

中央環境審議会自然環境部会

第3回遺伝子組換え生物等専門委員会

<議題関係補足資料>

【議題1】バイオセーフティに関するカルタヘナ議定書の責任及び救済に関する名古屋・クアラルンプール補足議定書に対応した国内措置のあり方について

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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

THE EUROPEAN PARLIAMENT AND THE
COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European
Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the Opinion of the European Economic and
Social Committee ⁽²⁾,

After consulting the Committee of the Regions ,

Acting in accordance with the procedure laid down in Article
251 of the Treaty ⁽³⁾, in the light of the joint text approved by
the Conciliation Committee on 10 March 2004,

Whereas:

(1) There are currently many contaminated sites in the
Community, posing significant health risks, and the loss
of biodiversity has dramatically accelerated over the last
decades. Failure to act could result in increased site
contamination and greater loss of biodiversity in the
future. Preventing and remedying, insofar as is possible,
environmental damage contributes to implementing the
objectives and principles of the Community's
environment policy as set out in the Treaty. Local
conditions should be taken into account when deciding
how to remedy damage.

(2) The prevention and remedying of environmental
damage should be implemented through the furtherance
of the 'polluter pays' principle, as indicated in the Treaty

and in line with the principle of sustainable
development. The fundamental principle of this
Directive should therefore be that an operator whose
activity has caused the environmental damage or the
imminent threat of such damage is to be held financially
liable, in order to induce operators to adopt measures
and develop practices to minimise the risks of
environmental damage so that their exposure to
financial liabilities is reduced.

(3) Since the objective of this Directive, namely to establish
a common framework for the prevention and
remedying of environmental damage at a reasonable
cost to society, cannot be sufficiently achieved by the
Member States and can therefore be better achieved at
Community level by reason of the scale of this Directive
and its implications in respect of other Community
legislation, namely Council Directive 79/409/EEC of 2
April 1979 on the conservation of wild birds ⁽⁴⁾,
Council Directive 92/43/EEC of 21 May 1992 on the
conservation of natural habitats and of wild fauna and
flora ⁽⁵⁾, 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 policy ⁽⁶⁾, the Community may adopt
measures in accordance with the principle of
subsidiarity as set out in Article 5 of the Treaty. In
accordance with the principle of proportionality, as set
out in that Article, this Directive does not go beyond
what is necessary in order to achieve that objective.

(4) Environmental damage also includes damage caused by
airborne elements as far as they cause damage to water,
land or protected species or natural habitats.

(5) Concepts instrumental for the correct interpretation and
application of the scheme provided for by this Directive
should be defined especially as regards the definition of
environmental damage. When the concept in question
derives from other relevant Community legislation, the
same definition should be used so that common criteria
can be used and uniform application promoted.

⁽¹⁾ OJ C 151 E, 25.6.2002, p. 132.

⁽²⁾ OJ C 241, 7.10.2002, p. 162.

⁽³⁾ Opinion of the European Parliament of 14 May 2003 (not yet
published in the Official Journal), Council Common Position of 18
September 2003 (OJ C 277 E, 18.11.2003, p.10) and Position of the
European Parliament of 17 December 2003 (not yet published in
the Official Journal). Legislative resolution of the European
Parliament of 31 March 2004 and Council Decision of 30 March
2004.

⁽⁴⁾ OJ L 103, 25.4.1979, p. 1. Directive as last amended by Regulation
(EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

⁽⁵⁾ OJ L 206, 22.7.1992, p. 7. Directive as last amended by Regulation
(EC) No 1882/2003 of the European Parliament and of the Council
(OJ L 284, 31.10.2003, p. 1).

⁽⁶⁾ OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No
2455/2001/EC (OJ L 331, 15.12.2001, p. 1).

- (6) Protected species and natural habitats might also be defined by reference to species and habitats protected in pursuance of national legislation on nature conservation. Account should nevertheless be taken of specific situations where Community, or equivalent national, legislation allows for certain derogations from the level of protection afforded to the environment.
- (7) For the purposes of assessing damage to land as defined in this Directive the use of risk assessment procedures to determine to what extent human health is likely to be adversely affected is desirable.
- (8) This Directive should apply, as far as environmental damage is concerned, to occupational activities which present a risk for human health or the environment. Those activities should be identified, in principle, by reference to the relevant Community legislation which provides for regulatory requirements in relation to certain activities or practices considered as posing a potential or actual risk for human health or the environment.
- (9) This Directive should also apply, as regards damage to protected species and natural habitats, to any occupational activities other than those already directly or indirectly identified by reference to Community legislation as posing an actual or potential risk for human health or the environment. In such cases the operator should only be liable under this Directive whenever he is at fault or negligent.
- (10) Express account should be taken of the Euratom Treaty and relevant international conventions and of Community legislation regulating more comprehensively and more stringently the operation of any of the activities falling under the scope of this Directive. This Directive, which does not provide for additional rules of conflict of laws when it specifies the powers of the competent authorities, is without prejudice to the rules on international jurisdiction of courts as provided, inter alia, in Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters ⁽¹⁾. This Directive should not apply to activities the main purpose of which is to serve national defence or international security.
- (11) This Directive aims at preventing and remedying environmental damage, and does not affect rights of compensation for traditional damage granted under any relevant international agreement regulating civil liability.
- (12) Many Member States are party to international agreements dealing with civil liability in relation to specific fields. These Member States should be able to remain so after the entry into force of this Directive, whereas other Member States should not lose their freedom to become parties to these agreements.
- (13) Not all forms of environmental damage can be remedied by means of the liability mechanism. For the latter to be effective, there need to be one or more identifiable polluters, the damage should be concrete and quantifiable, and a causal link should be established between the damage and the identified polluter(s). Liability is therefore not a suitable instrument for dealing with pollution of a widespread, diffuse character, where it is impossible to link the negative environmental effects with acts or failure to act of certain individual actors.
- (14) This Directive does not apply to cases of personal injury, to damage to private property or to any economic loss and does not affect any right regarding these types of damages.
- (15) Since the prevention and remedying of environmental damage is a task directly contributing to the pursuit of the Community's environment policy, public authorities should ensure the proper implementation and enforcement of the scheme provided for by this Directive.
- (16) Restoration of the environment should take place in an effective manner ensuring that the relevant restoration objectives are achieved. A common framework should be defined to that end, the proper application of which should be supervised by the competent authority.
- (17) Appropriate provision should be made for those situations where several instances of environmental damage have occurred in such a manner that the competent authority cannot ensure that all the necessary remedial measures are taken at the same time. In such a case, the competent authority should be entitled to decide which instance of environmental damage is to be remedied first.
- (18) According to the 'polluter-pays' principle, an operator causing environmental damage or creating an imminent threat of such damage should, in principle, bear the cost of the necessary preventive or remedial measures. In cases where a competent authority acts, itself or through a third party, in the place of an operator, that

⁽¹⁾ OJ L 12, 16.1.2001, p. 1. Regulation as amended by Commission Regulation (EC) No 1496/2002 (OJ L 225, 22.8.2002, p. 13).

- authority should ensure that the cost incurred by it is recovered from the operator. It is also appropriate that the operators should ultimately bear the cost of assessing environmental damage and, as the case may be, assessing an imminent threat of such damage occurring.
- (19) Member States may provide for flat-rate calculation of administrative, legal, enforcement and other general costs to be recovered.
- (20) An operator should not be required to bear the costs of preventive or remedial actions taken pursuant to this Directive in situations where the damage in question or imminent threat thereof is the result of certain events beyond the operator's control. Member States may allow that operators who are not at fault or negligent shall not bear the cost of remedial measures, in situations where the damage in question is the result of emissions or events explicitly authorised or where the potential for damage could not have been known when the event or emission took place.
- (21) Operators should bear the costs relating to preventive measures when those measures should have been taken as a matter of course in order to comply with the legislative, regulatory and administrative provisions regulating their activities or the terms of any permit or authorisation.
- (22) Member States may establish national rules covering cost allocation in cases of multiple party causation. Member States may take into account, in particular, the specific situation of users of products who might not be held responsible for environmental damage in the same conditions as those producing such products. In this case, apportionment of liability should be determined in accordance with national law.
- (23) Competent authorities should be entitled to recover the cost of preventive or remedial measures from an operator within a reasonable period of time from the date on which those measures were completed.
- (24) It is necessary to ensure that effective means of implementation and enforcement are available, while ensuring that the legitimate interests of the relevant operators and other interested parties are adequately safeguarded. Competent authorities should be in charge of specific tasks entailing appropriate administrative discretion, namely the duty to assess the significance of the damage and to determine which remedial measures should be taken.
- (25) Persons adversely affected or likely to be adversely affected by environmental damage should be entitled to ask the competent authority to take action. Environmental protection is, however, a diffuse interest on behalf of which individuals will not always act or will not be in a position to act. Non-governmental organisations promoting environmental protection should therefore also be given the opportunity to properly contribute to the effective implementation of this Directive.
- (26) The relevant natural or legal persons concerned should have access to procedures for the review of the competent authority's decisions, acts or failure to act.
- (27) Member States should take measures to encourage the use by operators of any appropriate insurance or other forms of financial security and the development of financial security instruments and markets in order to provide effective cover for financial obligations under this Directive.
- (28) Where environmental damage affects or is likely to affect several Member States, those Member States should cooperate with a view to ensuring proper and effective preventive or remedial action in respect of any environmental damage. Member States may seek to recover the costs for preventive or remedial actions.
- (29) This Directive should not prevent Member States from maintaining or enacting more stringent provisions in relation to the prevention and remedying of environmental damage; nor should it prevent the adoption by Member States of appropriate measures in relation to situations where double recovery of costs could occur as a result of concurrent action by a competent authority under this Directive and by a person whose property is affected by the environmental damage.
- (30) Damage caused before the expiry of the deadline for implementation of this Directive should not be covered by its provisions.
- (31) Member States should report to the Commission on the experience gained in the application of this Directive so as to enable the Commission to consider, taking into account the impact on sustainable development and future risks to the environment, whether any review of this Directive is appropriate,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Subject matter

The purpose of this Directive is to establish a framework of environmental liability based on the 'polluter-pays' principle, to prevent and remedy environmental damage.

Article 2

Definitions

For the purpose of this Directive the following definitions shall apply:

1. 'environmental damage' means:

- (a) damage to protected species and natural habitats, which is any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species. The significance of such effects is to be assessed with reference to the baseline condition, taking account of the criteria set out in Annex I;

Damage to protected species and natural habitats does not include previously identified adverse effects which result from an act by an operator which was expressly authorised by the relevant authorities in accordance with provisions implementing Article 6(3) and (4) or Article 16 of Directive 92/43/EEC or Article 9 of Directive 79/409/EEC or, in the case of habitats and species not covered by Community law, in accordance with equivalent provisions of national law on nature conservation.

- (b) water damage, which is any damage that significantly adversely affects the ecological, chemical and/or quantitative status and/or ecological potential, as defined in Directive 2000/60/EC, of the waters concerned, with the exception of adverse effects where Article 4(7) of that Directive applies;
- (c) land damage, which is any land contamination that creates a significant risk of human health being adversely affected as a result of the direct or indirect introduction, in, on or under land, of substances, preparations, organisms or micro-organisms;

2. 'damage' means a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly;

3. 'protected species and natural habitats' means:

- (a) the species mentioned in Article 4(2) of Directive 79/409/EEC or listed in Annex I thereto or listed in Annexes II and IV to Directive 92/43/EEC;
- (b) the habitats of species mentioned in Article 4(2) of Directive 79/409/EEC or listed in Annex I thereto or listed in Annex II to Directive 92/43/EEC, and the natural habitats listed in Annex I to Directive 92/43/EEC and the breeding sites or resting places of the species listed in Annex IV to Directive 92/43/EEC; and
- (c) where a Member State so determines, any habitat or species, not listed in those Annexes which the Member State designates for equivalent purposes as those laid down in these two Directives;

4. 'conservation status' means:

- (a) in respect of a natural habitat, the sum of the influences acting on a natural habitat and its typical species that may affect its long-term natural distribution, structure and functions as well as the long-term survival of its typical species within, as the case may be, the European territory of the Member States to which the Treaty applies or the territory of a Member State or the natural range of that habitat;

The conservation status of a natural habitat will be taken as 'favourable' when:

- its natural range and areas it covers within that range are stable or increasing,
- the specific structure and functions which are necessary for its long-term maintenance exist and are likely to continue to exist for the foreseeable future, and
- the conservation status of its typical species is favourable, as defined in (b);

- (b) in respect of a species, the sum of the influences acting on the species concerned that may affect the long-term distribution and abundance of its populations within, as the case may be, the European territory of the Member States to which the Treaty applies or the territory of a Member State or the natural range of that species;

The conservation status of a species will be taken as 'favourable' when:

- population dynamics data on the species concerned indicate that it is maintaining itself on a long-term basis as a viable component of its natural habitats,
- the natural range of the species is neither being reduced nor is likely to be reduced for the foreseeable future, and
- there is, and will probably continue to be, a sufficiently large habitat to maintain its populations on a long-term basis;

5. 'waters' mean all waters covered by Directive 2000/60/EC;
6. 'operator' means any natural or legal, private or public person who operates or controls the occupational activity or, where this is provided for in national legislation, to whom decisive economic power over the technical functioning of such an activity has been delegated, including the holder of a permit or authorisation for such an activity or the person registering or notifying such an activity;
7. 'occupational activity' means any activity carried out in the course of an economic activity, a business or an undertaking, irrespectively of its private or public, profit or non-profit character;
8. 'emission' means the release in the environment, as a result of human activities, of substances, preparations, organisms or micro-organisms;
9. 'imminent threat of damage' means a sufficient likelihood that environmental damage will occur in the near future;
10. 'preventive measures' means any measures taken in response to an event, act or omission that has created an imminent threat of environmental damage, with a view to preventing or minimising that damage;
11. 'remedial measures' means any action, or combination of actions, including mitigating or interim measures to restore, rehabilitate or replace damaged natural resources and/or impaired services, or to provide an equivalent alternative to those resources or services as foreseen in Annex II;
12. 'natural resource' means protected species and natural habitats, water and land;
13. 'services' and 'natural resources services' mean the functions performed by a natural resource for the benefit of another natural resource or the public;
14. 'baseline condition' means the condition at the time of the damage of the natural resources and services that would have existed had the environmental damage not occurred, estimated on the basis of the best information available;
15. 'recovery', including 'natural recovery', means, in the case of water, protected species and natural habitats the return of damaged natural resources and/or impaired services to baseline condition and in the case of land damage, the elimination of any significant risk of adversely affecting human health;
16. 'costs' means costs which are justified by the need to ensure the proper and effective implementation of this Directive including the costs of assessing environmental damage, an imminent threat of such damage, alternatives for action as well as the administrative, legal, and enforcement costs, the costs of data collection and other general costs, monitoring and supervision costs.

Article 3

Scope

1. This Directive shall apply to:
 - (a) environmental damage caused by any of the occupational activities listed in Annex III, and to any imminent threat of such damage occurring by reason of any of those activities;
 - (b) damage to protected species and natural habitats caused by any occupational activities other than those listed in Annex III, and to any imminent threat of such damage occurring by reason of any of those activities, whenever the operator has been at fault or negligent.
2. This Directive shall apply without prejudice to more stringent Community legislation regulating the operation of any of the activities falling within the scope of this Directive and without prejudice to Community legislation containing rules on conflicts of jurisdiction.

