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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the prevention and management of the introduction and spread of invasive alien
species

{SWD(2013) 321 final}

{SWD(2013) 322 final}

{SWD(2013) 323 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Invasive alien species (IAS) are species that are initially transported through human action outside of their natural range across ecological barriers, and that then survive, reproduce and spread, and that have negative impacts on the ecology of their new location as well as serious economic and social consequences. It has been estimated that of the over 12 000 alien species that are found in the European environment, 10-15% have reproduced and spread, causing environmental, economic and social damage.

The impact of IAS on biodiversity is significant. IAS are one of the major, and growing, causes of biodiversity loss and species extinction. When it comes to social and economic impacts, IAS can be vectors of diseases or directly cause health problems (e.g. asthma, dermatitis and allergies). They can damage infrastructure and recreational facilities, hamper forestry or cause agricultural losses, to mention but a few. IAS are estimated to cost the Union at least €12 billion per year and damage costs are continuing to rise.

With the 2020 Biodiversity Strategy, the Union undertook to halt the loss of biodiversity by 2020, in line with the international commitments adopted by the parties to the Convention for Biological Diversity in 2010 in Nagoya, Japan. Indeed, the problem of IAS is not limited to Europe, but found throughout the world. Unlike some of its trading partners, the European Union currently lacks a comprehensive framework to address the threats posed by IAS..

Regulatory framework

There is currently no EU framework for tackling IAS comprehensively. Few IAS are addressed by EU legislation. Disease agents and pests of animals and plants and their products are covered respectively by the animal health regime (various regulations and directives) and by the plant health regime (2000/29/EC). The Wildlife Trade Regulation (338/97) restricts imports of endangered species, including imports of seven IAS. The Regulation on the use of alien and locally absent species in aquaculture (708/2007) addresses the release of alien species for aquaculture purposes. The regulations on plant protection products (1107/2009) and on biocides (528/2012) address the intentional release of micro-organisms as plant protection products or biocide respectively. Finally, the Birds Directive (2009/147/EC) and the Habitats Directive (92/43/EEC), the Water Framework Directive (2000/60/EC) and the Marine Strategy Framework Directive (2008/56/EC) require the restoration of ecological conditions and refer to the need to take IAS into consideration. Nevertheless, existing Union action leaves most IAS unaddressed.

Member States are taking a number of measures to tackle IAS, but such action remains predominantly reactive, seeking to minimise the damage already being caused without paying sufficient attention to prevention or to detecting and responding to new threats. Efforts are fragmented, with substantial gaps in species coverage, and are often poorly coordinated. IAS do not respect borders and can easily spread from one Member State to another. Thus, action taken at national level will be insufficient to protect the Union from the threat of certain IAS. Moreover, this fragmented approach can lead to action in one Member State being undermined by a lack of action in neighbouring Member States. Furthermore, different restrictions on the commercialisation of IAS between Member States are highly ineffective, as species can easily be transported or spread across borders throughout the Union. Moreover, such differentiated bans are hampering the free circulation of goods in the internal market and disrupting the level playing field for sectors which use or trade in alien species.

Problem analysis

IAS are being introduced into the Union through two channels: 1) some alien species are desirable and are brought into the Union intentionally (e.g. commercial interests, ornamental purposes, companion animals, biological control); 2) some alien species are introduced unintentionally as contaminants of goods (trade in other commodities), as hitchhikers or stowaways in transport vectors, or can be transported unwittingly by travellers. Some IAS can also travel through transport infrastructure (e.g. Danube-Main canal).

IAS affect **businesses, citizens, public authorities and the environment**. In the case of **small and micro enterprises** in particular, IAS often affects primary producers in agriculture, animal husbandry, fisheries, aquaculture and forestry, suffering considerable economic damage as a result. Businesses linked to tourism and recreational activities, which rely on pristine landscapes, clean water bodies and healthy ecosystems, are often also affected. However, other small and micro enterprises, e.g. traders in companion animals and horticultural species, draw benefits from IAS as they focus mainly on trade in alien species. IAS also affect **society at large**, causing a loss of biodiversity and compromising the ability of ecosystems to provide ecosystem services. Moreover, they may transmit diseases, damage property and affect cultural heritage.

All the Member States are facing problems caused by IAS. While some IAS affect most Member States, others are only a problem in certain regions, or under certain ecological or climatic conditions. Nevertheless, all the Member States do have IAS on their territory. IAS impacts are relevant to the whole of the Union and all the Member States will be equally affected by IAS, albeit at different times and by different species. Coordinated action to tackle IAS would thus benefit all the Member States, while clearly requiring efforts from all of them.

If no action is taken to tackle the problem, it will get worse as new IAS establish themselves and those already established spread further. This will result in an increase in damage costs and management costs.

Objectives of the proposal

This proposal aims to tackle the issues highlighted above by establishing a framework for action to prevent, minimise and mitigate the adverse impacts of IAS on biodiversity and ecosystem services. Furthermore, it will seek to limit social and economic damage. This will be achieved through measures to ensure coordinated action, focusing resources on priority species and on increasing preventive measures, in accordance with the Convention of Biological Diversity approach and with the Union's plant and animal health regimes. In practical terms, the proposal seeks to attain these objectives through measures addressing the intentional introduction of IAS into the Union and their intentional release into the environment, the unintentional introduction and release of IAS, the need to set up an early warning and rapid response system, and the need to manage the IAS spread throughout the Union.

2. RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES AND IMPACT ASSESSMENTS

Consultation process

In 2008 the European Commission published a Communication '*Towards an EU Strategy on Invasive Species (2008)*' setting out the case for tackling IAS. The 2010 Communication '*Our life insurance, our natural capital: an EU biodiversity strategy to 2020*' proposes action on IAS. Both Communications were preceded and followed by thorough consultations.

A series of intensive rounds of stakeholder consultations took place between 2008 and 2012, which attracted the whole spectrum of interested parties, from nature conservation organisations to operators in the private sector, including organisations representing Small and Medium-sized Enterprises (SMEs) relying on alien species for their business. An online public consultation was held in 2008 and a second one in 2012. A working group composed of Commission departments, Member States, stakeholders and academics was convened in 2008 and produced a discussion paper¹ bringing together the latest information and summarising opinions on key issues. This Working Group was then reconvened and reorganised into three working groups in 2010-2011, which drew up possible policy options to address prevention, early warning/rapid response and the management of established species respectively. Finally a stakeholder consultation meeting was held in September 2010.

