Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment* (OJ L 156, 25.6.2003, p. 17).

- (30) *The participation of the scientific community is important in order to provide an adequate knowledge base to address the problems raised by invasive alien species. A dedicated Scientific Forum should be set up to provide advice on the scientific aspects related to the application of this Regulation, in particular as regards establishing and updating the list of invasive species of Union concern, risk assessment, emergency measures and rapid eradication measures.*
- (31) In order to ensure uniform conditions for the *implementation* of this Regulation, *implementing powers should be conferred on the Commission in respect of the adoption and updating of the list of invasive alien species of Union concern, the format of the documents serving as evidence for permits, granting derogations from the obligation of rapid eradication and adoption of Union emergency measures, the requirements to apply certain provisions in Member States in the case of enhanced regional cooperation, and the formats for reporting to the Commission.* Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹ .

¹ *Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).*

- (32) In order to take into account the latest scientific developments in the environmental field, the power to adopt acts in accordance with Article 290 of the *TFEU* should be delegated to the Commission in respect of determining how to conclude that invasive alien species are capable of establishing viable populations and of spreading, as well as for setting out the common elements for the development of risk assessments. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (33) In order to guarantee compliance with this Regulation, it is important that Member States impose dissuasive, effective and proportionate sanctions for infringements taking into account the nature and gravity of the infringement, *the principle of recovery of the costs and the polluter pays principle*.
- (34) *By measures taken under this Regulation, Member States may impose obligations on holders or users of alien species as well as owners and tenants of lands concerned.*

- (35) In order to enable non-commercial owners to continue keeping their companion animals that belong to species listed as invasive alien species of Union concern until the animal's natural death, it is necessary to provide transitional measures, on the condition that all measures are put in place to avoid escape or reproduction.
- (36) In order to enable commercial operators, who may have legitimate expectations, for instance those who have received an authorisation in accordance with Regulation (EC) No 708/2007, to exhaust their stock of invasive alien species of Union concern **by the time of entry** into force **of this Regulation**, it is justified to allow them two years to slaughter, **humanely cull**, sell or, **where relevant**, hand over the specimens to research or ex-situ conservation establishments.

- (37) Since the objectives of *this Regulation*, namely the prevention and management of invasive alien species, cannot be sufficiently achieved by the Member States *but* can *rather*, by reason of *its* scale and effects ■ , be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this act does not go beyond what is necessary in order to achieve *those objectives*.
- (38) *Member States may maintain or adopt rules on invasive alien species of Union concern that are more stringent than those laid down in this Regulation; they may, in addition, apply provisions such as those set out in this Regulation for invasive alien species of Union concern to invasive alien species of Member State concern. Those measures should be compatible with the TFEU and be notified to the Commission in accordance with Union law,*

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

This Regulation sets out rules to prevent, minimise and mitigate the adverse impacts of the introduction and spread, both intentional and unintentional, of invasive alien species on biodiversity *within the Union*.

Article 2

Scope

1. This Regulation applies to all invasive alien species ■ .
2. This Regulation does not apply to:
 - (a) species changing their natural range without human intervention, in response to changing ecological conditions and climate change;
 - (b) genetically modified organisms as defined in Article 2 of Directive 2001/18/EC;

- (c) *pathogens that cause animal diseases; for this purpose, animal disease means the occurrence of infections and infestations in animals, caused by one or more pathogens transmissible to animals or to humans;*
- (d) *harmful organisms listed in Annex I or in Annex II to Directive 2000/29/EC, and harmful organisms for which measures have been adopted in accordance with Article 16(3) of that Directive;*
- (e) species listed in Annex IV to Regulation (EC) No 708/2007 *when used in aquaculture;*
- (f) micro-organisms manufactured or imported for use in plant protection products already *authorised* or for which an assessment is on-going under Regulation (EC) No 1107/2009;
- (g) micro-organisms manufactured or imported for use in biocidal products already *authorised or for which an assessment is ongoing under* Regulation (EU) No 528/2012.

Article 3
Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'alien species' means any live specimens of species, subspecies or lower taxon of animals, plants, fungi or micro-organisms introduced outside its natural **range**; it includes any part, gametes, seeds, eggs, or propagules of such species, as well as any hybrids, varieties or breeds that might survive and subsequently reproduce;
- (2) 'invasive alien species' means an alien species whose introduction or spread has been found **■** to threaten **or adversely impact upon** biodiversity and **the related** ecosystem services **■** ;
- (3) 'invasive alien species of Union concern' means invasive alien species whose **adverse** impact has been deemed such as to require concerted action at the level of the Union pursuant to Article 4(3);
- (4) ***'invasive alien species of Member State concern' means invasive alien species other than invasive alien species of Union concern, for which a Member State considers on the basis of scientific evidence that the adverse impact from their release and spread, even where not fully ascertained, is of significance for its territory, or part of it, and requires action at the level of that Member State;***

- (5) 'biodiversity' means the variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;
- (6) 'ecosystem services' means the direct and indirect contributions of ecosystems to human wellbeing;
- (7) 'introduction' means the movement, *as a consequence of* human intervention, of a species outside its ■ natural *range*;
- (8) 'research' means descriptive or experimental work, undertaken under regulated conditions to *obtain* new *scientific findings* or to develop new products, including the initial phases of identification, characterisation and isolation of genetic features, other than *those features which make a species invasive*, of invasive alien species only insofar as essential for enabling the breeding of those features into non-invasive species;
- (9) 'contained holding' means keeping an organism in closed facilities from which escape or spread is not possible;