3. Without prejudice to relevant national legislation, this Directive shall not give private parties a right of compensation as a consequence of environmental damage or of an imminent threat of such damage.

Article 4

Exceptions

1. This Directive shall not cover environmental damage or an imminent threat of such damage caused by:

- (a) an act of armed conflict, hostilities, civil war or insurrection;
- (b) a natural phenomenon of exceptional, inevitable and irresistible character.

2. This Directive shall not apply to environmental damage or to any imminent threat of such damage arising from an incident in respect of which liability or compensation falls within the scope of any of the International Conventions listed in Annex IV, including any future amendments thereof, which is in force in the Member State concerned.

3. This Directive shall be without prejudice to the right of the operator to limit his liability in accordance with national legislation implementing the Convention on Limitation of Liability for Maritime Claims (LLMC), 1976, including any future amendment to the Convention, or the Strasbourg Convention on Limitation of Liability in Inland Navigation (CLNI), 1988, including any future amendment to the Convention.

4. This Directive shall not apply to such nuclear risks or environmental damage or imminent threat of such damage as may be caused by the activities covered by the Treaty establishing the European Atomic Energy Community or caused by an incident or activity in respect of which liability or compensation falls within the scope of any of the international instruments listed in Annex V, including any future amendments thereof.

5. This Directive shall only apply to environmental damage or to an imminent threat of such damage caused by pollution of a diffuse character, where it is possible to establish a causal link between the damage and the activities of individual operators.

6. This Directive shall not apply to activities the main purpose of which is to serve national defence or international security nor to activities the sole purpose of which is to protect from natural disasters.

Article 5

Preventive action

1. Where environmental damage has not yet occurred but there is an imminent threat of such damage occurring, the operator shall, without delay, take the necessary preventive measures.

2. Member States shall provide that, where appropriate, and in any case whenever an imminent threat of environmental damage is not dispelled despite the preventive measures taken by the operator, operators are to inform the competent authority of all relevant aspects of the situation, as soon as possible.

3. The competent authority may, at any time:

- (a) require the operator to provide information on any imminent threat of environmental damage or in suspected cases of such an imminent threat;
- (b) require the operator to take the necessary preventive measures;
- (c) give instructions to the operator to be followed on the necessary preventive measures to be taken; or
- (d) itself take the necessary preventive measures.

4. The competent authority shall require that the preventive measures are taken by the operator. If the operator fails to comply with the obligations laid down in paragraph 1 or 3(b) or (c), cannot be identified or is not required to bear the costs under this Directive, the competent authority may take these measures itself.

Article 6

Remedial action

1. Where environmental damage has occurred the operator shall, without delay, inform the competent authority of all relevant aspects of the situation and take:

- (a) all practicable steps to immediately control, contain, remove or otherwise manage the relevant contaminants and/or any other damage factors in order to limit or to prevent further environmental damage and adverse effects on human health or further impairment of services and
- (b) the necessary remedial measures, in accordance with Article 7.

2. The competent authority may, at any time:
- (a) require the operator to provide supplementary information on any damage that has occurred;
 - (b) take, require the operator to take or give instructions to the operator concerning, all practicable steps to immediately control, contain, remove or otherwise manage the relevant contaminants and/or any other damage factors in order to limit or to prevent further environmental damage and adverse effect on human health, or further impairment of services;
 - (c) require the operator to take the necessary remedial measures;
 - (d) give instructions to the operator to be followed on the necessary remedial measures to be taken; or
 - (e) itself take the necessary remedial measures.

3. The competent authority shall require that the remedial measures are taken by the operator. If the operator fails to comply with the obligations laid down in paragraph 1 or 2(b), (c) or (d), cannot be identified or is not required to bear the costs under this Directive, the competent authority may take these measures itself, as a means of last resort.

Article 7

Determination of remedial measures

1. Operators shall identify, in accordance with Annex II, potential remedial measures and submit them to the competent authority for its approval, unless the competent authority has taken action under Article 6(2)(e) and (3).
2. The competent authority shall decide which remedial measures shall be implemented in accordance with Annex II, and with the cooperation of the relevant operator, as required.
3. Where several instances of environmental damage have occurred in such a manner that the competent authority cannot ensure that the necessary remedial measures are taken at the same time, the competent authority shall be entitled to decide which instance of environmental damage must be remedied first.

In making that decision, the competent authority shall have regard, *inter alia*, to the nature, extent and gravity of the various instances of environmental damage concerned, and to the possibility of natural recovery. Risks to human health shall also be taken into account.

4. The competent authority shall invite the persons referred to in Article 12(1) and in any case the persons on whose land remedial measures would be carried out to submit their observations and shall take them into account.

Article 8

Prevention and remediation costs

1. The operator shall bear the costs for the preventive and remedial actions taken pursuant to this Directive.
2. Subject to paragraphs 3 and 4, the competent authority shall recover, *inter alia*, via security over property or other appropriate guarantees from the operator who has caused the damage or the imminent threat of damage, the costs it has incurred in relation to the preventive or remedial actions taken under this Directive.

However, the competent authority may decide not to recover the full costs where the expenditure required to do so would be greater than the recoverable sum or where the operator cannot be identified.

3. An operator shall not be required to bear the cost of preventive or remedial actions taken pursuant to this Directive when he can prove that the environmental damage or imminent threat of such damage:

- (a) was caused by a third party and occurred despite the fact that appropriate safety measures were in place; or
- (b) resulted from compliance with a compulsory order or instruction emanating from a public authority other than an order or instruction consequent upon an emission or incident caused by the operator's own activities.

In such cases Member States shall take the appropriate measures to enable the operator to recover the costs incurred.

4. The Member States may allow the operator not to bear the cost of remedial actions taken pursuant to this Directive where he demonstrates that he was not at fault or negligent and that the environmental damage was caused by:

- (a) an emission or event expressly authorised by, and fully in accordance with the conditions of, an authorisation conferred by or given under applicable national laws and regulations which implement those legislative measures adopted by the Community specified in Annex III, as applied at the date of the emission or event;

(b) an emission or activity or any manner of using a product in the course of an activity which the operator demonstrates was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the emission was released or the activity took place.

5. Measures taken by the competent authority in pursuance of Article 5(3) and (4) and Article 6(2) and (3) shall be without prejudice to the liability of the relevant operator under this Directive and without prejudice to Articles 87 and 88 of the Treaty.

Article 9

Cost allocation in cases of multiple party causation

This Directive is without prejudice to any provisions of national regulations concerning cost allocation in cases of multiple party causation especially concerning the apportionment of liability between the producer and the user of a product.

Article 10

Limitation period for recovery of costs

The competent authority shall be entitled to initiate cost recovery proceedings against the operator, or if appropriate, a third party who has caused the damage or the imminent threat of damage in relation to any measures taken in pursuance of this Directive within five years from the date on which those measures have been completed or the liable operator, or third party, has been identified, whichever is the later.

Article 11

Competent authority

1. Member States shall designate the competent authority(ies) responsible for fulfilling the duties provided for in this Directive.

2. The duty to establish which operator has caused the damage or the imminent threat of damage, to assess the significance of the damage and to determine which remedial measures should be taken with reference to Annex II shall rest with the competent authority. To that effect, the competent authority shall be entitled to require the relevant operator to carry out his own assessment and to supply any information and data necessary.

3. Member States shall ensure that the competent authority may empower or require third parties to carry out the necessary preventive or remedial measures.

4. Any decision taken pursuant to this Directive which imposes preventive or remedial measures shall state the exact grounds on which it is based. Such decision shall be notified forthwith to the operator concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time-limits to which such remedies are subject.

Article 12

Request for action

1. Natural or legal persons:

(a) affected or likely to be affected by environmental damage or

(b) having a sufficient interest in environmental decision making relating to the damage or, alternatively,

(c) alleging the impairment of a right, where administrative procedural law of a Member State requires this as a precondition,

shall be entitled to submit to the competent authority any observations relating to instances of environmental damage or an imminent threat of such damage of which they are aware and shall be entitled to request the competent authority to take action under this Directive.

What constitutes a 'sufficient interest' and 'impairment of a right' shall be determined by the Member States.

To this end, the interest of any non-governmental organisation promoting environmental protection and meeting any requirements under national law shall be deemed sufficient for the purpose of subparagraph (b). Such organisations shall also be deemed to have rights capable of being impaired for the purpose of subparagraph (c).

2. The request for action shall be accompanied by the relevant information and data supporting the observations submitted in relation to the environmental damage in question.

3. Where the request for action and the accompanying observations show in a plausible manner that environmental damage exists, the competent authority shall consider any such observations and requests for action. In such circumstances the competent authority shall give the relevant operator an opportunity to make his views known with respect to the request for action and the accompanying observations.

4. The competent authority shall, as soon as possible and in any case in accordance with the relevant provisions of national law, inform the persons referred to in paragraph 1, which submitted observations to the authority, of its decision to

accede to or refuse the request for action and shall provide the reasons for it.

5. Member States may decide not to apply paragraphs 1 and 4 to cases of imminent threat of damage.

Article 13

Review procedures

1. The persons referred to in Article 12(1) shall have access to a court or other independent and impartial public body competent to review the procedural and substantive legality of the decisions, acts or failure to act of the competent authority under this Directive.

2. This Directive shall be without prejudice to any provisions of national law which regulate access to justice and those which require that administrative review procedures be exhausted prior to recourse to judicial proceedings.

Article 14

Financial security

1. Member States shall take measures to encourage the development of financial security instruments and markets by the appropriate economic and financial operators, including financial mechanisms in case of insolvency, with the aim of enabling operators to use financial guarantees to cover their responsibilities under this Directive.

2. The Commission, before 30 April 2010 shall present a report on the effectiveness of the Directive in terms of actual remediation of environmental damages, on the availability at reasonable costs and on conditions of insurance and other types of financial security for the activities covered by Annex III. The report shall also consider in relation to financial security the following aspects: a gradual approach, a ceiling for the financial guarantee and the exclusion of low-risk activities. In the light of that report, and of an extended impact assessment, including a cost-benefit analysis, the Commission shall, if appropriate, submit proposals for a system of harmonised mandatory financial security.

Article 15

Cooperation between Member States

1. Where environmental damage affects or is likely to affect several Member States, those Member States shall cooperate, including through the appropriate exchange of information, with a view to ensuring that preventive action and, where necessary, remedial action is taken in respect of any such environmental damage.

2. Where environmental damage has occurred, the Member State in whose territory the damage originates shall provide sufficient information to the potentially affected Member States.

3. Where a Member State identifies damage within its borders which has not been caused within them it may report the issue to the Commission and any other Member State concerned; it may make recommendations for the adoption of preventive or remedial measures and it may seek, in accordance with this Directive, to recover the costs it has incurred in relation to the adoption of preventive or remedial measures.

Article 16

Relationship with national law

1. This Directive shall not prevent Member States from maintaining or adopting more stringent provisions in relation to the prevention and remedying of environmental damage, including the identification of additional activities to be subject to the prevention and remediation requirements of this Directive and the identification of additional responsible parties.

2. This Directive shall not prevent Member States from adopting appropriate measures, such as the prohibition of double recovery of costs, in relation to situations where double recovery could occur as a result of concurrent action by a competent authority under this Directive and by a person whose property is affected by environmental damage.

Article 17

Temporal application

This Directive shall not apply to:

- damage caused by an emission, event or incident that took place before the date referred to in Article 19(1),
- damage caused by an emission, event or incident which takes place subsequent to the date referred to in Article 19(1) when it derives from a specific activity that took place and finished before the said date,
- damage, if more than 30 years have passed since the emission, event or incident, resulting in the damage, occurred.

Article 18

Reports and review

1. Member States shall report to the Commission on the experience gained in the application of this Directive by 30 April 2013 at the latest. The reports shall include the information and data set out in Annex VI.

2. On that basis, the Commission shall submit a report to the European Parliament and to the Council before 30 April 2014, which shall include any appropriate proposals for amendment.

3. The report, referred to in paragraph 2, shall include a review of:

(a) the application of:

- Article 4(2) and (4) in relation to the exclusion of pollution covered by the international instruments listed in Annexes IV and V from the scope of this Directive, and
- Article 4(3) in relation to the right of an operator to limit his liability in accordance with the international conventions referred to in Article 4(3).

The Commission shall take into account experience gained within the relevant international fora, such as the IMO and Euratom and the relevant international agreements, as well as the extent to which these instruments have entered into force and/or have been implemented by Member States and/or have been modified, taking account of all relevant instances of environmental damage resulting from such activities and the remedial action taken and the differences between the liability levels in Member States, and considering the relationship between shipowners' liability and oil receivers' contributions, having due regard to any relevant study undertaken by the International Oil Pollution Compensation Funds.

- b) the application of this Directive to environmental damage caused by genetically modified organisms (GMOs), particularly in the light of experience gained within relevant international fora and Conventions, such as the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, as well as the results of any incidents of environmental damage caused by GMOs;
- c) the application of this Directive in relation to protected species and natural habitats;

- d) the instruments that may be eligible for incorporation into Annexes III, IV and V.

Article 19

Implementation

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2007. They shall forthwith inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

Article 20

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 21

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 21 April 2004.

For the European Parliament

The President

P. COX

For the Council

The President

D. ROCHE

ANNEX I

CRITERIA REFERRED TO IN ARTICLE 2(1)(A)

The significance of any damage that has adverse effects on reaching or maintaining the favourable conservation status of habitats or species has to be assessed by reference to the conservation status at the time of the damage, the services provided by the amenities they produce and their capacity for natural regeneration. Significant adverse changes to the baseline condition should be determined by means of measurable data such as:

- the number of individuals, their density or the area covered,
- the role of the particular individuals or of the damaged area in relation to the species or to the habitat conservation, the rarity of the species or habitat (assessed at local, regional and higher level including at Community level),
- the species' capacity for propagation (according to the dynamics specific to that species or to that population), its viability or the habitat's capacity for natural regeneration (according to the dynamics specific to its characteristic species or to their populations),
- the species' or habitat's capacity, after damage has occurred, to recover within a short time, without any intervention other than increased protection measures, to a condition which leads, solely by virtue of the dynamics of the species or habitat, to a condition deemed equivalent or superior to the baseline condition.

Damage with a proven effect on human health must be classified as significant damage.

The following does not have to be classified as significant damage:

- negative variations that are smaller than natural fluctuations regarded as normal for the species or habitat in question,
- negative variations due to natural causes or resulting from intervention relating to the normal management of sites, as defined in habitat records or target documents or as carried on previously by owners or operators,
- damage to species or habitats for which it is established that they will recover, within a short time and without intervention, either to the baseline condition or to a condition which leads, solely by virtue of the dynamics of the species or habitat, to a condition deemed equivalent or superior to the baseline condition.

ANNEX II

REMEDYING OF ENVIRONMENTAL DAMAGE

This Annex sets out a common framework to be followed in order to choose the most appropriate measures to ensure the remedying of environmental damage.