The Commission's work on IAS has also been supported by several external studies and research². Furthermore, all of the analysis set out in the impact assessment was based on scientifically robust data, mostly retrieved from peer-reviewed scientific articles. Information on damage cost, spread of species and the costs of measures in place were also provided or checked by Member States. Special efforts were made to contact directly the stakeholders involved in this issue, including those sectors that might be negatively impacted by the introduction of measures to tackle the IAS problem. Finally, the analysis also benefited from the input of the world's top experts on IAS within and beyond the Union.

Impact assessment

Various options were identified for addressing the IAS issue, and in particular for addressing all aspects of the problem that were identified, but with a different level of ambition.

Based on feedback from the consultation, a number of levels of ambition and intervention were identified for each of the operational objectives pinpointed through the analysis of the problem, resulting in different sub-options for the design of the legislative instrument. An initial screening led to the discarding of sub-options that were not feasible, or simply not as effective as others. For each option identified, each of the operational objectives was addressed systematically, proposing practical measures to tackle IAS.

In addition to the baseline option (option 0), which would maintain the status quo, the following options were identified:

Option 1 — Enhancing cooperation and supporting voluntary action: This would include the development of guidelines, sectoral codes of conduct and other awareness-raising and educational campaigns. This option would also seek to encourage cooperation between Member States in setting up an early warning and rapid response system. The Commission could promote existing initiatives in this area through communication campaigns.

Option 2.1 — Basic legislative instrument: This involves a series of legal obligations banning the import, keeping, sale, purchase and exchange of certain IAS listed as IAS of Union concern. Further obligations would be linked to release into the environment of IAS of Union concern, rapid response to newly establishing IAS of Union concern and management of widely spread IAS of Union concern.

¹ http://www.acceptance.ec.europa.eu/environment/nature/invasivealien/docs/ias_discussion_paper.pdf.

² All studies are accessible from http://ec.europa.eu/environment/nature/invasivealien/index_en.htm.

Option 2.2 — Basic legislative instrument + permits for release of IAS of Member State concern: This option would go beyond the list of IAS of Union concern for the release into the environment, by requiring permits for IAS deemed of concern by Member States.

Option 2.3 — Basic legislative instrument + a strict general ban on the release of alien species, unless found to be safe: This option would go beyond the list of IAS of Union concern for release into the environment by prohibiting the release of any alien species unless they are included in a Union list of alien species approved for release.

Option 2.4 — Basic legislative instrument + an obligation for the rapid eradication of newly establishing IAS of Union concern: With this option, when it comes to rapid response, Member States would not have a choice, but rather an obligation to eradicate quickly any newly establishing IAS of Union concern and share information. Derogations are possible if approved by the Commission.

Option 2.4 was retained and informs the present proposal.

3. LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

The legal basis of this proposal is Article 192(1) of the Treaty on the Functioning of the European Union, implementing the EU objectives of preserving, protecting and improving the quality of the environment, protecting human health, ensuring prudent and rational utilisation of natural resources, and promoting measures dealing with regional or worldwide environmental problems.

Subsidiarity

Union-level action is necessary as IAS problems are increasing and are cross-border by nature. In view of the lack of Union-level action, Member States are putting measures in place to cope with the problem at national level. They are investing resources and efforts in eradicating harmful IAS but such efforts can be undermined by a lack of action in a neighbouring Member State where the species is also present. Equally, there is no coordinated Union action to ensure that when IAS first enter the Union, Member States take prompt measures for the benefit of other Member States not yet affected. Furthermore, the protection of the internal market — and the free circulation of goods — have to be taken into consideration. A coordinated approach will ensure legal clarity and a level playing field for those sectors using or trading alien species while avoiding a fragmentation of the internal market due to different restrictions on the commercialisation of IAS between Member States.

Current efforts are highly fragmented and inconsistent, leaving considerable policy gaps. These lead to ineffectiveness and do not solve the IAS problem. A mixture of Union and national, regional and local measures will be needed, in line with the principle of subsidiarity. However, a coherent approach at Union level will increase the effectiveness of the measures.

Guiding principles

This proposal puts forward measures based on the following guiding principles:

Prioritisation — There are over 12,000 alien species in the EU out of which 10 to 15% are causing damage (which means 1200 to 1800 invasive alien species) and new ones keep arriving. There is ample scope for a prioritised and proportionate approach, building upon existing efforts and increasing the efficiency and effectiveness of current action.

Shift towards prevention — Prevention is internationally recognised as the most effective way of avoiding the IAS problem. Measures focusing on prevention need to be accompanied by an effective early warning system to take prompt action on species eluding the prevention measures.

Building upon existing systems — Valuable work is already being done in the Union both at national level and at Union level. This proposal intends to maximise the efficiency of the system and to make full use of what already exists.

Gradual and phased-in approach — Member States need legal certainty and reassurance regarding the extent and costs of the actions they will be expected to take. Therefore, this proposal includes a prioritisation of invasive alien species based on very stringent listing criteria, as well as an initial capping of the number of priority species to the top 3% of some 1500 invasive alien species in Europe. Further, a review clause will allow to develop the system progressively and build upon the experience gained. Any extension of the list of species of EU concern will only take place following this review.

Structure of the proposal

Chapter I — General provisions. This section sets out the subject matter, the scope and the basic obligation of the proposal. It also provides the tools for prioritising IAS of Union concern to enable Union resources to be prioritised on the basis of risk and scientific evidence.

Chapter II — Prevention. This section sets out the measures necessary to prevent the introduction into the Union and the introduction or release into the environment of IAS.

Chapter III — Early detection and rapid eradication. This section sets out the tools to ensure that IAS of Union concern can be detected early in the environment and at the Union borders and describes the measures that are triggered when these IAS are detected.

Chapter IV — Management of IAS that are widely spread. This section sets out the obligations necessary to tackle IAS of Union concern that are already present in the Union or new ones that have eluded the prevention measures and early detection measures and managed to spread widely.