- (10) 'ex-situ conservation' means the conservation of components of biological diversity outside their natural habitat;
- (11) 'pathways' means the routes and mechanisms of ***introduction and spread of invasive alien species***;
- (12) 'early detection' means the confirmation of the presence of specimens of an invasive alien species in the environment before it has become widely spread;
- (32) 'eradication' means the complete and permanent removal of a population of invasive alien species by ***lethal or non-lethal*** means;
- (14) 'widely spread' means an invasive alien species whose population has gone beyond the naturalisation stage, in which a population maintains a self-sustaining population, and has spread to colonise a large part of the potential range where it can survive and reproduce;
- (15) 'management' means any ***lethal or non-lethal*** action aimed at the eradication, population control or containment of a population of an invasive alien species, ***while also minimising the impact on non-targeted species and their habitats***;

- (16) 'containment' means actions aimed at creating barriers which minimise the risk for a population of an invasive alien species to disperse and spread beyond the invaded area;
- (17) 'population control' means *lethal* or *non-lethal* actions applied to a population of invasive alien species, *while also minimising impact on non-targeted species and their habitats*, with the aim of keeping the number of individuals as low as possible, so that, while not being able to eradicate the species, its invasive capacity and adverse impacts on biodiversity, *the related* ecosystem services, ■ on human health *or* the economy, are minimised.

Article 4

List of invasive alien species of Union concern

1. ***The Commission shall adopt, by way of implementing acts, a list of invasive alien species of Union concern ■ on the basis of the criteria laid down in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2). The draft implementing act shall be submitted to the Committee referred to in Article 27(1) by ... ****

* ***OJ please insert the date - 12 months of the entry into force of this Regulation.***

2. *The Commission shall make a comprehensive review of the list at the latest every six years and shall, in the meantime, update it with the addition of new species or the removal, if they no longer meet any of the criteria laid down in paragraph 3, of listed species as appropriate in accordance with the procedure referred to in paragraph 1.*
3. Invasive alien species shall only be included on the list referred to in paragraph 1 *of this Article* if they meet all of the following criteria:
 - (a) they are *found, based on available* scientific evidence ■ to be alien to the territory of the Union excluding the outermost regions;
 - (b) they are *found, based on available* scientific evidence ■, to be capable of establishing a viable population and spreading in the environment under current or foreseeable climate change conditions *in one biogeographical region shared by more than two Member States or one marine subregion* excluding *their* outermost regions;
 - (c) *they are, based on available scientific evidence, likely to have significant adverse impacts on biodiversity or the related ecosystem services, and may also have an adverse impact on human health or the economy;*

- (d) it is demonstrated by a risk assessment performed pursuant to Article 5(1) that action at Union level is required to prevent their *introduction*, establishment and spread;
- (e) *it is likely that the inclusion in the list will effectively prevent, minimise or mitigate their adverse impacts.*

4. Member States may submit to the Commission requests for the inclusion of invasive alien species on the list referred to in paragraph 1 *of this Article*. Those requests shall include all of the following¹ :

- (a) the name of the species;
- (b) a risk assessment performed in accordance with Article 5(1);
- (c) evidence that¹ the criteria set out in paragraph 3 *of this Article are met.*

5. The list referred to in paragraph 1 *of this Article shall make reference, where relevant, to the goods with which the species are generally associated and their Combined Nomenclature codes as provided by Council Regulation (EEC) No 2658/87¹, indicating the categories of goods that shall be subject to official controls pursuant Article 15 of this Regulation.*

¹ *Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).*

6. *In adopting or updating the list, the Commission shall apply the criteria of paragraph 3 with due consideration to the implementation cost for the Member States, the cost of non-action, the cost-effectiveness and the socio-economic aspects. The list shall include as a priority those invasive alien species that:*
- (a) are not yet present in the Union or are at an early stage of invasion and are most likely to have significant adverse impacts;*
 - (b) are already established in the Union and have the most significant adverse impacts.*
7. *When proposing the list of invasive alien species of Union concern, the Commission shall also justify that the objectives of this Regulation are better achieved by measures at Union level.*

Article 5

Risk assessment ■

1. The ■ risk assessment referred to in Article 4(3)(d) *shall be carried out, across the current and potential range of invasive alien species*, having regard to the following elements:
 - (a) a description of the species with its taxonomic identity, its history, *natural and* potential range;
 - (b) a description of its reproduction and spread patterns *and dynamics* including an assessment of whether the environmental conditions necessary for reproduction and spread exist;
 - (c) a description of the potential pathways of *introduction* and spread, both intentional and unintentional, including where relevant the commodities with which the species are generally associated;
 - (d) a thorough assessment of the risk of *introduction*, establishment, spread in relevant biogeographical regions in current conditions and in foreseeable climate change conditions;

- (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*;
- (f) a description of the *adverse* impact on biodiversity and *the 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 impacts having regard to available scientific knowledge*;
- (g) *an assessment of the potential costs of damage*;
- (h) a description of the *known* uses and *social and economic* benefits deriving from those uses ■ .

2. *The Commission shall carry out the risk assessments referred to in Article 4(3)(d), having regard to the elements referred to in paragraph 1 of this Article, when proposing species for listing as invasive alien species of Union concern. Whenever a Member State submits a request for the inclusion of a species on the list of invasive alien species of Union concern it shall be responsible for carrying out a risk assessment having regard to the elements of paragraph 1 of this Article. Where necessary, the Commission may assist the Member States in the development of such risk assessments in so far as it relates to their European dimension.*

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 29 to further specify the type of **■** evidence *acceptable* in Article 4(3)(b) and **■** provide a detailed description of the application of *points* (a) to (h) of *paragraph 1* of this Article. *The detailed description shall include* the methodology to be applied in the assessment of such elements **■** taking into account relevant national and international standards and the need to prioritise action against species associated with, or that have the potential to cause, significant *adverse impacts on biodiversity or the related ecosystem services, as well as on human health or the economy being considered as aggravating factors. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.*