1. Remediation of damage to water or protected species or natural habitats

Remedying of environmental damage, in relation to water or protected species or natural habitats, is achieved through the restoration of the environment to its baseline condition by way of primary, complementary and compensatory remediation, where:

- (a) 'Primary' remediation is any remedial measure which returns the damaged natural resources and/or impaired services to, or towards, baseline condition;
- (b) 'Complementary' remediation is any remedial measure taken in relation to natural resources and/or services to compensate for the fact that primary remediation does not result in fully restoring the damaged natural resources and/or services;
- (c) 'Compensatory' remediation is any action taken to compensate for interim losses of natural resources and/or services that occur from the date of damage occurring until primary remediation has achieved its full effect;
- (d) 'interim losses' means losses which result from the fact that the damaged natural resources and/or services are not able to perform their ecological functions or provide services to other natural resources or to the public until the primary or complementary measures have taken effect. It does not consist of financial compensation to members of the public.

Where primary remediation does not result in the restoration of the environment to its baseline condition, then complementary remediation will be undertaken. In addition, compensatory remediation will be undertaken to compensate for the interim losses.

Remedying of environmental damage, in terms of damage to water or protected species or natural habitats, also implies that any significant risk of human health being adversely affected be removed.

1.1. Remediation objectives

Purpose of primary remediation

- 1.1.1. The purpose of primary remediation is to restore the damaged natural resources and/or services to, or towards, baseline condition.

Purpose of complementary remediation

- 1.1.2. Where the damaged natural resources and/or services do not return to their baseline condition, then complementary remediation will be undertaken. The purpose of complementary remediation is to provide a similar level of natural resources and/or services, including, as appropriate, at an alternative site, as would have been provided if the damaged site had been returned to its baseline condition. Where possible and appropriate the alternative site should be geographically linked to the damaged site, taking into account the interests of the affected population.

Purpose of compensatory remediation

- 1.1.3. Compensatory remediation shall be undertaken to compensate for the interim loss of natural resources and services pending recovery. This compensation consists of additional improvements to protected natural habitats and species or water at either the damaged site or at an alternative site. It does not consist of financial compensation to members of the public.

1.2. *Identification of remedial measures*

Identification of primary remedial measures

- 1.2.1. Options comprised of actions to directly restore the natural resources and services towards baseline condition on an accelerated time frame, or through natural recovery, shall be considered.

Identification of complementary and compensatory remedial measures

- 1.2.2. When determining the scale of complementary and compensatory remedial measures, the use of resource-to-resource or service-to-service equivalence approaches shall be considered first. Under these approaches, actions that provide natural resources and/or services of the same type, quality and quantity as those damaged shall be considered first. Where this is not possible, then alternative natural resources and/or services shall be provided. For example, a reduction in quality could be offset by an increase in the quantity of remedial measures.
- 1.2.3. If it is not possible to use the first choice resource-to-resource or service-to-service equivalence approaches, then alternative valuation techniques shall be used. The competent authority may prescribe the method, for example monetary valuation, to determine the extent of the necessary complementary and compensatory remedial measures. If valuation of the lost resources and/or services is practicable, but valuation of the replacement natural resources and/or services cannot be performed within a reasonable time-frame or at a reasonable cost, then the competent authority may choose remedial measures whose cost is equivalent to the estimated monetary value of the lost natural resources and/or services.

The complementary and compensatory remedial measures should be so designed that they provide for additional natural resources and/or services to reflect time preferences and the time profile of the remedial measures. For example, the longer the period of time before the baseline condition is reached, the greater the amount of compensatory remedial measures that will be undertaken (other things being equal).

1.3. *Choice of the remedial options*

- 1.3.1. The reasonable remedial options should be evaluated, using best available technologies, based on the following criteria:
- The effect of each option on public health and safety,
 - The cost of implementing the option,
 - The likelihood of success of each option,
 - The extent to which each option will prevent future damage, and avoid collateral damage as a result of implementing the option,
 - The extent to which each option benefits to each component of the natural resource and/or service,
 - The extent to which each option takes account of relevant social, economic and cultural concerns and other relevant factors specific to the locality,
 - The length of time it will take for the restoration of the environmental damage to be effective,
 - The extent to which each option achieves the restoration of site of the environmental damage,
 - The geographical linkage to the damaged site.

- 1.3.2. When evaluating the different identified remedial options, primary remedial measures that do not fully restore the damaged water or protected species or natural habitat to baseline or that restore it more slowly can be chosen. This decision can be taken only if the natural resources and/or services foregone at the primary site as a result of the decision are compensated for by increasing complementary or compensatory actions to provide a similar level of natural resources and/or services as were foregone. This will be the case, for example, when the equivalent natural resources and/or services could be provided elsewhere at a lower cost. These additional remedial measures shall be determined in accordance with the rules set out in section 1.2.2.
- 1.3.3. Notwithstanding the rules set out in section 1.3.2. and in accordance with Article 7(3), the competent authority is entitled to decide that no further remedial measures should be taken if:
- (a) the remedial measures already taken secure that there is no longer any significant risk of adversely affecting human health, water or protected species and natural habitats, and
 - (b) the cost of the remedial measures that should be taken to reach baseline condition or similar level would be disproportionate to the environmental benefits to be obtained.

2. Remediation of land damage

The necessary measures shall be taken to ensure, as a minimum, that the relevant contaminants are removed, controlled, contained or diminished so that the contaminated land, taking account of its current use or approved future use at the time of the damage, no longer poses any significant risk of adversely affecting human health. The presence of such risks shall be assessed through risk-assessment procedures taking into account the characteristic and function of the soil, the type and concentration of the harmful substances, preparations, organisms or micro-organisms, their risk and the possibility of their dispersion. Use shall be ascertained on the basis of the land use regulations, or other relevant regulations, in force, if any, when the damage occurred.

If the use of the land is changed, all necessary measures shall be taken to prevent any adverse effects on human health.

If land use regulations, or other relevant regulations, are lacking, the nature of the relevant area where the damage occurred, taking into account its expected development, shall determine the use of the specific area.

A natural recovery option, that is to say an option in which no direct human intervention in the recovery process would be taken, shall be considered.

ANNEX III

ACTIVITIES REFERRED TO IN ARTICLE 3(1)

1. The operation of installations subject to permit in pursuance of Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control ⁽¹⁾. That means all activities listed in Annex I of Directive 96/61/EC with the exception of installations or parts of installations used for research, development and testing of new products and processes.
2. Waste management operations, including the collection, transport, recovery and disposal of waste and hazardous waste, including the supervision of such operations and after-care of disposal sites, subject to permit or registration in pursuance of Council Directive 75/442/EEC of 15 July 1975 on waste ⁽²⁾ and Council Directive 91/689/EEC of 12 December 1991 on hazardous waste ⁽³⁾.

Those operations include, inter alia, the operation of landfill sites under Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste ⁽⁴⁾ and the operation of incineration plants under Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste ⁽⁵⁾.

For the purpose of this Directive, Member States may decide that those operations shall not include the spreading of sewage sludge from urban waste water treatment plants, treated to an approved standard, for agricultural purposes.

3. All discharges into the inland surface water, which require prior authorisation in pursuance of Council Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances, discharged into the aquatic environment of the Community ⁽⁶⁾.
4. All discharges of substances into groundwater which require prior authorisation in pursuance of Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances ⁽⁷⁾.
5. The discharge or injection of pollutants into surface water or groundwater which require a permit, authorisation or registration in pursuance of Directive 2000/60/EC.
6. Water abstraction and impoundment of water subject to prior authorisation in pursuance of Directive 2000/60/EC.
7. Manufacture, use, storage, processing, filling, release into the environment and onsite transport of
 - (a) dangerous substances as defined in Article 2(2) of Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances ⁽⁸⁾;
 - (b) dangerous preparations as defined in Article 2(2) of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽⁹⁾;
 - (c) plant protection products as defined in Article 2(1) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁰⁾;
 - (d) biocidal products as defined in Article 2(1)(a) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽¹¹⁾.

⁽¹⁾ OJ L 257, 10.10.1996, p. 26. Directive as last amended by Regulation (EC) No 1882/2003.

⁽²⁾ OJ L 194, 25.7.1975, p. 39. Directive as last amended by Regulation (EC) No 1882/2003.

⁽³⁾ OJ L 377, 31.12.1991, p. 20. Directive as amended by Directive 94/31/EC (OJ L 168, 2.7.1994, p. 28).

⁽⁴⁾ OJ L 182, 16.7.1999, p. 1. Directive as amended by Regulation (EC) No 1882/2003.

⁽⁵⁾ OJ L 332, 28.12.2000, p. 91.

⁽⁶⁾ OJ L 129, 18.5.1976, p. 23. Directive as last amended by Directive 2000/60/EC.

⁽⁷⁾ OJ L 20, 26.1.1980, p. 43. Directive as amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).

⁽⁸⁾ OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003.

⁽⁹⁾ OJ L 200, 30.7.1999, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

⁽¹⁰⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽¹¹⁾ OJ L 123, 24.4.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003.

8. Transport by road, rail, inland waterways, sea or air of dangerous goods or polluting goods as defined either in Annex A to Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road ⁽¹⁾ or in the Annex to Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail ⁽²⁾ or as defined in Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods ⁽³⁾.
9. The operation of installations subject to authorisation in pursuance of Council Directive 84/360/EEC of 28 June 1984 on the combating of air pollution from industrial plants ⁽⁴⁾ in relation to the release into air of any of the polluting substances covered by the aforementioned Directive.
10. Any contained use, including transport, involving genetically modified micro-organisms as defined by Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms ⁽⁵⁾.
11. Any deliberate release into the environment, transport and placing on the market of genetically modified organisms as defined by Directive 2001/18/EC of the European Parliament and of the Council ⁽⁶⁾.
12. Transboundary shipment of waste within, into or out of the European Union, requiring an authorisation or prohibited in the meaning of Council Regulation (EEC) No 259/93 of 1 February 1993 on the supervision and control of shipments of waste within, into and out of the European Community ⁽⁷⁾.

⁽¹⁾ OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2003/28/EC (OJ L 90, 8.4.2003, p. 45).

⁽²⁾ OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2003/29/EC (OJ L 90, 8.4.2003, p. 47).

⁽³⁾ OJ L 247, 5.10.1993, p. 19. Directive as last amended by Directive 2002/84/EC of the European Parliament and of the Council (OJ L 324, 29.11.2002, p. 53).

⁽⁴⁾ OJ L 188, 16.7.1984, p. 20. Directive as amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).

⁽⁵⁾ OJ L 117, 8.5.1990, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

⁽⁶⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

⁽⁷⁾ OJ L 30, 6.2.1993, p. 1. Regulation as last amended by Commission Regulation (EC) No 2557/2001 (OJ L 349, 31.12.2001, p. 1).

ANNEX IV

INTERNATIONAL CONVENTIONS REFERRED TO IN ARTICLE 4(2)

- (a) the International Convention of 27 November 1992 on Civil Liability for Oil Pollution Damage;
 - (b) the International Convention of 27 November 1992 on the Establishment of an International Fund for Compensation for Oil Pollution Damage;
 - (c) the International Convention of 23 March 2001 on Civil Liability for Bunker Oil Pollution Damage;
 - (d) the International Convention of 3 May 1996 on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea;
 - (e) the Convention of 10 October 1989 on Civil Liability for Damage Caused during Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels.
-

ANNEX V

INTERNATIONAL INSTRUMENTS REFERRED TO IN ARTICLE 4(4)

- (a) the Paris Convention of 29 July 1960 on Third Party Liability in the Field of Nuclear Energy and the Brussels Supplementary Convention of 31 January 1963;
 - (b) the Vienna Convention of 21 May 1963 on Civil Liability for Nuclear Damage;
 - (c) the Convention of 12 September 1997 on Supplementary Compensation for Nuclear Damage;
 - (d) the Joint Protocol of 21 September 1988 relating to the Application of the Vienna Convention and the Paris Convention;
 - (e) the Brussels Convention of 17 December 1971 relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material.
-

ANNEX VI

INFORMATION AND DATA REFERRED TO IN ARTICLE 18(1)

The reports referred to in Article 18(1) shall include a list of instances of environmental damage and instances of liability under this Directive, with the following information and data for each instance:

1. Type of environmental damage, date of occurrence and/or discovery of the damage and date on which proceedings were initiated under this Directive.
2. Activity classification code of the liable legal person(s) ⁽¹⁾.
3. Whether there has been resort to judicial review proceedings either by liable parties or qualified entities. (The type of claimants and the outcome of proceedings shall be specified.)
4. Outcome of the remediation process.
5. Date of closure of proceedings.

Member States may include in their reports any other information and data they deem useful to allow a proper assessment of the functioning of this Directive, for example:

1. Costs incurred with remediation and prevention measures, as defined in this Directive:
 - paid for directly by liable parties, when this information is available;
 - recovered ex post facto from liable parties;
 - unrecovered from liable parties. (Reasons for non-recovery should be specified.)
2. Results of the actions to promote and the implementation of the financial security instruments used in accordance with this Directive.
3. An assessment of the additional administrative costs incurred annually by the public administration in setting up and operating the administrative structures needed to implement and enforce this Directive.

⁽¹⁾ The NACE code can be used (Council Regulation (EEC) No 3037/90 of 9 October 1990 on the statistical classification of economic activities in the European Community (OJ L 293, 24.10.1990, p. 1).

Commission declaration on Article 14(2) — Environmental liability Directive

The Commission takes note of article 14(2). In accordance with this article, the Commission will present a report, six years after the entry into force of the Directive, covering, *inter alia*, the availability at reasonable costs and conditions of insurance and other types of financial security. The report will in particular take into account the development by the market forces of appropriate financial security products in relation to the aspects referred to. It will also consider a gradual approach according to the type of damage and the nature of the risks. In the light of the report, the Commission will, if appropriate, submit as soon as possible proposals. The Commission will carry out an impact assessment, extended to the economic, social and environmental aspects, in accordance with the relevant existing rules and in particular the inter-institutional agreement on Better Law-Making and its Communication on Impact Assessment [COM(2002) 276 final].

STATUTORY INSTRUMENTS

2009 No. 153

ENVIRONMENTAL PROTECTION, ENGLAND

**The Environmental Damage (Prevention and Remediation)
Regulations 2009**

<i>Made</i> - - - -	<i>29th January 2009</i>
<i>Laid before Parliament</i>	<i>2nd February 2009</i>
<i>Coming into force</i> - -	<i>1st March 2009</i>

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The Secretary of State has been designated in respect of the environment^(a) for the purposes of section 2(2) of the European Communities Act 1972^(b), and makes these Regulations under the powers conferred by that section as read with paragraph 1A of Schedule 2 to that Act.

The Regulations make provision for a purpose mentioned in section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972 and it appears to the Secretary of State that it

(a) S.I. 2008/301.

(b) 1972 c. 68. Paragraph 1A was inserted into Schedule 2 by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51).

is expedient for the Community instruments referred to in these Regulations to be construed as references to those instruments as amended from time to time.

PART 1

Introductory provisions

Title, commencement and application

1.—(1) These Regulations may be cited as the Environmental Damage (Prevention and Remediation) Regulations 2009 and come into force on 1st March 2009.

(2) They apply in England and the areas specified in regulation 6.