Chapter V — Final provisions. This section sets out reporting obligations and the legal tools needed to ensure implementation, enforcement and review of the proposed measures.

4. BUDGETARY IMPLICATION

There will be only some limited financial implication to be financed under Heading 5 of the Multi-annual Financing Framework 2014-2020 for the Committee under Article 22. See Financial Fiche attached.

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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 Committee³

Having regard to the opinion of the Committee of the Regions⁴,

Acting in accordance with the ordinary legislative procedure,

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 and 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 negative impact on human health and the economy. It is only live specimens, or parts that can reproduce, that

³ OJ ref

⁴ OJ ref

represent a threat to biodiversity and ecosystem services, human health or the economy.

- (4) The Union, as a party to the Convention on Biological Diversity, approved by Council Decision 93/626/EEC⁵, is bound by the provisions of Article 8(h) therein, 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/EEC⁶, 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 Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds⁷, Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora⁸, 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)⁹ and 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 policy¹⁰, the primary objective of this Regulation should be to prevent, minimise and mitigate the adverse effects of invasive alien species on biodiversity and ecosystem services, as well as to reduce their economic and social impact.
- (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.
- (8) At Union level, the proposal for a new Regulation of the European Parliament and the Council on Animal Health¹¹ include provisions on animal diseases, and the new Regulation of the European Parliament and the Council on protective measures against pests of plants¹² provides rules for pests of plants, and 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/EEC¹³ sets out the regime applicable to genetically modified organisms. Therefore, the new rules on invasive alien species

⁵ OJ L 309, 13.12.1993, p. 1.

⁶ OJ L 38, 10.2.1982, p. 1.

⁷ OJ L 20, 26.1.2010, p. 7.

⁸ OJ L 206, 22.7.1992, p. 7.

⁹ OJ L 164, 25.6.2008, p. 19.

¹⁰ OJ L 327, 22.12.2000, p. 1.

¹¹ COM(2013) 260 final

¹² COM(2013) 267 final

¹³ OJ L 106, 17.4.2001, p. 1.

should align and not overlap with those Union acts and shall not apply to the organisms targeted by those acts.

- (9) Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture¹⁴, 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 products¹⁵ and 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/EEC¹⁶ 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 these new rules as they do not pose unacceptable risks to the environment, human health and the economy. In order to ensure a coherent legal framework, those species should thus be excluded from the new rules.
- (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. 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 in line with a gradual and phased-in approach including an initial capping of the number of invasive alien species of Union concern to the top 3% of some 1500 invasive alien species in Europe and be focused on those species that cause or are likely to cause significant economic damage, including that deriving from biodiversity loss.
- (11) The criteria to list invasive alien species considered to be of Union concern is the core instrument to apply these new rules. The Commission will do its utmost to submit a proposal for a list based on those criteria within one year of the entry into force of this legislation to the Committee. The criteria should include a risk assessment pursuant to the applicable provisions under the Agreements of the World Trade Organisation on placing trade restriction on species.
- (12) In order to ensure compliance with the rules of the World Trade Organisation and ensure the coherent application of these new rules 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 entry into the Union, the negative economic, social and biodiversity impacts of the species, the potential benefits of uses and the costs of mitigation to weight them

¹⁴ OJ L 168, 28.6.2007, p.1.

¹⁵ OJ L 167, 27.6.2012, p. 1.

¹⁶ OJ L 309, 24.11.2009, p. 1.

against the negative impacts, as well as a quantified forecast of the environmental, economic and social damage costs at Union level 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 after five years.

- (13) Some invasive alien animals are included in Annex B to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein¹⁷, and their import into the Union is prohibited because their invasive character has been recognised and their introduction into the Union has a negative impact on native species. These 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 at Union level on invasive alien species, those invasive alien animals should be considered as a matter of priority for listing as invasive alien species of Union concern.
- (14) Prevention is generally more environmentally desirable and cost-effective than reaction after the fact and should be prioritised, and 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.
- (15) Some of the species that are invasive in the Union may be native in some of the Union's Outermost Regions and vice versa. In the Communication from the Commission on "The outermost regions: an asset for Europe"¹⁸ it was recognised that the remarkable biodiversity of the outermost regions calls for the development and implementation of measures to prevent and manage invasive alien species in those regions as defined by the Treaty on the Functioning of the European Union taking into account European Council Decisions 2010/718/EU of 29 October 2010 amending the status with regard to the European Union of the island of Saint-Barthélemy¹⁹ and 2012/419/EU of 11 July 2012 amending the status of Mayotte with regard to the European Union²⁰. Therefore all the provisions of these new rules should apply to the Union's Outermost Regions except for provisions relating to invasive alien species of Union concern which are native to those regions. In addition, to allow for the necessary protection of the biodiversity in such regions, it is necessary that the concerned Member States draw up, as a complement to the list of invasive alien species of Union concern, specific lists of invasive alien species for their Outermost Regions to which these new rules should also apply.
- (16) 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 bringing into the Union, reproducing,

¹⁷ OJ L 61, 3.3.1997, p. 1.

¹⁸ COM (2008)642 final.

¹⁹ OJ L 325, 9.12.2010, p. 4.

²⁰ OJ L 204, 31.7.2012, p. 131.

growing, transporting, buying, selling, using, exchanging, keeping and releasing invasive alien species of Union concern, to ensure that 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.

- (17) 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 facilities 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.
- (18) 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 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 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.
- (19) Member States should be able to adopt more stringent measures to tackle invasive alien species and to take measures proactively in respect of any species that are not listed as invasive alien species of Union concern. In order to adopt a more proactive stance on unlisted species, it should therefore be required that to release invasive alien species into the environment that are not listed as invasive alien species of Union concern, but for which Member States have found evidence that they pose a risk, an authorisation for release should be issued. Detailed rules for the authorisation of alien species to be used in aquaculture have already been established by Regulation (EC) No 708/2007 and should be taken into account by Member States in this context.
- (20) A large proportion of invasive alien species are introduced unintentionally into the Union. It is therefore crucial to manage the pathways of unintentional introduction. 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.