Article 6

Provisions for the outermost regions

1. *Invasive alien species of Union concern* shall not be subject to *Article 7, and* Articles **■** 13 **■** to 20 in the outermost *regions*.
2. By ... **■** ^{*}, each Member State with outermost regions shall adopt a list of invasive alien species of concern for each of its outermost regions, in consultation with those regions.
3. *As regards the* species included on the lists referred to in paragraph 2 *of this Article, Member States may*, within the respective outermost regions, *apply measures as those provided for in* Articles 7, 8, 9, 13 to 17, 19 and 20, *as appropriate. Those measures shall be compatible with the TFEU and be notified to the Commission in accordance with the* Union law.
4. Member States shall immediately notify the Commission and shall inform the other Member States of the lists referred to in paragraph 2 and of any update of those lists.

* *OJ please insert the date - 24 months from the entry into force of this Regulation.*

CHAPTER II
PREVENTION

Article 7

Restrictions

1. ***Invasive*** alien species of Union concern ■ shall not be intentionally:
 - (a) brought into ■ the ■ territory ***of the Union, including transit under customs supervision;***
 - (b) ***kept, including in contained holding;***
 - (c) ***bred, including in contained holding;***
 - (d) transported ***to, from or within the Union,*** except for the transportation of species to facilities ***in the context of*** eradication;
 - (e) placed on the market;
 - (f) used or exchanged;
 - (g) ***permitted to reproduce, grown or cultivated,*** including in contained holding;
 - (h) released into the environment.
2. Member States shall ***take all necessary steps to*** prevent the unintentional introduction ***or spread*** of invasive alien species of Union concern. ***This shall also cover such introduction or spread by gross negligence, where applicable.***

Article 8

Permits

1. By way of derogation from the *restrictions* set out in points (a), (b), (c), (d), (f) and (g) of Article 7(1), Member States shall establish a permit system allowing establishments to carry out research or ex-situ conservation on invasive alien species of Union concern *in accordance with paragraph 2 of this Article. Where the use of products derived from invasive alien species of Union concern is unavoidable to advance human health, Member States can also include scientific production and subsequent medicinal use within the permit system.*
2. Member States shall empower the relevant competent authorities to issue the permits referred to in paragraph 1 for activities carried out in contained holding that fulfil all of the following conditions:
 - (a) the invasive alien species of Union concern is kept in and handled in *contained holdings* as referred to in paragraph 3;
 - (b) the activity is to be carried out by *appropriately qualified* personnel as prescribed by the competent authorities;
 - (c) transport to and from the *contained holding* is carried out under conditions that exclude escape of the invasive alien species *as established by the permit*;

- (d) in *the* case of invasive alien species *of Union concern* that are animals, they are marked *or otherwise effectively identified where appropriate, using methods that do not cause preventable pain, distress or suffering*;
- (e) the risk of escape or spread or removal is effectively managed, taking into account the identity, biology and means of dispersal of the species, the activity and the *contained holding* envisaged, the interaction with the environment and other relevant factors **■** ;
- (f) a continuous surveillance and a contingency plan to cater for possible escape or spread is drawn up, including an eradication plan. *The contingency plan shall be approved by the relevant competent authority. If an escape or spread occurs, the contingency plans shall be implemented immediately and the permit can be withdrawn, temporarily or permanently*;
- (g) *the* permit referred to in paragraph 1 shall be limited to *a* number of species and specimens that *does* not exceed the capacity of the *contained holding*. It shall include the restrictions necessary to mitigate the risk of escape or spread of the species concerned. It shall accompany the invasive alien species to which it refers at all times when these are kept, brought into and transported within the Union.

3. Specimens shall be considered to be kept in *contained holdings* if the following conditions are fulfilled:
 - (a) they are physically isolated and they cannot escape or spread or be removed *by unauthorised persons* from the *holdings where* they are kept **█** ; cleaning, *waste handling* and maintenance protocols shall ensure that no specimens or reproducible parts can escape, spread or be removed by unauthorised persons;
 - (b) their removal from the *holdings*, disposal or destruction *or humane cull* is done in such way as to exclude propagation or reproduction outside of the *holdings*.
4. When applying for a permit, the *applicant* shall provide all necessary evidence to allow the competent authority to assess whether the conditions referred to in paragraphs 2 and 3 are fulfilled.
5. *Member States shall empower the relevant competent authority to withdraw the permit at any point in time, temporarily or permanently, if unforeseen events with adverse impacts on biodiversity or ecosystem services occur. Any withdrawal of a permit must be justified on scientific grounds and, where scientific information is as yet insufficient, on the grounds of the precautionary principle and having due regard to national administrative rules.*

6. *The Commission shall adopt, by way of an implementing act, the format of the document serving as evidence for the permit granted by a Member State. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(2). Member States shall use this format for a document accompanying the permit.*
7. *For all permits issued in accordance with paragraph 1 of this Article, Member States, shall make, without delay, publicly available on line at least the following:*
 - (a) *the scientific and common names of the invasive alien species of Union concern for which the permit has been granted;*
 - (b) *the number or the volume of specimens concerned;*
 - (c) *the purpose for which the permit has been granted; and*
 - (d) *the codes of Combined Nomenclature as provided by Regulation (EEC) No 2658/87.*
8. *Member States shall ensure that inspections are carried out by the competent authority to ensure that the establishment comply with the conditions set out in the permit issued.*