Interpretation

2.—(1) In these Regulations—

“activity” means any economic activity, whether public or private and whether or not carried out for profit and “operator” means the person who operates or controls such an activity, including the holder of a permit or authorisation relating to that activity, or the person registering or notifying such an activity;

“groundwater” means all water that is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil;

“local authority” means—

(a) where there is a unitary authority for that local government area, that authority;

(b) where there is not a unitary authority—

(i) in a metropolitan district, the council of that district;

(ii) in a non-metropolitan county, the district council;

(iii) in each London borough, the council of that borough;

(iv) in the City of London, the Common Council;

(v) on the Isles of Scilly, the Council of the Isles of Scilly;

“natural habitat” means—

(a) the habitats of species mentioned in Article 4(2) of, or Annex I to, Council Directive 79/409/EEC on the conservation of wild birds(a) or listed in Annex II to Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora(b);

(b) the natural habitats listed in Annex I to Council Directive 92/43/EEC; and

(c) the breeding sites or resting places of the species listed in Annex IV to Council Directive 92/43/EEC;

“natural resource” means—

(a) protected species;

(b) natural habitats;

(c) species or habitats on a site of special scientific interest for which the site has been notified under section 28 of the Wildlife and Countryside Act 1981(c);

(a) OJ No L 103, 25.4.1979, p. 1 as last amended by Council Directive 2008/102/EC, OJ No L323, 3.12.008, p. 31).

(b) OJ No L 206, 22.7.1992, p. 7 as last amended by Council Directive 2006/105/EC (OJ No L 363, 20.12.2006, p. 368).

(c) 1981 c.69. Part II of the Act (which includes section 28) was inserted by Schedule 9 to the Countryside and Rights of Way Act 2000 (2000 c. 37) and subsequently amended by Schedule 11 to the Natural Environment and Rural Communities Act 2006 (2006 c. 16).

(d) water; and

(e) land;

“protected species” means the species mentioned in Article 4(2) of Council Directive 79/409/EEC or listed in Annex I to that Directive or Annexes II and IV to Council Directive 92/43/EEC;

“services” means the functions performed by a natural resource for the benefit of another natural resource or the public.

(2) Unless otherwise defined in these Regulations, expressions used in Directive 2004/35/EC of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage(a) have the same meaning in these Regulations.

References to Community instruments

3. References in Schedule 2 to Community instruments are references to those instruments as amended from time to time.

Meaning of “environmental damage”

4.—(1) These Regulations apply in relation to the prevention and remediation of environmental damage; and “environmental damage” is damage to—

- (a) protected species or natural habitats, or a site of special scientific interest,
- (b) surface water or groundwater, or
- (c) land,

as specified in this regulation.

(2) Environmental damage to protected species or natural habitats or a site of special scientific interest means damage of a kind specified in Schedule 1.

(3) Environmental damage to surface water means damage to a surface water body classified as such pursuant to Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy(b) such that—

- (a) a biological quality element listed in Annex V to that Directive,
- (b) the level of a chemical listed in the legislation in Annex IX or a chemical listed in Annex X to that Directive, or
- (c) a physicochemical quality element listed in Annex V to that Directive,

changes sufficiently to lower the status of the water body in accordance with Directive 2000/60/EC of the European Parliament and of the Council (whether or not the water body is in fact reclassified as being of lower status).

(4) Environmental damage to groundwater means any damage to a body of groundwater such that its conductivity, level or concentration of pollutants changes sufficiently to lower its status pursuant to Directive 2000/60/EC of the European Parliament and of the Council (and for pollutants Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration(c)) (whether or not the body of groundwater is in fact reclassified as being of lower status).

(5) Environmental damage to land means contamination of land by substances, preparations, organisms or micro-organisms that results in a significant risk of adverse effects on human health.

(a) OJ No L 143, 30.4.2004, p. 56 as amended by Directive 2006/21/EC (OJ No L102, 11.4.2006, p. 15).

(b) OJ No L 327, 22.12.2000, p. 1 as last amended by Directive 2008/105/EC of the European Parliament and of the Council (OJ No L 348, 24.12.2008, p. 84).

(c) OJ No L 372, 27.12/2006, p. 19.

Environmental damage to which these Regulations apply

5.—(1) These Regulations apply in relation to environmental damage if it is caused by an activity in Schedule 2.

(2) In the case of environmental damage to protected species or natural habitats or a site of special scientific interest the Regulations also apply in relation to environmental damage caused by any other activity if the operator—

- (a) intended to cause environmental damage; or
- (b) was negligent as to whether environmental damage would be caused.

Areas of application

6.—(1) The damage must be in an area specified in the following table.

<i>Type of damage</i>	<i>Area in which these Regulations apply</i>
Damage to water	England and all water up to one nautical mile seaward from the baseline in England
Damage in a site of special scientific interest	England
Damage to protected species or natural habitats	England The seabed of the continental shelf ^(a) Anywhere other than the seabed in the renewable energy zone ^(a)
Damage to land	England

^(a) These areas do not include areas that form part of Northern Ireland, Scotland or Wales or the territorial sea adjacent to the Isle of Man, Jersey^(a) or Guernsey; and for these purposes—

- (i) Wales is as defined in section 158(1) of the Government of Wales Act 2006^(b);
- (ii) Scotland is as defined in section 126(1) of the Scotland Act 1998^(c); and
- (iii) Northern Ireland is as defined in section 98 of the Northern Ireland Act 1998^(d).

(2) In this table—

“the baseline” means the baselines from which the breadth of the territorial sea is measured for the purposes of the Territorial Sea Act 1987^(e);

“the continental shelf” means the areas designated by Order in Council under section 1(7) of the Continental Shelf Act 1964^(f); and

“the renewable energy zone” means the waters superjacent to the seabed situated within the areas designated by Order in Council under section 84(4) of the Energy Act 2004^(g).

(a) See section 1 of the Territorial Sea Act 1987 (c. 49) as extended to Jersey by the Territorial Sea Act 1987(Jersey) Order 1997 (S. I. 1997/278) as amended by S.I. 2002/250, and to the Isle of Man by the Territorial Sea Act 1987 (Isle of Man) Order 1991 (S.I. 1991/1722).

(b) 2006 c. 32.

(c) 1998 c. 46.

(d) 1998 c. 47.

(e) 1987 c. 49.

(f) 1964 c. 29. Areas have been designated under section 1(7) by S.I. 1987/1265, 2000/3062 and 2001/3670. Section 1(7) was amended by paragraph 1 of Schedule 3 to the Oil and Gas (Enterprise) Act 1982 (c. 23).

(g) 2004 c. 20. Areas have been designated under section 84(4) by S.I. 2004/2668.

Other legislation

7.—(1) These Regulations are without prejudice to any other enactment concerning damage to the environment.

(2) They are without prejudice to the right of an operator to limit liability in accordance with the Convention on Limitation of Liability for Maritime Claims 1976(a).

Exemptions

8.—(1) These Regulations do not apply in relation to—

- (a) damage that took place before the coming into force of these Regulations;
- (b) damage that takes place after that date, or is threatened after that date, but is caused by an incident, event or emission that took place before that date; or
- (c) damage caused by an incident, event or emission that takes place after that date if it derives from an activity that took place and finished before that date.

(2) They do not apply in relation to environmental damage caused by—

- (a) an act of terrorism;
- (b) an exceptional natural phenomenon, provided the operator of the activity concerned took all reasonable precautions to protect against damage being caused by such an event;
- (c) activities the sole purpose of which is to protect from natural disasters;
- (d) an incident in respect of which liability or compensation falls within the scope of—
 - (i) the International Convention of 27 November 1992 on Civil Liability for Oil Pollution Damage;
 - (ii) the International Convention of 27 November 1992 on the Establishment of an International Fund for Compensation for Oil Pollution Damage(b); or
 - (iii) the International Convention on Civil Liability for Bunker Oil Pollution Damage 2001(c);
- (e) activities the main purpose of which is to serve national defence or international security;
- (f) radioactivity from an activity covered by the Treaty establishing the European Atomic Energy Community or caused by an incident or activity in respect of which liability or compensation falls within the scope of the Paris Convention of 29 July 1960 on Third Party Liability in the Field of Nuclear Energy and the Brussels Supplementary Convention of 31 January 1963; or
- (g) damage caused in the course of commercial sea fishing if all legislation relating to that fishing was complied with.

(3) They only apply to environmental damage caused by pollution of a diffuse character if it is possible to establish a causal link between the damage and specific activities.

Exemption from damage to water

9.—(1) Damage to water does not include—

- (a) damage caused by new modifications to the physical characteristics of a surface water body,
- (b) an alteration to the level of a body of groundwater pursuant to Directive 2000/60/EC of the European Parliament and of the Council, or

(a) The Convention is set out in Schedule 7 to the Merchant Shipping Act 1995 (c. 21).

(b) Both these conventions were implemented in the Merchant Shipping Act 1995 (1995 c. 21).

(c) Implemented in the Merchant Shipping Act 1995 by amendments made to that Act by S.I. 2006/1244.

- (c) deterioration from high status to good status of a body of surface water resulting from new sustainable human development activities pursuant to that Directive,

if all the conditions in paragraph (2) are fulfilled.

(2) The conditions are—

- (a) all practicable steps are taken to mitigate the adverse impact on the status of the body of water;
- (b) the reasons for those modifications or alterations are specifically set out and explained in the river basin management plan required under Article 13 of Directive 2000/60/EC of the European Parliament and of the Council and the objectives are reviewed every six years;
- (c) the reasons for those modifications or alterations are of overriding public interest, or the result of the damage is outweighed by the benefits of the new modifications or alterations to human health, to the maintenance of human safety or to sustainable development; and
- (d) the beneficial objectives served by those modifications or alterations of the water body cannot for reasons of technical feasibility or disproportionate cost be achieved by other means.

Enforcing authorities under the Environmental Permitting (England and Wales) Regulations 2007

10.—(1) These Regulations are enforced in accordance with this regulation if the damage is caused by an installation, waste operation or mobile plant that requires a permit or registration under the Environmental Permitting (England and Wales) Regulations 2007(a).

(2) If the Environment Agency is responsible for granting the permit, they are enforced by the Environment Agency in all cases.

(3) If the local authority is responsible for granting the permit—

- (a) Part 2 is enforced by the local authority;
- (b) Part 3 is enforced by—
 - (i) the local authority if the damage is to land;
 - (ii) the Environment Agency if the damage is to water;
 - (iii) Natural England if the damage is to natural habitats or protected species or a site of special scientific interest.

Enforcing authorities in other cases

11. If the damage is caused by an activity that does not require a permit or registration under the Environmental Permitting (England and Wales) Regulations 2007 these Regulations are enforced in accordance with the following table.

<i>Type of environmental damage</i>	<i>Area of damage</i>	<i>Enforcing authority</i>
Damage to water—		Environment Agency

(a) S. I. 2007/3538.

<i>Type of environmental damage</i>	<i>Area of damage</i>	<i>Enforcing authority</i>
Damage to protected species or natural habitats or a site of special scientific interest—	land	Natural England
	water but not in the sea ⁽¹⁾	Environment Agency
	the continental shelf or in the sea up to the limit of the renewable energy zone	- if the damage is due to an activity authorised by the Environment Agency, the Environment Agency; - otherwise the Secretary of State
Damage to land—		Local authority

⁽¹⁾ "Sea" includes—

- (a) any area submerged at mean high water spring tide; and
- (b) each of the following, so far as the tide flows at mean high water spring tide—
 - (i) every estuary or arm of the sea; and
 - (ii) the waters of any channel, creek, bay or river.

Enforcement

12.—(1) If there is more than one type of damage, so that there is more than one enforcing authority, these Regulations are enforced by any or all of the specified enforcing authorities.

(2) An enforcing authority may appoint any other enforcing authority to act on its behalf.

PART 2

Preventing environmental damage

Preventing environmental damage

13.—(1) An operator of an activity that causes an imminent threat of environmental damage, or an imminent threat of damage which there are reasonable grounds to believe will become environmental damage, must immediately—

- (a) take all practicable steps to prevent the damage; and
- (b) (unless the threat has been eliminated) notify all relevant details to the enforcing authority appearing to be the appropriate one.

(2) The enforcing authority may serve a notice on that operator that—

- (a) describes the threat;
- (b) specifies the measures required to prevent the damage; and
- (c) requires the operator to take those measures, or measures at least equivalent to them, within the period specified in the notice.

(3) Failure to comply with paragraph (1) or a notice served under paragraph (2) is an offence.

Preventing further environmental damage

14.—(1) An operator of an activity that has caused environmental damage, or has caused damage where there are reasonable grounds to believe that the damage is or will become environmental damage, must immediately—

- (a) take all practicable steps to prevent further damage; and
 - (b) notify all relevant details to the enforcing authority appearing to be the appropriate one.
- (2) The enforcing authority may serve a notice on that operator that—
- (a) describes the damage;
 - (b) requires the operator to provide additional information on any damage that has occurred;
 - (c) specifies the measures required to prevent further damage; and
 - (d) requires the operator to take those measures, or measures at least equivalent to them, within the period specified in the notice.
- (3) Failure to comply with paragraph (1) or a notice served under paragraph (2) is an offence.

Action by the enforcing authority

15. Any duty in this Part on the operator of an activity may be carried out by the enforcing authority instead of the operator—

- (a) in an emergency;
- (b) if the operator cannot be ascertained; or
- (c) if the operator fails to comply with a notice.

Following instructions from a public authority

16. When an operator acts in accordance with the instructions of a public authority, and as a result causes or threatens to cause environmental damage, and accordingly action is taken under regulations 13, 14 or 15 then, unless the instructions related to an emission or incident caused by the operator's own activities, the operator may recover the costs of actions under those regulations from that public authority.

PART 3

Remediation

Assessment of damage

17. Where damage has been caused, and there are reasonable grounds for believing that it is, or may be, environmental damage, the enforcing authority must establish whether or not it is environmental damage.

Determining liability to remediate

18.—(1) If the enforcing authority decides that the damage is environmental damage it must notify the operator of any activity or activities that caused the damage (referred to in these Regulations as “the responsible operator”) that—

- (a) the damage is environmental damage;
- (b) the responsible operator's activity was a cause of the environmental damage;
- (c) the responsible operator must submit proposals, within a time specified by the enforcing authority, for measures that will achieve the remediation of the environmental damage in accordance with Schedule 4; and

(d) the responsible operator has a right to appeal.

(2) The enforcing authority may withdraw the notification if it is satisfied that the notification should not have been served or that an appeal against the notice is likely to succeed.

Appeals against liability to remediate

19.—(1) A person served with notification under regulation 18 may notify the Secretary of State that that person intends to appeal against that notification.

(2) Notice of appeal must be within 28 days of service of the notification under regulation 18 unless the time limit is extended by the Secretary of State.

(3) The grounds of appeal are—

- (a) the operator's activity was not a cause of the environmental damage;
- (b) the enforcing authority has acted unreasonably in deciding that the damage is environmental damage;
- (c) the environmental damage resulted from compliance with an instruction from a public authority (except an instruction relating to an emission or incident caused by the operator's own activities);
- (d) the responsible operator was not at fault or negligent and the environmental damage was caused by an emission or event expressly authorised by, and fully in accordance with the conditions of a permit listed in Schedule 3;
- (e) the responsible operator was not at fault or negligent and the environmental damage was caused by an emission or activity or any manner of using a product in the course of an activity that the operator demonstrates was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the emission was released or the activity took place;
- (f) the environmental damage was the result of an act of a third party and occurred despite the fact that the responsible operator took all appropriate safety measures.