- (21) 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 local communities. Surveillance systems should imply paying continuous attention to any new invasive alien species anywhere in the Union. In the interest of efficiency and cost-effectiveness, existing systems of border control, surveillance and monitoring already established in Union legislation should be applied, in particular those set out Directives 2009/147/EC, 92/43/EEC, 2008/56/EC and 2000/60/EC.
- (22) 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 posts designated by Member States in accordance with Regulation (EU) No XXX/XXXX [on official controls COM(2013)265]. In order to ensure efficiency gains and avoid creating parallel systems of border controls, the verification whether these species are invasive alien species of Union concern should also be carried out at the first Border Control Post of arrival. Animal and plants, not falling under the scope of Regulation (EU) No XXX/XXXX [on official controls COM(2013)265] or exempted from official controls at border control posts, shall enter the customs territory of the Community through other entry points and subject to checks therein.
- (23) 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.
- (24) Eradicating and managing some invasive alien species, while necessary, 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 minimise 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 (OIE).
- (25) Invasive alien species generally cause damage to ecosystems and reduce their resilience. Therefore restoration measures are required 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 Article 4 of Directive 2009/147/EC and Article 6 of Directive 92/43/EEC, the ecological status of inland surface waters, transitional waters, coastal waters and groundwater in accordance with Article 11 of Directive 2000/60/EC, and the environmental status of marine waters in accordance with Article 13 of Directive 2008/56/EC.

- (26) 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.
- (27) 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 environment²¹ establishes 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.
- (28) In order to ensure uniform conditions for the application of this Regulation, for adopting and updating the list of invasive alien species of Union concern, for granting derogations from the obligation of rapid eradication and for the adoption of Union emergency measures, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with 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 powers²².
- (29) 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 Treaty on the Functioning of the European Union 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.

²¹ OJ L 156, 25.6.2003, p. 17.

²² OJ L 55, 28.2.2011, p. 13.

- (30) 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.
- (31) 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.
- (32) 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 when these new rules enter into force, it is justified to allow them two years to slaughter, sell or hand over the specimens to research or ex-situ conservation establishments.
- (33) Since the objectives of the proposed action, namely the prevention and management of invasive alien species, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the measures, 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 that objective,

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 and ecosystem services.

Article 2

Scope

1. This Regulation applies to all invasive alien species in the Union as defined in Article 3(2).
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) animal disease regulated as defined in Article 4(1)(14) of Regulation (EU) No XXX/XXXX [animal health law- COM(2013) 260 final];
- (d) pests of plants listed pursuant to Article 5(2) or Article 32(3) or subject to measures pursuant to Article 29(1) of Regulation (EU) No XXX/XXXX [on plant health COM(2013) 267 final];
- (e) species listed in Annex IV of Regulation (EC) No 708/2007;
- (f) micro-organisms manufactured or imported for use in plant protection products already approved 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 approved or which are being made available on the Union market pursuant to 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 past or present distribution; 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, through risk assessment, to threaten biodiversity and ecosystem services, and that may also have a negative impact on human health or the economy;
- (3) 'invasive alien species of Union concern' means invasive alien species whose negative impact has been deemed such as to require concerted action at the level of the Union pursuant to Article 4(2);
- (4) '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;
- (5) 'ecosystem services' means the direct and indirect contributions of ecosystems to human wellbeing;
- (6) 'introduction' means the movement by human intervention of a species outside its past or present natural distribution;
- (7) 'research' means descriptive or experimental work, undertaken under regulated conditions to acquire new knowledge or to develop new products, including the initial phases of identification, characterisation and isolation of genetic features,

other than invasiveness, of invasive alien species only insofar as essential for enabling the breeding of those features into non-invasive species;

- (8) 'contained holding' means keeping an organism in closed facilities from which escape or spread is not possible;
- (9) 'ex-situ conservation' means the conservation of components of biological diversity outside their natural habitat;
- (10) 'pathways' means the routes and mechanisms of biological invasions;
- (11) 'early detection' means the confirmation of the presence of specimens of an invasive alien species in the environment before it has become widely spread;
- (12) 'eradication' means the complete and permanent removal of a population of invasive alien species by physical, chemical or biological means;
- (13) '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;
- (14) 'management' means any physical, chemical or biological action aimed at the eradication, population control or containment of a population of an invasive alien species;
- (15) '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;
- (16) 'population control' means physical, chemical or biological actions applied to a population of invasive alien species 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 and ecosystem services, or on human health and the economy, are minimised.

Article 4

List of invasive alien species of Union concern

1. A list of invasive alien species of Union concern shall be adopted, and updated, by the Commission by means of implementing acts on the basis of the criteria in paragraph 2. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).
2. Invasive alien species shall only be included on the list referred to in paragraph 1 if they meet all of the following criteria:
 - (a) they are, having regard to scientific evidence available, found to be alien to the territory of the Union excluding the outermost regions;
 - (b) they are, having regard to scientific evidence available, found to be capable of establishing a viable population and spreading in the

environment under current or foreseeable climate change conditions anywhere in the Union excluding the outermost regions;

- (c) it is demonstrated by a risk assessment performed pursuant to Article 5(1) that action at Union level is required to prevent their establishment and spread .
3. Member States may submit to the Commission requests for the inclusion of invasive alien species on the list referred to in paragraph 1. Those requests shall include all of the following criteria:
- (a) the name of the species;
 - (b) a risk assessment performed in accordance with Article 5(1);
 - (c) evidence that the species complies with the criteria set out in paragraph 2.
4. The list referred to in paragraph 1 shall comprise a maximum of fifty species including any species which may be added as result of the emergency measures foreseen by Article 9.

Article 5

Risk assessment and delegated acts

1. The Commission or the Member States, as relevant, shall carry out the risk assessment referred to in Article 4(2)(c) and (3)(b) having regard to the following elements:
- (a) a description of the species with its taxonomic identity, its history, native range, potential range;
 - (b) a description of its reproduction and spread patterns including an assessment of whether the environmental conditions necessary for reproduction and spread exist;
 - (c) a description of the potential pathways of entry 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 entry, 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;
 - (f) a description of the negative impact on biodiversity and ecosystem services, including on native species, protected sites, endangered habitats, on human health and the economy including an assessment of the magnitude of future impact;

- (g) a quantified forecast of the damage costs at Union level demonstrating the significance for the Union, so as to further justify action because the overall damage would outweigh the cost of mitigation;
 - (h) a description of the possible uses and benefits deriving from those uses of the species.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 23 to further specify the type of admissible scientific evidence referred to in Article 4(2)(b) and to provide a detailed description of the application of the elements set out in paragraph 1(a) to (h) of this Article, including 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 economic damage, including that deriving from biodiversity loss.