Article 9
Authorisations

1. *In exceptional cases, for reasons of compelling public interest, including those of a social or economic nature, Member States may allow permits for establishments to carry out activities other than the activities of Article 8(1) following an authorisation by the Commission, in accordance with the procedure of this Article and under the conditions specified in Articles 8(2) and (3).*
2. *The Commission shall set up and operate an electronic authorisation system and shall decide on applications for authorisation within 60 days of receipt.*
3. *Applications for authorisation shall be submitted by Member States using the system referred to in paragraph 2.*
4. *An application for an authorisation shall include the following:*
 - (a) *specification of the establishment or groups of establishments including their name and address;*
 - (b) *the scientific and common names of the invasive alien species of Union concern for which an authorisation is requested;*
 - (c) *the codes of Combined Nomenclature as provided by Regulation (EEC) No 2658/87;*

- (d) the number or the volume of specimens concerned;*
- (e) the reasons that justify the need for the requested authorisation;*
- (f) a detailed description of the foreseen measures to ensure that escape or spread are not possible from contained holding facilities in which the species is to be kept in and handled, as well as of the measures to ensure that any transport of the species that may be necessary is carried out under conditions that exclude escapes;*
- (g) an assessment of the risk of escape of the invasive alien species of Union concern for which an authorisation is requested, accompanied by a description of the risk mitigation measures to be put in place;*
- (h) a description of the surveillance system planned and of the contingency plan drawn to cater for possible escape or spread, including an eradication plan where necessary;*
- (i) a description of relevant national legislation applicable to these establishments.*

5. *The authorisation is issued by the Commission and is notified to the relevant competent authority of the Member State and includes the information referred to in paragraph 4 as well as its duration. Irrespectively of the application procedure followed in accordance with point (a) of paragraph 4, each authorisation refers to a specific establishment. It shall also include provisions regarding the supply to the establishment of additional or replacement stock for which an authorisation is requested.*
6. *Following the authorisation by the Commission, the relevant competent authority may issue the permit referred to in paragraph 1 of this Article in accordance with Articles 8(4) to (8). The competent authority is obliged to include in the permits provisions specified in the authorisation by the Commission.*
7. *The Commission shall reject the authorisation application if any relevant obligations set out in this Regulation are not complied with.*
8. *The Commission shall, as soon as possible, inform the Member State concerned of any authorisation application rejected pursuant to paragraph 7, specifying the reason for the rejection.*

Article 10

Emergency measures

1. Where a Member State has evidence concerning the presence in, or imminent danger of *introduction* into its territory of an invasive alien species, which is not included on the list *of invasive alien species of Union concern* but which the relevant competent authorities have found, on the basis of preliminary scientific evidence, to be likely to meet the criteria set out in Article 4(3), it may immediately take emergency measures, consisting of any of the *restrictions* set out in Article 7(1).
2. The Member State introducing emergency measures in their national territory which include the application of points (a), (d) or (e) of Article 7(1) shall immediately notify to the Commission and *all* other Member States of the measures taken and the evidence justifying those measures.
3. The Member State concerned shall carry out a risk assessment pursuant to Article 5 for the species subject to the emergency measures without delay, given the available technical and scientific information, and in any case within 24 months from the day of the adoption of the decision to introduce emergency measures, with a view to include those species on the list *of invasive alien species of Union concern*.

4. Where the Commission receives the notification referred to in paragraph 2 *of this Article* or has other evidence concerning the presence in or imminent *risk of introduction* into the Union of an invasive alien species which is not included on the list *of invasive alien species of Union concern*, but is likely to meet the criteria set out in Article 4(3), it shall, by way of **■** implementing *acts*, conclude on the basis of preliminary scientific evidence whether the species is likely to meet these criteria and adopt emergency measures for the Union consisting of any of the *restrictions* set out in Article 7(1) for a limited time as regards the risks posed by that species, where it concludes that the criteria set out in Article 4(3) are likely to be fulfilled. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).
5. *Where an* implementing *act* referred to in paragraph 4 *is adopted* by the *Commission*, Member States *shall repeal or amend as appropriate their emergency measures taken*.
6. *Member States shall also repeal or amend their emergency measures, where the Commission, pursuant to Article 4(1), includes the invasive alien species on the list of invasive alien species of Union concern*.
7. *When, following the risk assessment carried out pursuant to paragraph 3 of this Article, the invasive alien species is not included on the list of invasive alien species of Union concern, Member States shall repeal their emergency measures taken pursuant to paragraph 1 of this Article and may include those species on a national list of invasive alien species of Member State concern, pursuant to Article 12(1) and consider enhanced regional cooperation in accordance with Article 11*.

Article 11

Invasive alien species of regional concern and species native to the Union

- 1. Member States may identify, from their national list of Member State concern in accordance with Article 12, species native or non native to the Union that require enhanced regional cooperation.*
- 2. At the request of Member States involved, the Commission shall act to facilitate the cooperation and coordination in accordance with Article 22(1). Where necessary, based on the impacts of certain invasive alien species on biodiversity or the related ecosystem services as well as human health and the economy and provided that it is thoroughly substantiated by a comprehensive analysis of the justification for an enhanced regional cooperation carried out by the requesting Member States, the Commission may require, by way of implementing acts, that the concerned Member States shall apply, mutatis mutandis, in their territory or part of it, the provisions of Articles 13, 14, 16, 17 notwithstanding the provisions of Article 18, as appropriate. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).*

3. *Invasive alien species of regional concern which are native in a Member State shall not be subject to the provisions of Articles 13, 14, 16, 17, 19, 20 and 24 in the territory of that Member State. Member States where these species are native, shall cooperate with the Member States concerned for the assessment of the pathways in accordance with Article 13 and, in consultation with the other Member States, may adopt relevant measures to avoid further spread of these species in accordance with the procedure referred to in Article 22(1).*