(4) Schedule 5 contains procedures for the appeal.

(5) The person deciding the appeal may confirm or quash the notice.

Remediation notices

20.—(1) Once it receives the proposals from the responsible operator (or, if a proposal is not received within the specified time limit, at any time after the time limit has expired), the enforcing authority must, so far as is practicable, consult—

- (a) anyone who has notified an enforcing authority under regulation 29, and
- (b) any person on whose land the remedial measures will be carried out,

and may consult any other person appearing to be necessary.

(2) Following consultation the enforcing authority must serve a remediation notice on the responsible operator that specifies—

- (a) the damage;
- (b) the measures necessary for remediation of the damage, together with the reasons;
- (c) the period within which those measures must be taken;
- (d) any additional monitoring or investigative measures that the responsible operator must carry out during remediation; and
- (e) the right of appeal against the remediation notice.

(3) Failure to comply with a remediation notice is an offence.

Appeal against the remediation notice

21.—(1) The responsible operator may notify the Secretary of State that that person intends to appeal against the remediation notice on the grounds that its contents are unreasonable.

(2) An appeal may only be brought against those parts of the remediation notice that are different from proposals made by the responsible operator.

(3) Notice of appeal must be served within 28 days of service of the remediation notice unless the time limit is extended by the Secretary of State.

(4) Schedule 5 contains procedures for the appeal.

(5) The Secretary of State or the appointed person may confirm, vary or quash the notice, and must give written notification of the final decision and the reasons for it, and may, if appropriate, add further compensatory remediation requirements necessitated by the lapse of time since the remediation notice was served.

(6) A remediation notice need not be complied with pending determination of an appeal unless the person hearing the appeal directs otherwise.

Further provisions on remediation notices

22. An enforcing authority may serve further remediation notices at any time while remediation is being carried out or, if remediation has not been achieved, at the end of the remediation period, requiring further or different remediation.

Action by the enforcing authority

23. Once it has established that in its opinion damage is environmental damage, the enforcing authority may carry out any reasonable works—

- (a) at any time if a responsible operator cannot be identified;
- (b) if a responsible operator fails to comply with a remediation notice, whether or not an appeal is pending; or
- (c) if the responsible operator is not required to remediate under these Regulations.

PART 4

Administration and enforcement

Costs when the enforcing authority acts instead of the operator

24.—(1) An operator liable to carry out works under Part 2 is liable for any reasonable costs incurred by the enforcing authority in taking any reasonable action under regulation 15.

(2) The responsible operator is liable for the reasonable costs of the enforcing authority for any action taken under regulation 23 unless the responsible operator was not liable for the action taken.

Costs concerned with administration

25.—(1) An operator liable to carry out works under Part 2 is liable for the reasonable costs incurred by the enforcing authority in preparing any notice under Part 2, or in ensuring compliance with that Part.

(2) The responsible operator is responsible for the costs incurred by the enforcing authority under Part 3 of—

- (a) assessing whether the damage is environmental damage;

- (b) establishing who is the responsible operator;
- (c) establishing what remediation is appropriate;
- (d) carrying out necessary consultation; and
- (e) monitoring the remediation, both during and after the work.

(3) Costs means costs that are justified by the need to ensure the proper and effective enforcement of these Regulations.

Proceedings for costs by an enforcing authority

26. No proceedings for the recovery of costs may be commenced by the enforcing authority under these Regulations after a period of 5 years has elapsed since—

- (a) the completion of the measures to which the proceedings relate, or
- (b) the identification of the operator liable to carry out the measures,

whichever is the later.

Costs recoverable from owner to be a charge on premises

27.—(1) Where any costs are recoverable under these Regulations by an enforcing authority from a person who is the owner of premises and the enforcing authority serves a notice on that person under this regulation—

- (a) the costs carry interest, at such reasonable rate as the authority may determine, from the date of service of the notice until the whole amount is paid; and
- (b) subject to the following, the costs and accrued interest are a charge on the premises.

(2) A notice served under this regulation must—

- (a) specify the amount of the costs that the enforcing authority claims is recoverable;
- (b) state the effect of paragraph (1) and the rate of interest determined by the enforcing authority under that paragraph; and
- (c) state the effect of paragraphs (4) to (6).

(3) On the date on which an enforcing authority serves a notice on a person under this regulation the authority must also serve a copy of the notice on every other person who, to the knowledge of the authority, has an interest in the premises capable of being affected by the charge.

(4) Subject to any order under paragraph (7)(b) or (c) below, the amount of any costs specified in a notice under this regulation and the accrued interest is a charge on the premises—

- (a) as from the end of the period of 21 days beginning with the date of service of the notice, or
- (b) where an appeal is brought under paragraph (6), as from the final determination of the appeal,

until the costs and interest are recovered.

(5) For the purposes of paragraph (4), the withdrawal of an appeal has the same effect as a final determination of the appeal.

(6) A person served with a notice or copy of a notice under this regulation may appeal against the notice to the county court within the period of 21 days beginning with the date of service.

(7) On such an appeal the court may—

- (a) confirm the notice without modification,
- (b) order that the notice is to have effect with the substitution of a different amount for the amount originally specified in it, or
- (c) order that the notice is to be of no effect.

(8) An enforcing authority has, for the purpose of enforcing a charge under this regulation, all the same powers and remedies under the Law of Property Act 1925(a), and otherwise, as if it were a mortgagee by deed having powers of sale and lease, of accepting surrenders of leases and of appointing a receiver.

(9) In this regulation, "owner", in relation to any premises, means a person (other than a mortgagee not in possession) who, whether in that person's own right or as trustee for any other person, is entitled to receive the rack rent of the premises or, where the premises are not let at a rack rent, would be so entitled if they were so let.

Recovery of costs from other persons

28. An operator who incurs liability to the enforcing authority under these Regulations (whether in carrying out work or in payment to the enforcing authority) may recover all or some of those costs from any other person who also caused the damage.

Requests for action by interested parties

29.—(1) Any person—

- (a) who is affected or likely to be affected by environmental damage, or
- (b) who otherwise has a sufficient interest,

may notify the appropriate enforcing authority of any environmental damage which is being, or has been caused or of which there is an imminent threat.

(2) A notification must be accompanied by—

- (a) a statement explaining the way the notifier will be affected by the damage, or the reason that the notifier has a sufficient interest; and
- (b) sufficient information to enable the enforcing authority to identify the location and nature of the incident.

(3) The enforcing authority must consider the notification and inform the notifier as to the action, if any, that it intends to take.

(4) Before taking any decision the enforcing authority must, if practicable—

- (a) notify the operator concerned of the notification and the accompanying information; and
- (b) invite that operator to submit comments on them.

(5) Paragraphs (3) and (4) do not apply if—

- (a) the notifier is not likely to be affected or does not have a sufficient interest;
- (b) in the opinion of the enforcing authority the information provided does not disclose any environmental damage or threat of environmental damage; or
- (c) as a result of the urgency of the situation, it is not practicable for the enforcing authority to comply with those paragraphs.

Grant of and compensation for rights of entry etc.

30.—(1) Any person whose consent is required before any works required by these Regulations may be carried out must grant, or join in granting, such rights in relation to any land or water as will enable the operator, or a person acting on behalf of the operator, to carry out that work.

(2) A person who grants, or joins in granting, any rights as required by paragraph (1) is entitled to compensation from the operator determined in accordance with Schedule 6.

(a) 1925 c. 20.

Powers of authorised persons

31.—(1) Enforcing authorities may authorise persons for the purposes of enforcing these Regulations.

(2) The powers in section 108 of the Environment Act 1995(a) apply in relation to these Regulations, and the powers of persons authorised by the Environment Agency in that section are exercisable by persons authorised by any enforcing authority.

(3) Those powers are extended to all areas to which these Regulations apply.

(4) In addition, a person authorised by the Secretary of State enforcing these Regulations in relation to the sea may at any time board and inspect—

(a) a ship or marine installation in the United Kingdom territorial waters adjacent to England; or

(b) a United Kingdom ship (within the meaning of section 1(3) of the Merchant Shipping Act 1995) or a marine installation in the renewable energy zone (as defined in section 84 of the Energy Act 2004(b)).

(5) For the purposes of exercising the powers in this Regulation, the authorised person may require a ship or marine installation—

(a) to stop; or

(b) to do anything else that will facilitate the boarding of that or any other ship or marine installation.

(6) An authorised person who has boarded a ship or marine installation may, for the purposes of disembarking from the ship or installation, require that or any other ship or marine installation—

(a) to stop; or

(b) to do anything else that will enable the authorised person, and any person accompanying that person, to disembark.

(7) An authorised person may require any person on board a vessel or marine installation to afford such facilities and assistance with respect to matters under that person's control as the authorised person considers would facilitate the exercise of any power conferred by this section.

(8) It is an offence to fail to comply with instructions given under this regulation, or knowingly to provide false or misleading information.

Provision of information to the enforcing authority

32. An enforcing authority may require an operator to provide such information as it may reasonably require to enable the enforcing authority to carry out its functions under these Regulations, and failure to provide such information is an offence.

Enforcement

33. No enforcement action may be taken under these Regulations 30 years or more after the emission, event or incident concerned.

Penalties

34.—(1) A person guilty of an offence under these Regulations is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or both; or

(a) 1995 c. 25.
(b) 2004 c. 20.

- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

(2) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of—

- (a) any director, manager, secretary or other similar person of the body corporate, or
- (b) any person who was purporting to act in any such capacity,

that person is guilty of the offence as well as the body corporate.

(3) For the purposes of paragraph (2), “director”, in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

Phil Hunt
Minister of State

29th January 2009

Department for Environment, Food and Rural Affairs

SCHEDULE 1

Regulation 4

Damage to protected species, natural habitats and sites of special scientific interest

Damage to protected species and natural habitats

1.—(1) In the case of protected species or natural habitat (other than damage on a site of special scientific interest to which paragraph 4 applies) the damage must be such that it has a significant adverse effect on reaching or maintaining the favourable conservation status of the protected species or natural habitat taking into account—

- (a) the conservation status at the time of the damage;
- (b) the services provided by the amenities they produce;
- (c) their capacity for natural regeneration;
- (d) the number of individuals, their density or the area covered;
- (e) the role of the particular individuals or of the damaged area in relation to the species or to the habitat conservation and the rarity of the species or habitat assessed at the relevant level whether local, regional or Community-wide;
- (f) the capacity of the species for propagation, its viability or the capacity of the habitat for natural regeneration; and
- (g) the capacity of the species or habitat to recover within a short time of the damage being caused to a condition that leads to its state at the time of the damage or better without any intervention other than increased protection measures.

Conservation status of natural habitats

2.—(1) A natural habitat’s conservation status is the sum of the influences acting on that habitat and its typical species that may affect its long term natural distribution, structure and functions as well as the long term survival of its typical species.

(2) Its conservation status is favourable if—

- (a) the natural range and areas covered within that natural range are stable or increasing;

- (b) the specific structure and functions which are necessary for the long term maintenance of the natural habitat exist and are likely to continue to exist for the foreseeable future; and
- (c) the conservation status of its typical species is favourable.

Conservation status of species

3.—(1) A species' conservation status is the sum of the influences acting on the species concerned that may affect the long term distribution and abundance of its populations.

(2) The conservation status is favourable if—

- (a) the population dynamics data on the species concerned indicate that it is maintaining itself on a long term basis as a viable component of its natural habitat;
- (b) the natural range of the species is neither being reduced nor is likely to be reduced for the foreseeable future; and
- (c) there is, and will probably continue to be, a sufficiently large habitat to maintain its populations on a long term basis.

Sites of special scientific interest

4.—(1) In the case of a site of special scientific interest, the damage must be to—

- (a) the species or habitats notified under section 28 of the Wildlife and Countryside Act 1981(a); or
- (b) protected species or natural habitats.

(2) The damage must have an adverse effect on the integrity of the site (that is, the coherence of its ecological structure and function, across its whole area, that enables it to sustain the habitat, complex of habitats or the levels of populations of the species affected).

Express authorisation

5. Damage to protected species and natural habitats, and damage on a site of special scientific interest, does not include damage caused by an act expressly authorised by the relevant authorities in accordance with the Conservation (Natural Habitats, etc.) Regulations 1994(b) or Part II of the Wildlife and Countryside Act 1981.

SCHEDULE 2

Regulation 5

Activities causing damage

Operations to which this Schedule applies

1. This Schedule lists the activities for which there is liability under regulation 5(1).

Operation of permitted installations

2. The operation of installations subject to permit in pursuance of Directive 2008/1/EC of the European Parliament and of the Council concerning integrated pollution prevention and control(c)

- (a) 1981 c. 69. Part II of the Act (which includes section 28) was inserted by Schedule 9 to the Countryside and Rights of Way Act 2000 (2000 c. 37) and subsequently amended by Schedule 11 to the Natural Environment and Rural Communities Act 2006 (2006 c. 16).
- (b) S.I. 1994/2716 as last amended by S.I. 2009/6.
- (c) OJ No L 24, 29.1.2008, p. 8.

(all activities listed in Annex I to that Directive with the exception of installations or parts of installations used for research, development and testing of new products and processes).

Waste management operations

3.—(1) Waste management operations, including the collection, transport, recovery and disposal of waste and hazardous waste, including the supervision of such operations and after-care of disposal sites, subject to permit or registration in pursuance of Directive 2006/12/EC of the European Parliament and of the Council on waste(a) and Council Directive 91/689/EEC on hazardous waste(b).

(2) The operation of landfill sites under Council Directive 1999/31/EC on the landfill of waste(c) and the operation of incineration plants under Directive 2000/76/EC of the European Parliament and of the Council on the incineration of waste(d).

(3) This does not include the spreading of sewage sludge from urban waste water treatment plants, treated to an approved standard, for agricultural purposes.

Mining waste

4. The management of extractive waste under Directive 2006/21/EC of the European Parliament and of the Council on the management of waste from extractive industries(e).

Discharges requiring authorisation

5.—(1) All discharges into the inland surface water that require prior authorisation in pursuance of Directive 2006/11/EC of the European Parliament and of the Council on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community(f).

(2) All discharges of substances into groundwater that require prior authorisation in pursuance of Council Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances(g).

(3) All discharges or injections of pollutants into surface water or groundwater that require a permit, authorisation or registration under Directive 2000/60/EC of the European Parliament and of the Council of establishing a framework for Community action in the field of water policy(h).

Water abstraction and impoundment

6. Water abstraction and impoundment of water subject to prior authorisation in pursuance of Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy.

Dangerous substances, plant protection products and biocidal products

7. Manufacture, use, storage, processing, filling, release into the environment and onsite transport of—

(a) OJ No L 114, 27.4.2006, p. 9 as last amended by Directive 2008/98/EC of the European Parliament and of the Council (OJ No L 312, 22.11.2008, p. 3).

(b) OJ No L 377, 31.12.91, p. 20 as last amended by Directive 2008/98/EC of the European Parliament and of the Council (OJ No L 312, 22.11.2008, p. 3).

(c) OJ No L 182, 16.7.99, p. 1 as last amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council (OJ No L 311, 21.11.2008, p. 1).

(d) OJ No L 332, 28.12.2000, p. 91 as corrected in OJ No L 145, 31.5.2001, p. 52.

(e) OJ No L 102, 11.4.2006, p. 15.