Article 6

Provisions for the outermost regions

1. Species included on the list referred to in Article 4(1) which are native in an outermost region shall not be subject to the provisions of Articles 7, 8, 11 and 13 to 17 in the outermost region where they are native.
2. By *[12 months from the entry into force of this Regulation – date to be inserted]* at the latest, 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. The species included on the lists referred to in paragraph 2 shall within the respective outermost regions be subject to Articles 7, 8, 11 and 13 to 17.
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.

CHAPTER II ***PREVENTION***

Article 7

Ban on invasive alien species of Union concern

1. Species included on the list referred to in Article 4(1) shall not be intentionally:
 - (a) brought into or transited through the Union territory;
 - (b) permitted to reproduce;
 - (c) transported, except for the transportation of species to facilities for eradication;
 - (d) placed on the market;

- (e) used or exchanged;
 - (f) kept or grown, including in contained holding;
 - (g) released into the environment.
2. Member States shall prevent the unintentional introduction of invasive alien species of Union concern in accordance with the provisions of Article 11(3) and (4).

Article 8

Permits for research and ex-situ conservation

1. By way of derogation from the bans set out in points (a), (b), (c), (e) and (f) of Article 7(1), Member States shall establish a permit system allowing establishments that are authorised to carry out research or ex-situ conservation to perform such activities on invasive alien species of Union concern.
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 closed facilities as referred to in paragraph 3;
 - (b) the activity is to be carried out by personnel possessing the scientific and technical qualifications prescribed by the competent authorities;
 - (c) transport to and from the closed facility is authorised by the competent authority and is carried out under conditions that exclude escape of the invasive alien species;
 - (d) in case of invasive alien species that are animals, they are marked where possible;
 - (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 closed facility envisaged, the interaction with the environment and other relevant factors relating to the risk posed by that species;
 - (f) a continuous surveillance and a contingency plan to cater for possible escape or spread is drawn up, including an eradication plan.
 - (g) The permit referred to in paragraph 1 shall be limited to the number of species and specimens that is necessary for the research or ex-situ conservation concerned and shall not exceed the capacity of the closed facility. 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 closed facilities if the following conditions are fulfilled:
 - (a) they are physically isolated and they cannot escape or spread or be removed from the facilities were they are kept by unauthorised persons; cleaning 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 facilities or disposal or destruction is done in such way as to exclude propagation or reproduction outside of the facilities.
4. When applying for a permit, the establishment shall provide all necessary evidence to allow the competent authority to assess whether the conditions referred to in paragraphs 2 and 3 are fulfilled.

Article 9
Emergency measures

1. Where a Member State has evidence concerning the presence in, or imminent danger of entry into its territory of an invasive alien species, which is not included on the list referred to in Article 4(1) 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(2), it may immediately take emergency measures, consisting of any of the bans set out in Article 7(1).
2. The Member State introducing emergency measures in their national territory which include the application of points (a), (c) or (d) of Article 7(1) shall immediately notify to the Commission and the 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 referred to in Article 4(1).
4. Where the Commission receives the notification referred to in paragraph 2 or has other evidence concerning the presence in or imminent danger of entry into the Union of an invasive alien species which is not included on the list referred to in Article 4(1) but is likely to meet the criteria set out in Article 4(2), it shall, by means of an implementing act, 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 bans 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(2) are likely to be fulfilled. Those

implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).

5. If provided for in the implementing acts referred to in paragraph 4 the measures taken by the Member States pursuant to paragraph 1 shall be repealed or amended.
6. The Member State taking emergency measures may maintain those measures until an implementing act has been adopted, establishing emergency measures at Union level in accordance with paragraph 4 or including the species on the list referred to in Article 4(1) on the basis of the risk assessment performed by the Member State concerned pursuant to paragraph 3.

Article 10

Restrictions on the intentional release of invasive alien species of Member State concern

1. Member States shall ban any intentional release into the environment, that is the process by which an organism is placed into the environment, for any purpose, without the necessary measures to prevent its escape and spread, of invasive alien species other than invasive alien species of Union concern for which Member States consider, on the basis of scientific evidence, that the adverse impact from their release and spread, even where not fully ascertained, is of significance on their national territory ('invasive alien species of Member State concern').
2. Member States shall inform the Commission and the other Member States of the species it considers as invasive alien species of Member State concern.
3. The competent authorities of Member States may issue authorisations for certain intentional releases of invasive alien species of Member State concern, provided that the following conditions have been fully taken into account:
 - (a) there are no alternative non-invasive species that can be used to obtain similar benefits;
 - (b) the benefits of the release are exceptionally high in comparison to the risks of damage of the species concerned;
 - (c) the release will include risk mitigation measures so as to minimise the impact on biodiversity and ecosystem services as well as on human health and the economy;
 - (d) adequate surveillance is in place and a contingency plan is drawn up to eradicate the species to be applied in case the damage caused by the species is considered by the competent authority to be unacceptable.
4. Any authorisation for the introduction of alien species for their use in aquaculture shall be issued in accordance with the provisions of Regulation (EC) No 708/2007.