Article 12

Invasive alien species of Member State concern

1. Member States *may establish a national list of invasive alien species of Member State concern. For these invasive alien species, Member States may apply, in their territory, measures such as those provided for in Articles 7, 8, 13 to, 17, 19 and 20, as appropriate. Those measures shall be compatible with the TFEU and be notified to the Commission in accordance with the Union law.*
2. Member States shall inform the Commission and the other Member States of the species *they consider* as invasive alien species of Member State concern *and of the restrictions set out in accordance with paragraph 1.*

Article 13

Action plans on the pathways of invasive alien species

1. Member States shall, ***within*** 18 months from the ***adoption of the list referred to in Article 4(1)*** of this Regulation █ carry out a comprehensive analysis of the pathways of unintentional introduction and spread of invasive alien species ***of Union concern, at least, in their territory, as well as in their marine waters as defined in Article 3(1) of Directive 2008/56/EC***, and identify the pathways which require priority action ('priority pathways'), because of the volume of species or of the ***potential*** damage caused by the species entering the Union through them. █
2. ***Within three*** years from the ***adoption of the list referred to in Article 4(1)***, each Member State shall establish and implement ***one single*** action plan ***or a set of action plans*** to address the priority pathways it has identified pursuant to paragraph 1 ***of this Article***. ***Action plans*** shall include ***timetables*** for action and shall describe the measures to be adopted ***and, as appropriate, voluntary actions and codes of good practice***, to address the priority pathways and to prevent the unintentional introduction and spread of invasive alien species into █ or within the ***Union***.

3. *Member States shall ensure coordination with the aim of establishing one single action plan or a set of action plans coordinated at the appropriate regional level according to the provisions of Article 22(1). Where such regional plans are not established, Member States shall establish and implement action plans covering their territory, as far as possible coordinated at the appropriate regional level.*
4. The action *plans* referred to in paragraph 2 *of this Article* shall include, *in particular*, measures *based on* █ an analysis of costs and benefits, *in order to*:
- (a) *raise* awareness;
 - (b) █ minimise contamination █ of goods and commodities, and any vehicle and equipment *by specimens of invasive alien species*, including measures tackling *transportation* of invasive alien species from third countries;
 - (c) █ ensure appropriate checks at the Union borders, other than the official controls pursuant to Article 15;
- █
5. The action *plans* developed in accordance with paragraph 2 shall be transmitted to the Commission without delay. *At least every six* years after the last transmission, Member States shall review the action plan and retransmit it to the Commission.

CHAPTER III
EARLY DETECTION AND RAPID ERADICATION

Article 14

Surveillance system

1. ***Within*** 18 months from the ***adoption of the list referred to in Article 4(1)***, Member States shall ***establish a*** surveillance system ***of invasive alien species of Union concern, or include it in their existing system***, which collects and records data on the occurrence in the environment of invasive alien species by survey, monitoring or other procedures to prevent the spread of invasive alien species into the Union.
2. The surveillance system referred to in paragraph 1 ***of this Article*** shall:
 - (a) cover the territory, ***including marine territorial waters***, of the Member States to determine the presence and distribution of new as well as already established invasive alien species of Union concern;
 - █**
 - (b) be sufficiently dynamic to detect rapidly the appearance in the environment of the territory or part of the territory of any invasive alien species of Union concern, whose presence was previously unknown;

- (c) *build upon, be compatible with, and avoid duplication of relevant provisions for assessment and monitoring laid down by Union law or under international agreements and* make use of the information provided by the existing systems of surveillance and monitoring set out in Article 11 of Directive 92/43/EEC, Article 11 of Directive 2008/56/EC and Article 8 of Directive 2000/60/EC;
- (d) *take into account the relevant transboundary impacts and transboundary features, to the extent possible.*

Article 15

Official controls ■

1. By ... *, Member States shall have in place fully functioning structures to perform the official controls ■ necessary to prevent the intentional introduction into the Union of invasive alien species of Union concern. *These official controls shall apply to the categories of goods falling within the Combined Nomenclature codes to which a reference is made in the list of invasive alien species of Union concern, pursuant to Article 4(5).*
2. *Competent* authorities shall perform the *appropriate risk-based* controls ■ on the goods mentioned in paragraph 1 *of this Article* verifying that ■ :
 - (a) ■ they are not on the list referred to in Article 4(1); *or*

* *OJ please insert the date - 12 months from the date of entry into force of this Regulation.*

(b) *they are covered by a valid permit as referred to in Article 8.*

3. *The controls referred to in paragraph 2 of this Article, consisting of documentary, identity and where necessary, physical checks, shall take place when goods referred to in paragraph 1 of this Article are brought into the Union. Where Union legislation on official controls already provides for specific official controls at border entities, as in accordance with Regulation (EC) No 882/2004, Directives 91/496/EEC and 97/78/EC or points of entry in accordance with Directive 2000/29/EC, for categories of goods referred to in paragraph 1 of this Article, Member States shall confer the responsibility of performing the controls referred to in paragraph 2 of this Article to the competent authorities tasked with those controls in accordance with Article 4 of Regulation (EC) No 882/2004 or in Article 2(1)(g) of Directive 2000/29/EC.*

█

4. *The handling in free zones or free warehouses and the placing of goods referred to in paragraph 1 under the customs procedures of release for free circulation, transit, customs warehousing, inward processing, processing under customs control and temporary admission shall be subject to the declaration to the customs authorities of:*
- (a) *the relevant entry document duly completed by the competent authorities referred to in paragraph 3 of this Article attesting that the conditions referred to in paragraph 2 of this Article are met, in cases where the controls have been carried out at border entities, in accordance with Regulation (EC) No 882/2004, Directives 91/496/EEC and 97/78/EC or at points of entry in accordance with Article 2(1)(j) of Directive 2000/29/EC. The customs procedure indicated therein must be followed; or*
 - (b) *other documentary evidence that the controls have been carried out with satisfactory results when goods are not subject to official controls according to Union legislation and the subsequent entry document.*

These documents can also be submitted electronically.