(f) OJ No L 64, 4.3.2006, p. 52.

(g) OJ No L 20, 26.1.80, p. 43 as amended by Council Directive 91/692/EC (OJ No L 377, 31.12.1991, p. 48).

(h) OJ No L 327, 22.12.2000, p. 1 as amended by Directive 2008/105/EC of the European Parliament and of the Council (OJ No L 348, 24.12.2008, p. 84).

- (a) dangerous substances as defined in Article 2(2) of Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances (a);
- (b) dangerous preparations as defined in Article 2(2) of Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations(b);
- (c) plant protection products as defined in Article 2(1) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market(c); and
- (d) biocidal products as defined in Article 2(1)(a) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market(d).

Transport

8. Transport by road, rail, inland waterways, sea or air of dangerous goods or polluting goods as defined in—

- (a) Annex A to Council Directive 94/55/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road(e);
- (b) the Annex to Council Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail(f); and
- (c) Council Directive 93/75/EEC concerning minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods(g).

Genetically modified organisms

9.—(1) Any contained use, including transport, involving genetically modified organisms (including genetically modified micro-organisms as defined by Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms(h)).

(2) Any deliberate release into the environment, transport and placing on the market of genetically modified organisms as defined by Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms(i).

Transboundary shipment of waste

10. Transboundary shipment of waste within, into or out of the Community, requiring an authorisation or prohibited under Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste(j).

-
- (a) OJ No 196, 16.8.67, p. 1 as last amended by Regulation (EC) No 2008/1272 of the European Parliament and of the Council (OJ No L 353, 31.12.2008, p. 1).
 - (b) OJ No L 200, 30.7.99, p. 1 as last amended by Regulation (EC) No 2008/1272 of the European Parliament and of the Council (OJ No L 353, 31.12.2008, p. 1).
 - (c) OJ No L 230, 19.8.91, p. 1 as last amended by Commission Directive 2008/127/EC (OJ No L 344, 20.12.2008, p. 89).
 - (d) OJ No L 123, 24.4.98, p. 1 as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ No L 81, 20.3.2008, p. 57).
 - (e) OJ No L 319, 12.12.94, p. 7 as last amended by Commission Directive 2006/89/EC (OJ No L 305, 4.11.2006, p. 4).
 - (f) OJ No L 235, 17.9.96, p. 25 as last amended by Commission Directive 2006/90/EC (OJ No L 305, 4.11.2006, p. 6).
 - (g) OJ No L 247, 5.10.93, p. 19 as last amended by Directive 2002/84/EC of the European Parliament and of the Council (OJ No L 324, 29.11.2002, p. 53).
 - (h) OJ No L 117, 8.5.90, p. 1 as last amended by Commission Decision 2005/174/EC (OJ No L 59, 5.3.2005, p. 20).
 - (i) OJ No L 106, 17.4.2001, p. 1 as last amended by Directive 2008/27/EC of the European Parliament and of the Council (OJ No L 81, 20.3.2008, p. 45).
 - (j) OJ No L 190, 12.7.2006, p. 1 as last amended by Commission Regulation (EC) No 669/2008 (OJ No L 188, 16.7.2008, p. 7).

SCHEDULE 3

Regulation 19

Permits, etc.

1. The following are permits for the purposes of regulation 19(3) in so far as they relate to an activity in Schedule 2—

- (a) a permit granted under the Environmental Permitting (England and Wales) Regulations 2007(a) or a registration under those Regulations;
- (b) a licence granted under Part II of the Food and Environment Protection Act 1985(b);
- (c) a water discharge consent, an ordinary or emergency drought order or a drought permit under the Water Resources Act 1991(c);
- (d) an authorisation under the Groundwater Regulations 1998(d);
- (e) a water abstraction or impoundment licence under the Water Resources Act 1991;
- (f) an approval of a pesticide under the Control of Pesticides Regulations 1986(e), an authorisation of a biocidal product under the Biocidal Products Regulations 2001(f) or an authorisation of a pesticide under the Plant Protection Products Regulations 2005(g);
- (g) a consent for the deliberate release of genetically modified organisms granted by the Secretary of State under section 111(1) of the Environmental Protection Act 1990(h) or a consent given in any other member State for the placing of a genetically modified organism on the market as a product or in a product in accordance with Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms(i);
- (h) an authorisation given in any member State in accordance with Article 7 or 19 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed(j).

SCHEDULE 4

Regulation 18

Remediation

PART 1

Remediation of damage to natural resources other than land

Application of Part 1

1. This Part relates to remediation of damage to natural resources other than land.

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- (a) S.I. 2007/3538.
 - (b) 1985 c. 48.
 - (c) 1991 c. 57 as amended by the Water Act 2003 (c. 37).
 - (d) S.I. 1998/2746 as last amended by S.I. 2007/3538.
 - (e) S.I. 1986/1510 to which there are amendments not relevant to these Regulations.
 - (f) S.I. 2001/880 to which there are amendments not relevant to these Regulations.
 - (g) S.I. 2005/1435 to which there are amendments not relevant to these Regulations.
 - (h) 1990 c. 43.
 - (i) OJ No L 106, 17.4.2001, p. 1 as last amended by Directive 2008/27/EC of the European Parliament and of the Council (OJ No L 81, 20.3.2008, p. 45).
 - (j) OJ No L 268, 18.10.2003, p. 1 as last amended by Regulation (EC) No 298/2008 of the European Parliament and of the Council (OJ No L 97, 9.4.2008, p. 64).

Risk to human health

2. Remediation must remove any significant risk to human health.

Objective

3. The objective of remediation is to achieve the same level of natural resource or services as would have existed if the damage had not occurred.

Primary and complementary remediation

- 4.—(1) The remediation must consist of such primary remediation or complementary remediation or both as will achieve the objective.

(2) Primary remediation is any remedial measure which returns the damaged natural resources or impaired services to, or towards, the state that would have existed if the damage had not occurred (natural recovery is a permitted form of primary remediation in appropriate cases).

(3) Complementary remediation is any remedial measure taken in relation to natural resources or services to compensate for the fact that primary remediation does not result in fully restoring the damaged natural resources or impaired services to the state that would have existed if the damage had not occurred.

Compensatory remediation

5.—(1) In addition compensatory remediation must be provided to compensate for interim losses of natural resources or services that occur from the date of damage until remediation has achieved its objective; and in this paragraph "interim losses" means losses which result from the fact that the damaged natural resources or services are not able to perform their ecological functions or provide services to other natural resources or to the public until the primary or complementary remediation has been carried out.

- (2) Compensatory remediation does not include financial compensation.

Choice of remediation

- 6.—(1) The remediation options must be evaluated using best available methods, and based on—

- (a) the effect of each option on public health and safety;
- (b) the cost of implementing the option;
- (c) the likelihood of success of each option;
- (d) the extent to which each option will prevent future damage, and avoid collateral damage as a result of implementing the option;
- (e) the extent to which each option benefits each component of the natural resource or service;
- (f) the extent to which each option takes account of relevant social, economic and cultural concerns and other relevant factors specific to the locality;
- (g) the length of time it will take for the restoration of the environmental damage to be effective;
- (h) the extent to which each option achieves the restoration of the site of the environmental damage; and
- (i) the geographical linkage to the damaged site.

Identification of complementary and compensatory remediation

7.—(1) If possible, complementary and compensatory remedial measures must provide natural resources or services of the same type, quality and quantity as those damaged.

(2) Where this is not possible, similar but different natural resources or services must be provided (for example, by offsetting a reduction in the quality of natural resources or services by increasing their quantity).

(3) Where this is not possible, different natural resources or services may be provided, and the remedial measures must have the same monetary valuation as the lost natural resources or services.

(4) If valuation of the lost natural resources or services is practicable, but valuation of the remedial measures cannot be made within a reasonable time or at a reasonable cost, then remedial measures may be provided whose cost (instead of monetary valuation) is equivalent to the value of the lost natural resources or services.

(5) In the case of complementary remediation at a new site, where possible and appropriate this site should be geographically linked to the damaged site.

Options

8.—(1) When evaluating the different identified remedial options, primary remedial measures that do not fully restore the damaged water or protected species or natural habitat to its state at the time of the incident or that restore it more slowly may be decided on (for example, when the equivalent natural resources or services could be provided elsewhere at a lower cost).

(2) This decision can be taken only if the natural resources or services foregone as a result of the decision are compensated for by increasing complementary or compensatory actions to provide a similar level of natural resources or services.

(3) The enforcing authority may at any time decide that no further remedial measures need be taken if—

- (a) the remedial measures already taken have removed any significant risk of adversely affecting human health, water or protected species and natural habitats; and
- (b) the cost of the remedial measures needed for restoration to its state before the incident would be disproportionate to the environmental benefits to be obtained.

PART 2

Remediation of damage to land

Remediation of damage to land

9.—(1) This Part applies in relation to damage to land.

(2) The remediation must ensure, as a minimum, that the relevant contaminants are removed, controlled, contained or diminished so that the land, taking account of its lawful current use or any planning permission in existence at the time of the damage, no longer poses any significant risk of adverse effects on human health.

(3) The presence of such risks must be assessed through risk-assessment procedures taking into account the characteristic and function of the soil, the type and concentration of the harmful substances, preparations, organisms or micro-organisms, their risk and the possibility of their dispersion.

(4) Natural recovery is a permitted form of remediation in appropriate cases.

Appeals

PART 1

Appeals when the Secretary of State is not the enforcing authority

1. This Part applies when the Secretary of State is not the enforcing authority.
2. Notification of appeal must contain—
 - (a) a copy of the notification or remediation notice appealed against; and
 - (b) the grounds of appeal.
3. When notification is received, the Secretary of State must send a copy of the notification of appeal to the enforcing authority, and the enforcing authority must immediately send a copy to any person who appears to it to have a particular interest in the subject matter of the appeal, and notify the Secretary of State whom it has notified.
4. The Secretary of State must notify the appellant of the time limit within which the appellant must provide in writing—
 - (a) a statement of case; and
 - (b) all relevant correspondence.
5. When these are received, the Secretary of State must send all the documents to the enforcing authority, giving the enforcing authority a time limit within which it must provide a written response.
6. At the same time the Secretary of State must notify any person notified under paragraph 3 of the time limit under paragraph 5 and invite them make representations before that date.
7. The Secretary of State must then decide whether further evidence is needed, and give directions accordingly.
8. The Secretary of State must then refer the appeal to a person appointed by the Secretary of State to deal with the appeal, and specify to the appointed person whether or not the appeal must be dealt with by written procedure or whether a hearing must be held.
9. Following the conclusion of the appeal by the appointed person, the appointed person must decide the matter or, if so directed by the Secretary of State at any stage before the decision is made, make a recommendation to the Secretary of State, who must decide the appeal.
10. The person deciding the appeal may make such order as to the costs of the parties (including parties who make representation) as is fit.

PART 2

Appeals when the Secretary of State is the enforcing authority

11. If the Secretary of State is the enforcing authority, the procedures in Part 1 apply except that—
 - (a) the Secretary of State must appoint an appointed person as soon as notification of appeal is received;
 - (b) the appointed person must carry out the functions of the Secretary of State specified in that Part; and

- (c) the appointed person must in all cases decide the appeal.

SCHEDULE 6

Regulation 30

Compensation

Compensation for grant of rights

1. This Schedule prescribes—

- (a) the period within which a person who grants, or joins in granting, any rights pursuant to regulation 30 may apply for compensation for the grant of those rights;
- (b) the manner in which, and the person to whom, such an application may be made; and
- (c) the manner of determining such compensation, for determining the amount of such compensation and for making supplemental provision relating to such compensation.

Interpretation

2. In this Schedule—

“the grantor” means the person who grants, or joins in granting, any right; and

“relevant interest” means an interest in land out of which a right has been granted or which is bound by a right granted.

Period for making an application

3. An application for compensation must be made before the expiry of a period of 12 months beginning with—

- (a) the date of the grant of the rights in respect of which compensation is claimed, or
- (b) where there is an appeal against the notice in relation to which those rights were granted, the date on which the appeal is determined or withdrawn,

whichever is the later date.

Manner of making an application

4.—(1) An application for compensation must be made in writing and delivered at or sent by pre-paid post to the last known address for correspondence of the person to whom the right was granted.

(2) The application must contain—

- (a) a copy of the grant of rights in respect of which the grantor is applying for compensation and of any plans attached to such grant;
- (b) a description of the exact nature of any interest in land in respect of which compensation is applied for; and
- (c) a statement of the amount of compensation applied for, distinguishing the amounts applied for under each of sub-paragraphs (a) to (e) of paragraph 5 and showing how the amount applied for under each sub-paragraph has been calculated.

Loss and damage for which compensation payable

5. Compensation is payable for loss and damage of the following descriptions—

- (a) any depreciation in the value of any relevant interest to which the grantor is entitled which results from the grant of the right;
- (b) loss or damage, in relation to any relevant interest to which the grantor is entitled, which—
 - (i) is attributable to the grant of the right or the exercise of it;
 - (ii) does not consist of depreciation in the value of that interest; and
 - (iii) is loss or damage for which the grantor would have been entitled to compensation by way of compensation for disturbance, if that interest had been acquired compulsorily under the Acquisition of Land Act 1981(a), in pursuance of a notice to treat served on the date on which the grant of the right was made;
- (c) damage to any interest in land to which the grantor is entitled which is not a relevant interest and which results from the grant of the right or from the exercise of it;
- (d) any loss or damage sustained by the grantor, other than in relation to any interest in land to which the grantor is entitled, which is attributable to the grant of the right or the exercise of it; and
- (e) the amount of any valuation and legal costs reasonably incurred by the grantor in granting the right and in the preparation of the application for and the negotiation of the amount of compensation.

Basis on which compensation assessed

6.—(1) The rules set out in section 5 of the Land Compensation Act 1961(b) (rules for assessing compensation) have effect, so far as applicable and subject to any necessary modifications, for the purpose of assessing any compensation as they have effect for the purpose of assessing compensation for the compulsory acquisition of an interest in land.

(2) Where the relevant interest in respect of which any compensation is to be assessed is subject to a mortgage—

- (a) the compensation must be assessed as if the interest were not subject to the mortgage;
- (b) no compensation is payable in respect of the interest of the mortgagee (as distinct from the interest which is subject to the mortgage); and
- (c) any compensation payable in respect of the interest that is subject to the mortgage must be paid to the mortgagee or, if there is more than one mortgagee, to the first mortgagee and must, in either case, be applied as if it were proceeds of sale.

Determination of disputes

7.—(1) Any question of disputed compensation must be referred to and determined by the Lands Tribunal.

(2) In relation to the determination of any such question of compensation the provisions of sections 2 and 4 of the Land Compensation Act 1961 (procedure on references to the Lands Tribunal and costs) shall apply as if—

- (a) the reference in section 2 of the Land Compensation Act 1961 to section 1 of that Act were a reference to sub-paragraph (1) of this paragraph; and
- (b) references in section 4 of that Act to the acquiring authority were references to the person to whom the rights were granted.

(a) 1981 c. 67.
 (b) 1961 c. 33.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2004/35/EC of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage.

They apply to damage to protected species, natural habitats, sites of special scientific interest, water and land (regulation 4).

They are enforced by the bodies specified in regulations 10 and 11.