Article 11

Action plans on the pathways of invasive alien species

1. Member States shall, by [*18 months from the entry into force of this Regulation – date to be inserted*] at the latest carry out a comprehensive analysis of the pathways of unintentional introduction and spread of invasive alien species in their territory and identify the pathways which require priority action ('priority pathways'), because of the volume of species or of the damage caused by the species entering the Union through them. In doing so, Member States shall in particular focus on an analysis of the pathways of introduction of invasive alien species of Union concern.
2. By [*3 years from the entry into force of this Regulation - date to be inserted*] at the latest, each Member State shall establish and implement an action plan to address the priority pathways it has identified pursuant to paragraph 1. That action plan shall include a timetable for action and shall describe the measures to be adopted to address the priority pathways and to prevent the unintentional introduction and spread of invasive alien species into the Union and into or within the environment.
3. The action plan referred to in paragraph 2 shall include measures designed on the basis of an analysis of costs and benefits with at least the following:
 - (a) awareness raising measures;
 - (b) regulatory measures to minimise contamination by invasive alien species of goods and commodities, and any vehicle and equipment, including measures tackling transport of invasive alien species from third countries;
 - (c) regulatory measures to ensure appropriate checks at the Union borders, other than the official controls pursuant to Article 13;
 - (d) the measures of the International Convention for the Control and Management of Ships Ballast Water and Sediments.
4. The action plan developed in accordance with paragraph 2 shall be transmitted to the Commission without delay. Every four 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 12

Surveillance system

1. By [*18 months from the date of entry into force of this Regulation – date to be inserted*] at the latest, Member States shall have an official surveillance system in place 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 shall:
 - (a) cover the territory of the Member States to determine the presence and distribution of new as well as already established invasive alien species of Union concern;
 - (b) include marine waters as defined in Article 3(1) of Directive 2008/56/EC;
 - (c) 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;
 - (d) 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.

Article 13

Official controls at the Union borders

1. By [12 months from the date of entry into force of this Regulation – date to be inserted] at the latest, Member States shall have in place fully functioning structures to perform the official controls on animals and plants including their seeds, eggs, or propagules, brought into the Union, necessary to prevent the intentional introduction into the Union of invasive alien species of Union concern.
2. Member States authorities shall perform the official controls at the Union borders on the goods mentioned in paragraph 1 being brought into the Union verifying that either of the following requirements are fulfilled:
 - (a) that they are not on the list referred to in Article 4(1);
 - (b) that the permits referred to in Article 8 are valid.
3. The verifications, through a documentary, identity and, where necessary, physical check, referred to in paragraph 2 shall take place:
 - (a) at border control posts provided for in Article 57 of Regulation (EU) No XXX/XXXX [on official controls COM(2013)265] in the case of goods mentioned in paragraph 1, falling under Article 45 of that Regulation and subject to official controls at border control posts; in this case Member States shall confer the responsibility to the competent authorities provided for in Article 3 of Regulation (EU) No XXX/XXXX [on official controls COM(2013)265]
 - (b) at the point of entry on the customs territory of the Community in the case of goods mentioned in paragraph 1 to which Article 45 of Regulation (EU) No XXX/XXXX [on official controls

COM(2013)265] does not apply or exempted from official controls at border control posts according to Article 46 of the same Regulation; in this case Member States shall confer the responsibility to the customs authorities for the placing under any customs procedure of these goods.

4. The authorities designated for border controls shall also be empowered with the responsibility to seize and confiscate the organisms not in compliance with the conditions pursuant to paragraph 2. Where organisms are confiscated, they shall be entrusted to the competent authority in charge of applying this Regulation. Member States may delegate specific functions to other authorities.
5. The record of the outcome of the official controls performed and any decisions taken on that basis, including the decision to reject a consignment, shall take into account the compliance with requirements in paragraph 2(a) and (b).
6. Member States shall put in place procedures to ensure the exchange of information relevant to arriving consignments and the efficient and effective coordination and cooperation for the verifications referred to in paragraph 2 between all authorities involved and the operator of the consignment.
7. Member States shall develop guidelines and training programmes to facilitate the identification and detection of invasive alien species of Union concern through cooperation between all authorities involved in the verifications referred to in paragraph 2. The training programmes for custom authorities shall include information on filling the Single Administrative Document on which the customs declaration is made.

Article 14

Early detection notifications

1. Member States shall use the surveillance system established in accordance with Article 12 and the information collected at official controls provided for by Article 13 to support early detection of the entry or presence of invasive alien species of Union concern.
2. Member States shall notify in writing without delay the early detection of the presence of invasive alien species of Union concern to the Commission 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 referred to in Article 4(1) after it has been reported as eradicated.

Article 15

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 14, 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, and ensuring that targeted animals are spared any avoidable pain, distress or suffering.
3. The surveillance system provided for in Article 12 shall be designed and used to monitor also the effectiveness of the eradication.
4. Member States shall notify the Commission and inform the other Member States when a population of an invasive alien species of Union concern has been eradicated.
5. Member States shall also inform the Commission and the other Member States of the effectiveness of the measures taken.

Article 16

Derogations from the rapid eradication obligation

1. Member States may submit to the Commission an application for a derogation from the obligation to apply the eradication measures referred to in Article 15 for invasive alien species of Union concern that have been subject to an early detection notification referred to in Article 14.
2. Applications for derogations shall be based on sound scientific evidence and only be submitted if the following conditions are 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 negative impacts on human health or the environment.
3. Member States shall submit applications for derogation, duly motivated and accompanied by the evidence referred to in points (a), (b) and (c) of paragraph 2, to the Commission.

4. The Commission shall decide, by means of implementing acts in accordance with paragraph 6, to approve or reject the application referred to in paragraph 3.
5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).
6. Member States shall ensure that containment measures are in place to avoid further spread of the species until an implementing decision is adopted on the derogation pursuant to paragraph 3.
7. Where a derogation from the eradication obligation is approved, the species shall be subject to the management measures referred to in Article 17. If the application for derogation is rejected, the Member State concerned shall apply the eradication measures referred to in Article 15 without delay.

CHAPTER IV

MANAGEMENT OF INVASIVE ALIEN SPECIES THAT ARE WIDELY SPREAD

Article 17

Management measures

1. By 12 months of an invasive alien species being included on the list referred to in Article 4(1) at the latest, Member States shall have in place 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 and ecosystem services, human health and the economy are minimised. Those management measures shall be based on an analysis of costs and benefits and also include the restoration measures referred to in Article 18.
2. The management measures shall consist of 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.
3. When applying management measures, Member States shall ensure that the methods used have due regard for human health and the environment and that, when animals are targeted, they are spared any avoidable pain, distress or suffering.
4. The surveillance system provided for in Article 12 shall be designed and used to monitor how effective eradication, population control or containment measures are in minimising the impacts on biodiversity and ecosystems services, human health or the economy.
5. Where there is a significant risk that an invasive alien species of Union concern will spread to a neighbouring Member State, the Member States in which the species is widely spread shall immediately notify the neighbouring 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 consider the need to inform the concerned third countries.