5. *If the controls establish non-compliance with this Regulation:*
- (a) *customs authorities shall suspend the placing under a customs procedure or detain the goods;*

(b) *competent authorities referred to in the second subparagraph of paragraph 3 shall detain the goods.*

Where goods are *detained*, they shall be entrusted to the competent authority in charge of applying this Regulation. *The latter authority shall act according to the national legislation in force.* Member States may delegate specific functions to other authorities.

6. *Costs incurred while the verification is completed and those arising from the non-compliance shall be at the expense of the natural or legal person within the Union who brought the goods into the Union, except where the Member State concerned determines otherwise.*
7. Member States shall put in place procedures to ensure the exchange of *relevant* information and the efficient and effective coordination and cooperation for the verifications referred to in paragraph 2 between all authorities involved .
8. *Based on best-practices, the Commission, together with the* Member States shall develop guidelines and training programmes to facilitate the identification and detection of invasive alien species of Union concern *and the performance of efficient and effective controls.*
9. *Where permits have been issued in accordance with Article 8, reference to a valid permit covering the declared goods shall be made in the customs declaration or relevant notifications to the border entity.*

Article 16

Early detection notifications

1. Member States shall use the surveillance system established in accordance with Article 14 and the information collected at official controls provided for by Article 15 to **confirm** early detection of the **introduction** or presence of invasive alien species of Union concern.
2. Member States shall notify in writing **the Commission** without delay **of** the early detection of the presence of invasive alien species of Union concern **■** and inform the other Member States, in particular:
 - (a) the appearance on their territory or part of their territory of any species included on the list referred to in Article 4(1) whose presence was previously unknown in their territory or in part of their territory;
 - (b) the re-appearance on their territory or part of their territory of any species included on the list **of invasive alien species of Union concern** after it has been reported as eradicated.

Article 17

Rapid eradication at an early stage of invasion

1. After early detection and within three months after the transmission of the early detection notification referred to in Article 16, Member States shall apply eradication measures and notify those measures to the Commission and inform the other Member States.
2. When applying eradication measures, Member States shall ensure that the methods used are effective in achieving the complete and permanent removal of the population of the invasive alien species concerned, with due regard to human health and the environment, ***especially for non-targeted species and their habitats***, and ensuring that ■ animals are spared any avoidable pain, distress or suffering.
3. ***Member States shall monitor the effectiveness of the eradication. Member States may use the surveillance system provided for in Article 14 to this effect. The monitoring shall also assess the impact on non-targeted species, as appropriate.***
4. Member States shall ***inform the Commission of the effectiveness of the measures taken and*** notify the Commission ■ when a population of an invasive alien species of Union concern has been eradicated. ***They shall also provide this information to other Member States concerned.***

■

Article 18

Derogations from the rapid eradication obligation

1. Member States may, ***based on robust scientific evidence decide, within two months of the detection of an invasive alien species referred to in Article 16, not to apply*** eradication measures **■** if ***at least one of*** the following conditions ***is*** met:

■

- (a) eradication is demonstrated to be technically unfeasible because the eradication methods available cannot be applied in the environment where the species are established;
- (b) a cost-benefit analysis demonstrates on the basis of the available data with reasonable certainty that the costs will, in the long term, be exceptionally high and disproportionate to the benefits of eradication;
- (c) eradication methods are not available or are available but have very serious ***adverse*** impacts on human health **■**, the environment ***or other species***.

In this case, the Member State concerned shall notify without delay the Commission of its decision in writing. The notification shall be accompanied by all the evidence referred to in points (a), (b) and (c) of this Article.

2. *The Commission may decide, by way of implementing acts, to reject the decision notified in accordance with paragraph 1 of this Article where the conditions set out therein are not met.*
3. *Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2). The draft implementing acts shall be submitted to the Committee referred to in Article 27(1) within two months of the date of notification.*
4. *Member States shall ensure that containment measures are in place to avoid further spread of the species to other Member States when, pursuant to paragraph 1 of this Article, no eradication measures are applied.*

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5. Where a derogation from the eradication obligation is *not objected by the Commission*, the species shall be subject to the management measures referred to in Article 19. If the application for derogation is rejected, the Member State concerned shall apply the eradication measures referred to in Article 17 without delay.

CHAPTER IV

MANAGEMENT OF INVASIVE ALIEN SPECIES THAT ARE WIDELY SPREAD

Article 19

Management measures

1. ***Within 18*** months of an invasive alien species being included on the list ***of invasive alien species of Union concern*** at the latest, Member States shall have in place ***effective*** management measures for those invasive alien species of Union concern which the Member States have found to be widely spread on their territory, so that their impacts on biodiversity, ***the related*** ecosystem services, ***and, where applicable, on*** human health ***or*** the economy are minimised.