They provide that, for certain economic activities, where there is a imminent risk of environmental damage, the operator must take steps to prevent it, and if it has occurred must prevent further damage. Where damage has occurred the enforcing authority must assess the damage and identify remedial measures. It must then serve a remediation notice on the responsible operator specifying what remediation is required (Part 3).

They make provision for enforcement (Part 4).

Breach of specified provisions of the Regulations is an offence punishable—

- (a) on summary conviction, with a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or both; or
- (b) on conviction on indictment, with a fine or to imprisonment for a term not exceeding two years or both.

An impact assessment has been prepared and placed in the libraries of both Houses of Parliament. It is available, together with a transposition note, on the Defra website at www.defra.gov.uk.

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STATUTORY INSTRUMENTS

2009 No. 153

ENVIRONMENTAL PROTECTION, ENGLAND

**The Environmental Damage (Prevention and Remediation)
Regulations 2009**

£5.00

E3668 2/2009 193668T 19585

**Act serving to implement the Directive of the European Parliament and of the Council
on Environmental Liability with Regard to the Prevention and Remedying
of Environmental Damage¹.**

of 10 May 2007

The *Bundestag* has adopted the following Act:

**Article 1
Environmental Damage Prevention and Remediation Act.
(Environmental Damage Act - EDA [USchadG])**

**§ 1
Relationship with other laws and regulations**

This Act shall govern as far as laws and regulations at federal or state (*Länder*) level do not cover the prevention and remediation of environmental damage in specific detail or their provisions fall short of this Act. Laws and regulations that go beyond this Act shall remain unaffected.

**§ 2
Definitions**

For the purpose of this Act,

1. Environmental damage: means
 - a) damage to species and natural habitats as defined in § 21a of the Federal Nature Conservation Act,
 - b) water damage as defined in § 22a of the Federal Water Resources Act,
 - c) land damage by impacts on soil functions as defined in § 2 Sec. 2 of the Federal Soil Protection Act, as a result of the direct or indirect introduction of substances, preparations, organisms or micro-organisms on, in or under land, that creates a threat to human health;
2. Damage or detriment: means a measurable adverse change in a natural resource (species and natural habitats, water and soil) or measurable impairment of a natural resource service which may occur directly or indirectly;
3. Responsible party: means any natural or legal person who engages in or controls the occupational activity, including the holder of a permit or authorisation for such an activity or the person registering or notifying such an activity, thereby directly causing environmental damage or the immediate threat of such damage.

¹ This Act serves to implement Directive 2004/35/EC 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 (Official Journal of the European Union No L 143, p. 56).

4. Occupational activity: means any activity carried out in the course of an economic activity, a business or an undertaking, irrespectively of its private or public, profit or non-profit character;
5. Imminent threat of environmental damage: means a sufficient likelihood that environmental damage will occur in the near future;
6. Preventive measure: means any measure taken in the case of an imminent threat of environmental damage with a view to preventing or minimising that damage;
7. Damage control measure: means any measure taken to immediately control, contain, remove or otherwise manage the relevant contaminants and other damage factors concerned in order to limit or prevent further environmental damage and adverse effects on human health or any further impairment of natural resource services;
8. Remedial measure: means any measure serving to remedy environmental damage in accordance with the special regulations;
9. Costs: means the necessary costs incurred in the proper and effective implementation of this Act including the costs of assessing environmental damage or an imminent threat of such damage, alternatives for action as well as the administrative, legal, and enforcement costs, the costs of data collection and other general costs, monitoring and supervision costs;
10. Special regulations: means the Federal Nature Conservation Act, the Federal Water Resources Act and the Federal Soil Protection Act, including the ordinances issued for their implementation.

§ 3 Scope

(1) This Act applies to

1. environmental damage and the imminent threat of such damage caused by any occupational activity listed in Annex 1;
2. damage to species and natural habitats as defined in § 21a Sec. 2 and 3 of the Federal Nature Conservation Act and the imminent threat of such damage caused by occupational activities other than those listed in Annex 1, to the extent the operator has been at fault or negligent.

(2) This Act applies to damage to species and natural habitats and the imminent threat of such damage occurring within the Exclusive Economic Zone and the continental shelf, as defined within the provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 (Federal Law Gazette 1994 II p. 1799).

(3) This Act does not apply to environmental damage or the imminent threat of such damage caused by:

1. armed conflicts, hostilities, civil war or insurrections,

...

2. an exceptional, inevitable and irresistible natural phenomenon,
3. an incident in which liability or compensation fall within the scope of any of the international conventions listed in Annex 2 in their respective versions applicable to Germany,
4. the exercise of activities covered by the Treaty establishing the European Atomic Energy Community, or
5. an incident or activity for which liability or compensation falls within the scope of any of the international instruments listed in Annex 3 in their respectively applicable versions.

(4) This Act shall only apply to cases in which the environmental damage or the imminent threat of such damage is caused by pollution of a diffuse character, where a causal link between the damage and the activities of individual responsible parties can be established.

(5) This Act does not apply to activities whose main purpose is to serve defence or international security nor to activities whose sole purpose is to protect from natural disasters.

§ 4 Information obligation

In the event of an imminent threat of an environmental damage, or when an environmental damage has occurred, the responsible party must promptly inform the competent authority of all relevant aspects of the situation.

§ 5 Threat prevention obligation

In the event of an imminent threat of an environmental damage, the responsible party must promptly take the necessary preventive measures.

§ 6 Remedial obligation

Where an environmental damage has occurred, the responsible party must

1. take the necessary damage control measures,
2. take the necessary remedial measures according to § 8.

§ 7 General obligations and powers of the competent authority

(1) The competent authority shall monitor the responsible party to ensure that the necessary preventive, damage control and remedial measures are taken.

...

(2) With regard to the obligations under §§ 4 to 6, the competent authority may require the responsible party to

1. provide all necessary information and data on an imminent threat of environmental damage, on a suspected imminent threat or on a damage that has occurred, along with the responsible party's own assessment,
2. take the necessary preventive measures,
3. take the necessary damage control and remedial measures.

§ 8

Determination of remedial measures

(1) The responsible party shall be obligated to identify, in accordance with the special regulations, the necessary remedial measures and to submit them to the competent authority for approval, unless the competent authority has taken the necessary remedial measures.

(2) The competent authority shall decide, in accordance with the special regulations, on the nature and extent of the remedial measures to be taken.

(3) If several instances of environmental damage do not allow for remedial measures taken at the same time, the competent authority can prioritise the remedial measures in due consideration of the nature, extent and gravity of the various instances of environmental damage, of the possibility of a natural recovery and of the risks to human health.

(4) The competent authority informs those affected and the appropriate associations entitled to an application per § 10 about the planned remedial measures, giving them an opportunity to submit their observations; such information may be in the form of a public announcement. Timely responses will be taken into account in the decision process.

§ 9

Costs of preventive and remedial measures

(1) Subject to any claims against public authorities or third parties the responsible party shall bear the costs of the preventive, damage control and remedial measures. For the enforcement of this Act by the *Länder* authorities the *Länder* shall issue provisions, necessary for implementing Directive 2004/35/EC 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 EC No L 143, p. 56), on cost allocations, cost exemptions and cost reimbursements including payment deadlines; in particular, the *Länder* may decide that, subject to the provisions of Article 8 Sec. 4 of Directive 2004/35/EC, the responsible party may not have to bear the costs of the remedial measures taken. In doing so the *Länder* will take into account the particular situation in the agricultural sector with regard to the use of pesticides.

(2) Multiple responsible parties, regardless of the manner in which they were obligated, shall have the right to compensatory claims among themselves. Unless stipulated otherwise, the obligation to provide such compensation and the extent of the compensation to be provided

...

shall depend on the degree to which the damage or threat was caused primarily by one party or the other; § 426 Sec. 1 s. 2 of the Civil Code is applicable accordingly. The statute of limitations for any compensatory claim will be three years; §§ 438, 548 and 606 of the Civil Code will not be applicable. The statute of limitations begins following collection of costs, when the competent authority carries out measures itself, otherwise it begins following completion of the measures by the responsible party and at the time at which the responsible party becomes aware of the identity of the person obligated to provide compensation. Regardless of such knowledge, the statute of limitation for such compensatory claim is 30 years following the completion of the measure. For legal actions, recourse to the ordinary courts shall be available.

(3) This Act does not influence the right of the responsible party to limit its liability in accordance with § 486 Sec. 1, 4 and 5, § 487 to 487e of the Commercial Code or § 4 to 5m of the Inland Waterways Act.

§ 10 Request for action

The competent authority will take action towards the enforcement of the remedial obligation under this Act ex officio or when an affected party or an association, entitled to appeal under § 11 Sec. 2, submits a corresponding application and when the facts on which that application is based plausibly suggest the occurrence of an environmental damage.

§ 11 Legal protection

(1) An administrative act taken pursuant to this law shall state the reasons and must be provided with an instruction about legal remedies available.

(2) For associations recognised or considered to have been recognised pursuant to § 3 Sec. 1 of the Environmental Appeals Act (of 7 December 2007, Federal Law Gazette I p. 2816), legal remedy against a decision or the omission of a decision by the competent authority according to this present Act is available through § 2 of the Environmental Appeals Act.

§ 12 Cooperation with the Member States of the European Union

(1) Where environmental damage affects or is likely to affect one or several Member States of the European Union, the competent authority shall cooperate with the corresponding authorities of the other Member States, exchanging to a reasonable extent the information needed to ensure the necessary preventive, damage control and remedial measures to be taken.

(2) In the event an environmental damage has been caused within the scope of validity of this Act, with a potential effect on the territory of another Member State of the European Union, the competent authority shall be required to provide adequate information to the potentially affected Member States.

(3) Where a competent authority identifies an environmental damage that was caused not

...

within the scope of validity of this Act but within the territory of another Member State of the European Union, it may make recommendations for the implementation of preventive, damage control and remedial measures, and it may seek to recover the costs it has incurred in relation to the adoption of such measures.

§ 13
Time-limited applicability

(1) This Act does not apply to damage caused by emissions, events or incidents that took place prior to 30 April 2007 or derive from specific activities that finished prior to that date.

(2) This Act does not apply to damage caused more than 30 years ago, if during that period no authority took action against the responsible party.

ANNEX 1 (to § 3 Sec. 1) Occupational activities

1. The operation of installations subject to permit in pursuance of Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control. That means all activities listed in Annex I of Directive 96/61/EC with the exception of installations or parts of installations used for research, development and testing of new products and processes.
2. Waste management operations (the collection, transport, recovery and disposal of waste and hazardous waste, including the supervision of such activities and after-care of disposal sites), subject to a permit, an announcement or a plan approval pursuant to regulations implementing Council Directive 75/442/EEC of 15 July 1975 on waste and Council Directive 91/689/EEC of 12 December 1991 on hazardous waste. These operations include, inter alia, the operation of landfill sites requiring a plan approval or planning permission according to § 31 Sec. 2 and 3 of the Closed Substance Cycle and Waste Management Act (KrW-/AbfG), as well as the operation of incineration plants requiring a permit in accordance with § 4 of the Federal Immission Control Act (BImSchG) in conjunction with the Annex to the Fourth Ordinance for the Implementation of the Federal Immission Control Act (4. BImSchV).
3. The introduction, discharge or other input of pollutants into surface waters pursuant to § 3 Sec. 1 No 4 and 4a as well as Sec. 2 No 2 of the Federal Water Resources Act (WHG) requiring a permit in accordance with § 2 Sec. 1 WHG.
4. The introduction, discharge or other input of pollutants into the groundwater pursuant to § 3 Sec. 1 No 5 as well as Sec. 2 No 2 WHG requiring a permit in accordance with § 2 Sec. 1 WHG.
5. The abstraction of water from bodies of water pursuant to § 3 Sec. 1 No 1 and 6 WHG requiring a permit or a licence in accordance with § 2 Sec. 1 WHG.
6. The impoundment of surface waters pursuant to § 3 Sec. 1 No 2 WHG requiring a permit or a licence in accordance with § 2 Sec. 1 WHG or a plan approval or a planning permission in accordance with § 31 Sec. 2 or 3 WHG.
7. The manufacture, use, storage, processing, filling, release into the environment and on-site transport of
 - a) dangerous substances as defined in § 3a Sec. 1 of the Chemicals Act (ChemG);

...

- b) dangerous preparations as defined in § 3a Sec. 1 ChemG;
 - c) plant protection products as defined in § 2 No 9 of the Plant Protection Act (PflSchG);
 - d) biocidal products as defined in § 3b Sec. 1 No 1 a) ChemG.
8. Transport by road, rail, inland waterways, sea or air of dangerous goods or polluting goods as defined in § 2 No 9 of the Regulation on Carriage of Dangerous Goods by Road and Rail or as defined in No 1.3 and 1.4 of the Annex to § 1 Sec. 1 of the Internal Waters Entering Requirements Ordinance.
 9. The operation of installations subject to authorisation in pursuance of Council Directive 84/360/EEC of 28 June 1984 on the combating of air pollution from industrial plants in relation to the release into air of any of the polluting substances covered by the aforementioned Directive.
 10. Genetic engineering activities as defined in § 3 No 2 of the Genetic Engineering Act (GenTG) involving micro-organisms in genetic engineering systems as defined in § 3 No 4 GenTG, as well as the extramural transport of genetically modified micro-organisms.
 11. Any deliberate release of genetically modified organisms into the environment as defined in § 3 No 5 first clause GenTG, as well as the transport and the placing on the market of such organisms as defined in § 3 No 6 GenTG.
 12. Transboundary shipment of waste within, into or out of the European Union, requiring an authorisation or prohibited in the meaning of Council Regulation (EEC) No 259/93 of 1 February 1993 on the supervision and control of shipments of waste within, into and out of the European Community.

ANNEX 2 (to § 3 Sec. 3 No 3)

International Conventions

- a) International Convention of 27 November 1992 on Civil Liability for Oil Pollution Damage (1992 Liability Convention, Federal Law Gazette 1996 II p. 670);
- b) International Convention of 27 November 1992 on the Establishment of an International Fund for Compensation for Oil Pollution Damage (1992 Fund Convention, Federal Law Gazette 1996 II p. 685);
- c) International Convention of 23 March 2001 on Civil Liability for Bunker Oil Pollution Damage;
- d) International Convention of 3 May 1996 on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea;
- e) Convention of 10 October 1989 on Civil Liability for Damage Caused during Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels.

...

ANNEX 3 (to § 3 Sec. 3 No 5)

International Instruments

- a) Paris Convention of 29 July 1960 on Third Party Liability in the Field of Nuclear Energy and the Brussels Supplementary Convention of 31 January 1963 (Federal Law Gazette 1975 II p. 957);
- b) Vienna Convention of 21 May 1963 on Civil Liability for Nuclear Damage (Federal Law Gazette 2001 II p. 202);
- c) Convention of 12 September 1997 on Supplementary Compensation for Nuclear Damage;
- d) Joint Protocol of 21 September 1988 relating to the Application of the Vienna Convention and the Paris Convention (Federal Law Gazette 2001 II p. 202);
- e) Brussels Convention of 17 December 1971 relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material (Federal Law Gazette 1975 II p. 957).