Article 18

Restoration of the damaged ecosystems

1. Member States shall take proportionate restoration measures to assist the recovery of an ecosystem that has been degraded, damaged, or destroyed by invasive alien species of Union concern.
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 to resist, absorb, accommodate to and recover from the effects of disturbance;
 - (b) measures ensuring the prevention of reinvasion following an eradication campaign.

CHAPTER V

FINAL PROVISIONS

Article 19

Reporting

1. By [*three years from the date of entry into force of this Regulation – date to be inserted*] at the latest, and every four years thereafter, Member States shall transmit to the Commission updated information on the following:
 - (a) a description of the surveillance system pursuant to Article 12 and official control system on alien species entering the Union pursuant to Article 13;
 - (b) the distribution of the invasive alien species of Union concern present in their territory;
 - (c) information about the species considered as invasive alien species of Member State concern pursuant to Article 10(2);
 - (d) the action plan referred to in Article 11(2);
 - (e) aggregated information covering the entire national territory on the eradication measures taken in accordance with Article 15 and the management measures provided for in Article 17 and their effectiveness.
 - (f) the format of the permits referred to in Article 8.
2. Member States shall notify the Commission and inform the other Member States of the competent authorities in charge of applying this Regulation.

3. Within 5 years from [*date of adoption*], the Commission shall assess the effectiveness of the current Regulation including the list referred to in Article 4(1), the action plans referred to in Article 11(3), the surveillance system, border checks, 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).

Article 20

Information support mechanism

1. The Commission shall gradually establish an information support mechanism necessary to facilitate the application of this Regulation.
2. In an initial phase 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 19.
3. In a second phase, the data support mechanism referred to in paragraph 2 shall become a tool to assist the Commission in handling the relevant notifications required in Article 14(2).
4. In a third phase, 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.

Article 21

Public participation

1. Where action plans are being established pursuant to Article 11 and where measures are being established pursuant to Article 17, 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 22

Committee

1. The Commission shall be assisted by the Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011²³.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

²³ OJ L 55, 28.2.2011, p. 13.

Article 23
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 delegation of power referred to in Article 5(2) shall be conferred on the Commission for an undetermined period of time from the entry into force of this Regulation.
3. The delegation of power referred to in Article 5(2) 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(2) 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 24
Administrative measures and sanctions

1. Member States shall lay down the rules on administrative measures and sanctions applicable to breaches of this Regulation. Member States shall take all necessary measures to ensure that they are enforced. The measures and sanctions provided for must be effective, proportionate and dissuasive.

Article 25
Sanctioning powers

1. Competent authorities shall have the power to impose administrative measures and sanctions on any natural or legal person who does not comply with this Regulation.
2. Without prejudice to their supervisory powers, competent authorities shall have the power to impose at least the following administrative measures and sanctions:
 - (a) an order requiring the natural or legal person responsible for the breach to cease the conduct and to desist from a repetition of that conduct;

- (b) an order requiring the confiscation of the non-compliant invasive alien species of Union concern at issue;
 - (c) a temporary ban on an activity;
 - (d) permanent withdrawal of the authorisation of an activity;
 - (e) administrative pecuniary sanctions;
 - (f) an order requiring the natural or legal person to take remedial measures.
3. When determining the type of administrative measures and sanctions, competent authorities shall take into account all relevant circumstances, including:
- (a) the gravity and duration of the breach;
 - (b) the degree of involvement of the person responsible for the invasion;
 - (c) the profit the natural or legal person makes from the breach;
 - (d) the environmental, social and economic damage caused by the breach;
 - (e) the level of cooperation of the person responsible with the competent authority;
 - (f) previous breaches by the person responsible.
4. Member States shall ensure that decisions taken by the competent authorities in accordance with this Article are subject to the right of appeal.

Article 26

Transitional provisions for non-commercial owners

1. By way of derogation from to Article 7(1)(c) and (f), owners of companion animals not kept for commercial purposes that belong to the species included on the list referred to in Article 4(1) shall be allowed to keep them until the end of the animals' natural life, provided the following conditions are met:
- (a) the specimens were kept before their inclusion on the list referred to in Article 4(1);
 - (b) the specimens 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 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, Member States shall offer to them the possibility of having

their specimens taken over from them and shall give due regard to animal welfare when handling them.

Article 27

Transitional provisions for commercial stocks

1. Keepers of a commercial stock of specimens of invasive alien species acquired before their inclusion on the list referred to in Article 4(1) 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 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 them to exhaust their stock.
2. 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, 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.

Article 28

Entry into force

This Regulation shall enter into force on the [*1 January or 1 July*] following 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,

For the European Parliament
The President

For the Council
The President

Simplified Financial Statement

TITLE OF DRAFT PROPOSAL:

Regulation of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species.

POLICY AREA(S) AND ABB ACTIVITY(IES) CONCERNED:

Title 07 Environment

07 01 02 External staff and other management expenditure in support of Environment policy area

LEGAL BASIS

Administrative autonomy

Other: Article 192(1) TFEU

DESCRIPTION AND GROUNDS:

Invasive alien species (IAS) are species that are transported across ecological boundaries, intentionally or unintentionally by human action, outside of their natural distribution and that establish and spread in their new location to an extent that they have a negative impact on biodiversity, but also on human health and the economy. IAS are a major cause of biodiversity loss, besides causing social and economic damage, and tackling them is crucial to meet the EU target of halting the loss of biodiversity by 2020. Furthermore, it has been estimated that IAS are costing €12 billion/year to the EU in terms of damage and control costs. The purpose of this draft Regulation is thus to establish an EU framework to prevent, minimise and mitigate the adverse impacts of IAS on biodiversity and ecosystem services and to seek to mitigate social and economic damage. Member States are already taking measures to tackle some IAS, but action is predominantly reactive, seeking to minimise the damage already being caused without sufficient attention to prevention or to detect and respond to new threats. Efforts are fragmented, not covering the entire EU and often poorly co-ordinated, which means that their overall effectiveness is reduced. Currently a comprehensive legal framework to tackle IAS at EU level does not exist. This draft Regulation aims to address this policy gap, in line also with its international commitments under the Convention of Biological Diversity.