Those management measures shall be ***proportionate to the impact on the environment and tailored to the specific circumstances of the Member States, be*** based on an analysis of costs and benefits and also include, ***as far as feasible,*** the restoration measures referred to in Article 20. ***They shall be prioritised based on the risk evaluation and their cost effectiveness.***

2. The management measures shall consist of *lethal or non-lethal* physical, chemical or biological actions aimed at the eradication, population control or containment of a population of an invasive alien species. Where appropriate, management measures shall include actions applied to the receiving ecosystem aimed at increasing its resilience to current and future invasions. *The commercial use of already established invasive alien species may be temporarily allowed as part of the management measures aimed at their eradication, population control or containment, under strict justification and provided that all appropriate controls are in place to avoid any further spread.*
3. When applying management measures, Member States shall ensure that the methods used have due regard for human health and the environment *especially for non-targeted species and their habitats* and that, when animals are targeted, they are spared any avoidable pain, distress or suffering, *without compromising the effectiveness of the management measures.*

4. The surveillance system provided for in Article 14 shall be designed and used to monitor how effective eradication, population control or containment measures are in minimising the impacts on biodiversity, *the related* ecosystems services, *and, where applicable, on* human health or the economy. *The monitoring shall also assess the impact on non-targeted species, as appropriate.*
5. Where there is a significant risk that an invasive alien species of Union concern will spread to *another* Member State, the Member States in which the species is *present* shall immediately notify the *other* Member States and the Commission. Where appropriate, the Member States concerned shall establish jointly agreed management measures. In the cases where third countries may also be affected by the spread, the Member State affected shall *endeavour* to inform the concerned third countries.

Article 20

Restoration of the damaged ecosystems

1. Member States shall take **appropriate** restoration measures to assist the recovery of an ecosystem that has been degraded, damaged, or destroyed by invasive alien species of Union concern ***unless a cost-benefit analysis demonstrates, on the basis of the available data and with reasonable certainty, that the costs of those measures will be high and disproportionate to the benefits of restoration.***
2. The restoration measures referred to in paragraph 1 shall include at least the following:
 - (a) measures to increase the ability of an ecosystem exposed to disturbance ***caused by the presence of invasive alien species of Union concern*** to resist, absorb, accommodate to and recover from the effects of disturbance;
 - (b) measures ***to support*** the prevention of reinvasion following an eradication campaign.

CHAPTER V
HORIZONTAL PROVISIONS

Article 21

Costs recovery

In accordance with the polluter pays principle and without prejudice to the provisions of Directive 2004/35/EC of the European Parliament and of the Council¹, Member States shall aim at recovering the costs of the measures needed to prevent, minimise or mitigate the adverse impacts of the invasive alien species, including environmental and resources costs as well as the restoration cost.

Article 22

Cooperation and coordination

- 1. Member States shall, when complying with their obligations under this Regulation in relation to invasive alien species, make every effort to ensure close coordination with all Member States concerned and, where practical and appropriate, use existing structures stemming from regional or international agreements. In particular, Member States concerned shall endeavour to ensure coordination with other Member States that share:**
 - (a) the same marine subregions in accordance with Article 4(3) of Directive 2008/56/EC, regarding marine species;**

¹ **Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004, p. 56).**

- (b) the same biogeographical region in accordance with Article 1(c)(iii) of Directive 92/43/EEC, regarding non marine species;*
- (c) the same borders;*
- (d) the same river basin in accordance with Article 2(13) of Directive 2000/60/EC regarding fresh water species;*
- (e) any other common concern.*

At the request of the Member States involved, the Commission shall act to facilitate the coordination.

- 2. Member States shall, when complying with their obligations under this Regulation in relation to invasive alien species, endeavour to cooperate with third countries, as appropriate, including by using existing structures stemming from regional or international agreements, for the purpose of meeting the objectives of this Regulation.*

3. *Member States may also apply the provisions such as those of paragraph 1 of this Article to ensure coordination and cooperation with other relevant Member States as regards invasive alien species of Member State concern identified in national lists adopted in accordance with Article 12(1). Member States may also establish mechanisms for cooperation at the appropriate level for these invasive alien species. Such mechanisms may include exchange of information and data, action plans on pathways and exchange of best practice on management, controlling and eradication of invasive alien species, early warning systems and programmes related to public awareness or education.*

Article 23

More stringent national rules

Member States may maintain or lay down more stringent national rules with the aim of preventing the introduction, establishment and spread of invasive alien species. These measures shall be compatible with the TFEU and be notified to the Commission in accordance with the Union law.

CHAPTER VI
FINAL PROVISIONS

Article 24

Reporting *and review*

1. By ***1 June 2019, and every six*** years thereafter, Member States shall transmit to the Commission updated information on the following:
 - (a) a description, ***or an updated version thereof***, of the surveillance system pursuant to Article 14 and official control system on alien species entering the Union pursuant to Article 15;
 - (b) the distribution of the invasive alien species of Union concern ***or regional concern in accordance with Article 11(2)*** present in their territory, ***including information regarding migratory or reproductive patterns***;
 - (c) information about the species considered as invasive alien species of Member State concern pursuant to Article 12(2);
 - (d) the action plan(s) referred to in Article 13(2);

- (e) aggregated information covering the entire national territory on the eradication measures taken in accordance with Article 17 and the management measures provided for in Article 19 and their effectiveness *as well as on the impact on non-targeted species*;
 - (f) the *number* of the permits *and the purpose for which they were granted* referred to in Article 8;
 - (g) *measures taken to inform the public about the presence of an alien species and any actions that citizens have been requested to take*;
 - (h) *the inspections required under Article 8(8); and*
 - (i) *information on the cost of action undertaken to comply with this Regulation, when available.*
2. Member States shall notify the Commission and inform the other Member States of the competent authorities in charge of applying this Regulation, *by ...* *.

* *OJ: please insert date - one year following the publication of this Regulation in the Official Journal of the European Union.*

3. ***By 1 June 2021***, the Commission shall assess the ***application of this*** Regulation including the list referred to in Article 4(1), the action plans referred to in Article 13(4), the surveillance system, ***customs controls***, eradication obligation and management obligations, and submit a report to the European Parliament and to the Council, which may be accompanied by proposals for its amendment including changes to the list in Article 4(1). ***This review shall also examine the effectiveness of the implementing provisions on invasive alien species of regional concern, the need and feasibility to include native species in the list referred to in Article 4(1) and whether further harmonisation is needed to increase the effectiveness of the action plans and measures taken by the Member States.***

4. ***The Commission shall, by way of implementing acts, specify the technical formats for reporting in order to simplify and streamline reporting obligations for the Member States in relation to the information pursuant to paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).***

Article 25

Information support *system*

1. The Commission shall *progressively* establish an information support *system* necessary to facilitate the application of this Regulation.
2. **By ... *** the system shall include a data support mechanism interconnecting existing data systems on invasive alien species, paying particular attention to information on the invasive alien species of Union concern, so as to facilitate the reporting pursuant to Article 24.

This data support mechanism **█** shall become a tool to assist the Commission **and the Member States** in handling the relevant notifications required in Article 16(2).

- █**
3. **By ... ****, the data support mechanism referred to in paragraph 2 shall become a mechanism for exchanging information on other aspects of the application of this Regulation. **It may also include information on invasive alien species of Member State concern, pathways, risk assessment, management and eradication measures, when available.**

* **OJ please insert date - one year from the date of entry into force of this Regulation.**

** **OJ please insert date - four years after the date of entry into force of this Regulation.**

Article 26

Public participation

■ Where action plans are being established pursuant to Article 13 *of this Regulation* and where measures are being established pursuant to Article **19 of this Regulation**, Member States shall ensure that the public is given early and effective opportunities to participate in their preparation, modification or review using the arrangements already determined by the Member States in accordance with the second subparagraph of Article 2(3) of Directive 2003/35/EC.

Article 27

Committee

1. The Commission shall be assisted by *a committee*. That *committee* shall be a committee within the meaning of Regulation (EU) No 182/2011 *and may be assisted in its tasks by the Scientific Forum referred to in Article 28*.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. *Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.*

Article 28
Scientific Forum

The Commission shall ensure the participation of representatives of the scientific community appointed by the Member States to provide advice on any scientific question related to the application of this Regulation, in particular as regards Articles 4, 5, 10 and 18. They shall meet in a Scientific forum. The rules of procedure of that forum shall be established by the Commission.

Article 29
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The █ power *to adopt delegated acts* referred to in Article 5(3) shall be conferred on the Commission for *a period of five years from ...* * *The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*

* *OJ: please insert the date of entry into force of this Regulation.*

3. The delegation of power referred to in Article 5(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated act already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article 5(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 30

Penalties

1. Member States shall lay down the ***provisions on penalties*** applicable to ***infringements of the provisions*** of this Regulation. Member States shall take all ***the measures*** necessary **█** to ensure that they are ***applied***.
2. The ***penalties*** provided for ***shall*** be effective, proportionate and dissuasive.
█
3. ***The penalties provided may include, inter alia:***
 - (a) ***fin******es***;
 - (b) ***seizure*** of the non-compliant invasive alien species of Union concern **█** ;
 - (c) ***immediate suspension or withdrawal of a permit granted in accordance with Article 8.***
█
4. ***By ... ****, Member States shall ***communicate to the Commission the provisions referred to in paragraph 1 and any subsequent amendments thereto without delay.***
█

* ***OJ: please insert date - one year from the date of entry into force of this Regulation.***

Article 31

Transitional provisions for non-commercial owners

1. By way of derogation from *points (b) and (d) of Article 7(1)* , owners of companion animals not kept for commercial purposes that belong to the species included on the list of *invasive alien species of Union concern* shall be allowed to keep them until the end of the animals' natural life, provided the following conditions are met:
 - (a) the *animals* were kept before their inclusion on the list of *invasive alien species of Union concern*;
 - (b) the *animals* are kept in contained holding and all appropriate measures are put in place to ensure that reproduction or escape are not possible.
2. Competent authorities shall *take all reasonable steps to* inform non-commercial owners of the risks posed by keeping the specimens referred to in paragraph 1 and the measures to be taken to minimise the risk of reproducing and escaping through awareness-raising and education programmes organised by Member States.
3. For non-commercial owners who cannot ensure that the conditions set out in paragraph 1 are met, *the invasive alien species of Union concern shall not be permitted to remain with that owner*. Member States *may* offer to them the possibility of having their specimens taken over from them. *Where this occurs* due regard to animal welfare *shall be given*.
4. *The specimens referred to in paragraph 3 of this Article may be kept by the establishments referred to in Article 8 or in facilities specially set up for that purpose.*

Article 32

Transitional provisions for commercial stocks

1. Keepers of a commercial stock of specimens of invasive alien species acquired before their inclusion on the list *of invasive alien species of Union concern* shall be allowed up to two years after inclusion of the species in that list to keep and transport in order to sell or hand over live specimens or reproducible parts of those species to the research or ex-situ conservation institutions *and medicinal activities* referred to in Article 8, provided that the specimens are kept and transported in contained holding and all appropriate measures are put in place to ensure that reproduction or escape are not possible, or to slaughter *or humanely cull* them to exhaust their stock.
2. *Selling or handing over live specimens to non-commercial users shall be allowed for one year after inclusion of the species in the list of invasive alien species of Union concern provided that the specimens are kept and transported in contained holding and all appropriate measures are put in place to ensure that reproduction or escape are not possible.*
3. Where a permit has been issued in accordance with Article 6 of Regulation (EC) No 708/2007 for an aquaculture species that is subsequently included in the list of alien species of Union concern, and the duration of the permit exceeds the period referred to in paragraph *1 of this Article*, the Member State shall withdraw the permit in accordance with Article 12 of Regulation (EC) No 708/2007 by the end of the period referred to in paragraph *1 of this Article*.

Article 33

Entry into force

1. This Regulation shall enter into force on ■ *1 January* ■ *of the year* following its publication in the *Official Journal of the European Union*.
2. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament
The President

For the Council
The President