DURATION AND ESTIMATED FINANCIAL IMPACT:

Period of application:

Proposal with a limited duration: in force from [date] to [date]

Proposal with an indefinite duration: in force from [forecasted 2015 tbc]

Estimated budgetary impact:

The draft proposal entails:

- savings
- additional costs (if so, specify the heading(s) of the multiannual financial framework concerned): Heading 5 of the MFF 2014-2020

Third-party contributions to the financing of the draft proposal:

The proposal does not provide for co-financing by third parties

Explanation of figures:

Implementation of aspects of this draft Regulation will require the running of a Committee. On the basis of the costs of running other similar Committees, we estimated the following costs under heading 07 01 02 11 03 – Committees (see table below):

- meetings/year
- 1 representative/MS
- maximum travel and subsistence cost of €800 euro/MS/meeting

This would bring the cost for the Commission to approximately €80,000/year

COMPATIBILITY WITH THE CURRENT MULTIANNUAL FINANCIAL FRAMEWORK:

- The proposal is compatible with existing financial programming.
- The proposal will entail reprogramming of the relevant heading in the multiannual financial framework.
- The proposal requires use of the flexibility instrument or revision of the multiannual financial framework²⁴.

IMPACT OF SAVINGS OR ADDITIONAL COSTS ON THE ALLOCATION OF RESOURCES:

- Resources to be obtained by means of internal redeployment within departments
- Resources already allocated to the department(s) concerned
- Resources to be requested during the next allocation procedure

The human and administrative resources required will be met by staff from the DG already assigned to the management of the action, with the support of staff already deployed to work on aspects linked to the implementation of this draft Regulation. The main tasks of the assigned officials will be: the management of the Committee, the management of the interaction with the Member States, to coordinate with the Joint Research Centre (JRC) and in general support the correct implementation of this draft Regulation.

²⁴ See points 19 and 24 of the Interinstitutional Agreement for the period 2007-2013.

The system is designed to pool resources and expertise from different services of the Commission, which will allow to run the system with limited dedicated staff resources: in particular, the IAS policy will benefit from the contribution of JRC staff involved in the EASIN project²⁵, as well as from the expertise of other Commission services and agencies working in areas of relevance to IAS policy (in particular, the European Environment Agency has dedicated staff working on IAS who will be mobilised in support of implementation work). If necessary, staff will be redeployed on the basis of the allocations which may be granted to the managing DG under the annual allocation procedure in the light of existing budgetary constraints.

²⁵ The European Alien Species Information Network (EASIN) aims at increasing access to data and information on alien species in Europe. EASIN facilitates the exploration of existing alien species information from distributed sources through a network of interoperable web services, following internationally recognized standards and protocols. The project was initiated in support of the implementation of the Biodiversity Strategy and the Marine Strategy Framework Directive and it is available to the public since May 2012

ESTIMATED FINANCIAL IMPACT (savings or additional costs) FOR APPROPRIATIONS OF AN ADMINISTRATIVE NATURE OR FOR HUMAN RESOURCES

FTE=Full-Time Equivalent

EUR million (to 3 decimal places)

FTE in persons/year	Year 2015		Year 2016		Year 2017		Year 2018		Year 2019		Year 2020		Year 2021		Total
	FTE	approp.													
Heading 5															
Establishment plan posts (officials and/or temporary staff)															
07 01 01 01 (Headquarters and Commission's Representation Offices)		0.199*													1.393
07 01 01 02 (Delegations)			0.199		0.199		0.199		0.199		0.199		0.199		
External staff															
07 01 02 01 ('Global envelope')		0.002**		0.002		0.002		0.002		0.002		0.002		0.002	0.014
07 01 02 02 (Delegations)															
Other budget lines (specify)															
Subtotal – Heading 5		0.201		0.201		0.201		0.201		0.201		0.201		0.201	1.407
Outside Heading 5															
Establishment plan posts (officials and/or temporary staff)															
07 01 05 01 (Indirect research)															
10 01 05 01 (Direct research)															
External staff															
07 01 04 yy															
- Headquarters															
- Delegations															
07 01 05 02 (Indirect research)															
10 01 05 02 (Direct research)															
Other budget lines (Specify)															
Subtotal – Outside Heading 5															
TOTAL		0.201		0.201		0.201		0.201		0.201		0.201		0.2014	1.407 for the first 7 years

"The human resources appropriations required will be met by appropriations from the DG **that are already assigned to management of the action** and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints."

*The estimated appropriation include staff from DG ENV as well as one FTE in JRC **Average allowance of an END

Other administrative appropriations

EUR million (to 3 decimal places)

	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021	TOTAL
Heading 5								
Headquarters:								
07 01 02 11 01 - Mission and representation expenses								
07 01 02 11 02 - Conference and meeting costs								
07 01 02 11 03 - Committees	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.56 for the first 7 years
07 01 02 11 04 - Studies and consultations								
07 01 03 01 03 – ICT equipment ²⁶								
07 01 03 01 04 – ICT services ²								
Other budget lines (specify where necessary)								
Delegations:								
07 01 02 12 01 – Missions, conferences and representation expenses								
07 01 02 12 02 - Further training of staff								
07 01 03 02 01 – Acquisition, renting and related expenditure								
07 01 03 02 02 Equipment, furniture, supplies and services								
Subtotal – Heading 5	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.56 for the first 7 years
Outside Heading 5								
07 01 04 yy – Expenditure on technical and administrative assistance (not including external staff) from operational appropriations (former 'BA' lines)								
- Headquarters								
- Delegations								
07 01 05 03 - Other management expenditure for indirect research								
10 01 05 03 - Other management expenditure for direct research								
Other budget lines (specify where necessary)								
Subtotal – Outside Heading 5								
GRAND TOTAL	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.56 for the first 7 years

²⁶

ICT: Information and Communication Technologies