**Article 2
Amendment of the Federal Water Resources Act**

The Federal Water Resources Act as promulgated in the Federal Law Gazette of 19 August 2002 (Federal Law Gazette I p. 3245), as amended last by Article 2 of the Law of 25 June 2005 (Federal Law Gazette I p. 1746), is amended as follows:

1. In § 1 Sec. 2, 2nd sentence, the statement "§ 22" is replaced by the statement "§§ 22 and 22a".

2. After § 22 the following § 22a is inserted:

**§ 22a
Water Damage**

(1) Water damage according to the Environmental Damage Act means any damage that significantly adversely affects:

- 1. the ecological or chemical status of surface waters or of coastal waters,
- 2. the ecological potential or the chemical status of artificial or heavily modified surface waters or coastal waters, or
- 3. the chemical or quantitative status of the groundwater,

...

excluding those adverse effects governed by § 25d Sec. 3, § 32c in conjunction with § 25d Sec. 3 and § 33a Sec. 4, 2nd sentence.

(2) In the event a responsible party according to the Environmental Damage Act has caused water damage, it will take the necessary remedial measures according to Annex II No 1 of Directive 2004/35/EC 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 EC No L 143, p. 56).

(3) Any additional regulations regarding damage to or other impairments of waters and appropriate remediation shall remain unaffected.

Article 3 Amendment of the Federal Nature Conservation Act

The Federal Nature Conservation Act of 25 March 2002 (Federal Law Gazette I p. 1193), as amended last by Article 8 of the Law of 9 December 2006 (Federal Law Gazette I p. 2833), is amended as follows:

1. In the Table of Contents, after the text for § 21, the following wording is inserted: "§ 21a Damage to certain species and natural habitats".

2. In § 11 1st sentence after the statement "§§ 21 and" the wording "'21a, in §" is inserted.

3. After § 21 Sec. 3 the following section 4 is added:

"(4) If in decisions on projects per § 34 of the Federal Building Code, consultation under section 3 is denied because there are indications to the effect that the project could cause damage as defined in § 21a Sec. 1, 1st sentence, the developer shall be so informed. At the request of the developer, the authority competent for the permit decision shall, in consultation with the authority responsible for nature conservation and landscape management, take decisions in accordance with § 19 or corresponding *Länder* law, as far as they serve the prevention, mitigation or compensation of damage according to § 21a Sec. 1, 1st sentence; in those cases § 21a Sec. 1, 2nd sentence will apply. Other than that, section 2, 1st sentence remains unaffected."

4. After § 21 the following § 21a is added:

“§21a Damage to certain species and natural habitats

...

(1) Damage to species and natural habitats according to the Environmental Damage Act includes any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species. In contrast to the 1st sentence, damage does not include previously identified adverse effects which result from an activity of a responsible party which the competent authority approved under the provisions of §§ 34, 34a, 35 or corresponding *Länder* law, of § 43 Sec. 8 or § 62 Sec. 1 or, if such an assessment is not required, in accordance with

1. § 19 or corresponding *Länder* law or
2. on the basis of the preparation of a land-use plan according to §§ 30 and 33 of the Federal Building Code

or which are allowed.

(2) Species according to Sec. 1 are those listed in

1. Article 4 Sec. 2 or Annex I of Directive 79/409/EEC or
2. the Annexes II and IV of Directive 92/43/EEC.

(3) Natural habitats according to Sec. 1 are

1. habitats of species listed in Article 4 Sec. 2 or Annex I of Directive 79/409/EEC or in Annex II of Directive 92/43/EEC,
2. natural habitats listed in Annex I of Directive 92/43/EEC, as well as
3. the breeding sites or resting places of the species listed in Annex IV of Directive 92/43/EEC.

(4) In the event a responsible party according to the Environmental Damage Act has caused damage to protected species or natural habitats, it will take the necessary remedial measures according to Annex II, No 1 of Directive 2004/35/EC 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 EC No L 143, p. 56).

(5) The significance of effects according to Sec. 1 shall be determined with reference to the baseline condition in due consideration of the criteria set forth in Annex I of Directive 2004/35/EC 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 EC No L 143, p. 56) whereas a significant damage normally is not on hand in the following cases:

- negative variations that are smaller than natural fluctuations regarded as normal for the species or habitat in question,
- negative variations due to natural causes or resulting from intervention relating to the normal management of sites, as defined in habitat records or target documents or as carried on previously by owners or operators,
- damage to species or habitats for which it is established that they will recover, within a short time and without intervention, either to the baseline condition or to a condition which leads, solely by virtue of the dynamics of the species or habitat, to a condition deemed equivalent or superior to the baseline condition.

...

(6) Sec. 1 to 5 also apply to the Exclusive Economic Zone and the continental shelf within the legal framework of the United Nations Convention on the Law of the Sea of 10 December 1982 (Federal Law Gazette 1994 II p. 1799). For that area the competent authority under the Environmental Damage Act is the Federal Agency for Nature Conservation."

Article 4
Entry into force; suspension

This Act shall enter into force as of the day in the sixth month following the month of its promulgation that matches the number of the day of the promulgation or, if there is no such calendar date, as of the first day of the following calendar month. Annex I No 9 of the Environmental Damage Act shall be suspended as of 30 October 2007.

The constitutional rights of the *Bundesrat* are safeguarded.

The foregoing law is hereby drawn up. It shall be published in the Federal Law Gazette.

Berlin, 10 May 2007.

The Federal President
The Federal Chancellor
The Federal Minister for the Environment,
Nature Conservation and Nuclear Safety

遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律

発令 ；平成15年6月18日号外法律第97号

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○遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律

[平成十五年六月十八日号外法律第九十七号]

[財務・文部科学・厚生労働・農林水産・経済産業・環境大臣署名]

遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律をここに公布する。

遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律

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附則

第一章 総則

（目的）

第一条 この法律は、国際的に協力して生物の多様性の確保を図るため、遺伝子組換え生物等の使用等の規制に関する措置を講ずることにより生物の多様性に関する条約のバイオセーフティに関するカルタヘナ議定書（以下「議定書」という。）の的確かつ円滑な実施を確保し、もって人類の福祉に貢献するとともに現在及び将来の国民の健康で文化的な生活の確保に寄与することを目的とする。

（定義）

第二条 この法律において「生物」とは、一の細胞（細胞群を構成しているものを除く。）又は細胞群であって核酸を移転し又は複製する能力を有するものとして主務省令で定めるもの、ウイルス及びウイロイドをいう。

2 この法律において「遺伝子組換え生物等」とは、次に掲げる技術の利用により得られた核酸又はその複製物を有する生物をいう。

一 細胞外において核酸を加工する技術であって主務省令で定めるもの

二 異なる分類学上の科に属する生物の細胞を融合する技術であって主務省令で定めるもの

3 この法律において「使用等」とは、食用、飼料用その他の用に供するための使用、栽培その他の育成、加工、保管、運搬及び廃棄並びにこれらに付随する行為をいう。

- 4 この法律において「生物の多様性」とは、生物の多様性に関する条約第二条に規定する生物の多様性をいう。
- 5 この法律において「第一種使用等」とは、次項に規定する措置を執らないで行う使用等をいう。
- 6 この法律において「第二種使用等」とは、施設、設備その他の構造物（以下「施設等」という。）の外の大気、水又は土壌中への遺伝子組換え生物等の拡散を防止する意図をもって行う使用等であって、そのことを明示する措置その他の主務省令で定める措置を執って行うものをいう。
- 7 この法律において「拡散防止措置」とは、遺伝子組換え生物等の使用等に当たって、施設等を用いることその他必要な方法により施設等の外の大気、水又は土壌中に当該遺伝子組換え生物等が拡散することを防止するために執る措置をいう。

（基本的事項の公表）

第三条 主務大臣は、議定書の的確かつ円滑な実施を図るため、次に掲げる事項（以下「基本的事項」という。）を定めて公表するものとする。これを変更したときも、同様とする。

- 一 遺伝子組換え生物等の使用等により生ずる影響であって、生物の多様性を損なうおそれのあるもの（以下「生物多様性影響」という。）を防止するための施策の実施に関する基本的な事項
- 二 遺伝子組換え生物等の使用等をする者がその行為を適正に行うために配慮しなければならない基本的な事項
- 三 前二号に掲げるもののほか、遺伝子組換え生物等の使用等が適正に行われることを確保するための重要な事項

第二章 国内における遺伝子組換え生物等の使用等により生ずる生物多様性影響の防止に関する措置

第一節 遺伝子組換え生物等の第一種使用等

（遺伝子組換え生物等の第一種使用等に係る第一種使用規程の承認）

第四条 遺伝子組換え生物等を作成し又は輸入して第一種使用等をしようとする者その他の遺伝子組換え生物等の第一種使用等をしようとする者は、遺伝子組換え生物等の種類ごとにその第一種使用等に関する規程（以下「第一種使用規程」という。）を定め、これにつき主務大臣の承認を受けなければならない。ただし、その性状等からみて第一種使用等による生物多様性影響が生じないことが明らかな生物として主務大臣が指定する遺伝子組換え生物等（以下「特定遺伝子組換え生物等」という。）の第一種使用等をしようとする場合、この項又は第九条第一項の規定に基づき主務大臣の承認を受けた第一種使用規程（第七条第一項（第九条第四項において準用する場合を含む。）の規定に基づき主務大臣により変更された第一種使用規程については、その変更後のもの）に定める第一種使用等をしようとする場合その他主務省令で定める場合は、この限りでない。

- 2 前項の承認を受けようとする者は、遺伝子組換え生物等の種類ごとにその第一種使用等による生物多様性影響について主務大臣が定めるところにより評価を行い、その結果を記載した図書（以下「生物多様性影響評価書」という。）その他主務省令で定める書類とともに、次の事項を記載した申請書を主務大臣に提出しなければならない。
 - 一 氏名及び住所（法人にあっては、その名称、代表者の氏名及び主たる事務所の所在地。第十三条第二項第一号及び第十八条第四項第二号において同じ。）

二 第一種使用規程

- 3 第一種使用規程は、主務省令で定めるところにより、次の事項について定めるものとする。
 - 一 遺伝子組換え生物等の種類の名称
 - 二 遺伝子組換え生物等の第一種使用等の内容及び方法
- 4 主務大臣は、第一項の承認の申請があった場合には、主務省令で定めるところにより、当該申請に係る第一種使用規程について、生物多様性影響に関し専門の学識経験を有する者（以下「学識経験者」という。）の意見を聴かなければならない。
- 5 主務大臣は、前項の規定により学識経験者から聴取した意見の内容及び基本的事項に照らし、第一項の承認の申請に係る第一種使用規程に従って第一種使用等をする場合に野生動植物の種又は個体群の維持に支障を及ぼすおそれがある影響その他の生物多様性影響が生ずるおそれがないと認めるときは、当該第一種使用規程の承認をしなければならない。
- 6 第四項の規定により意見を求められた学識経験者は、第一項の承認の申請に係る第一種使用規程及びその生物多様性影響評価書に関して知り得た秘密を漏らし、又は盗用してはならない。
- 7 前各項に規定するもののほか、第一項の承認に関して必要な事項は、主務省令で定める。（第一種使用規程の修正等）

第五条 前条第一項の承認の申請に係る第一種使用規程に従って第一種使用等をする場合に生物多様性影響が生ずるおそれがあると認めるときは、主務大臣は、申請者に対し、主務省令で定めるところにより、当該第一種使用規程を修正すべきことを指示しなければならない。ただし、当該第一種使用規程に係る遺伝子組換え生物等の第一種使用等を行うことが適当でないとき、この限りでない。

- 2 前項の規定による指示を受けた者が、主務大臣が定める期間内にその指示に基づき第一種使用規程の修正をしないときは、主務大臣は、その者の承認の申請を却下する。
- 3 第一項ただし書に規定する場合においては、主務大臣は、その承認を拒否しなければならない。（承認取得者の義務等）

第六条 第四条第一項の承認を受けた者（次項において「承認取得者」という。）は、同条第二項第一号に掲げる事項中に変更を生じたときは、主務省令で定めるところにより、その理由を付してその旨を主務大臣に届け出なければならない。

- 2 主務大臣は、次条第一項の規定に基づく第一種使用規程の変更又は廃止を検討しようとするときその他当該第一種使用規程に関し情報を収集する必要があるときは、当該第一種使用規程に係る承認取得者に対し、必要な情報の提供を求めることができる。（承認した第一種使用規程の変更等）

第七条 主務大臣は、第四条第一項の承認の時には予想することができなかつた環境の変化又は同項の承認の日以降における科学的知見の充実により同項の承認を受けた第一種使用規程に従って遺伝子組換え生物等の第一種使用等がなされるとした場合においてもなお生物多様性影響が生ずるおそれがあると認められるに至った場合は、生物多様性影響を防止するため必要な限度において、当該第一種使用規程を変更し、又は廃止しなければならない。

- 2 主務大臣は、前項の規定による変更又は廃止については、主務省令で定めるところにより、あらかじめ、学識経験者の意見を聴くものとする。
- 3 前項の規定により意見を求められた学識経験者は、第一項の規定による変更又は廃止に係

る第一種使用規程及びその生物多様性影響評価書に関して知り得た秘密を漏らし、又は盗用してはならない。

- 4 前三項に規定するもののほか、第一項の規定による変更又は廃止に関して必要な事項は、主務省令で定める。

(承認した第一種使用規程等の公表)

第八条 主務大臣は、次の各号に掲げる場合の区分に応じ、主務省令で定めるところにより、遅滞なく、当該各号に定める事項を公表しなければならない。

- 一 第四条第一項の承認をしたとき その旨及び承認された第一種使用規程
- 二 前条第一項の規定により第一種使用規程を変更したとき その旨及び変更後の第一種使用規程
- 三 前条第一項の規定により第一種使用規程を廃止したとき その旨

- 2 前項の規定による公表は、告示により行うものとする。

(本邦への輸出者等に係る第一種使用規程についての承認)

第九条 遺伝子組換え生物等を本邦に輸出して他の者に第一種使用等をさせようとする者その他の遺伝子組換え生物等の第一種使用等を他の者にさせようとする者は、主務省令で定めるところにより、遺伝子組換え生物等の種類ごとに第一種使用規程を定め、これにつき主務大臣の承認を受けることができる。

- 2 前項の承認を受けようとする者が本邦内に住所（法人にあっては、その主たる事務所。以下この項及び第四項において同じ。）を有する者以外の者である場合には、その者は、本邦内において遺伝子組換え生物等の適正な使用等のために必要な措置を執らせるための者を、本邦内に住所を有する者その他主務省令で定める者のうちから、当該承認の申請の際選任しなければならない。

- 3 前項の規定により選任を行った者は、同項の規定により選任した者（以下「国内管理人」という。）を変更したときは、その理由を付してその旨を主務大臣に届け出なければならない。

- 4 第四条第二項から第七項まで、第五条及び前条の規定は第一項の承認について、第六条の規定は第一項の承認を受けた者（その者が本邦内に住所を有する者以外の者である場合にあっては、その者に係る国内管理人）について、第七条の規定は第一項の規定により承認を受けた第一種使用規程について準用する。この場合において、第四条第二項第一号中「氏名及び住所」とあるのは「第九条第一項の承認を受けようとする者及びその者が本邦内に住所（法人にあっては、その主たる事務所）を有する者以外の者である場合にあっては同条第二項の規定により選任した者の氏名及び住所」と、第七条第一項中「第四条第一項」とあるのは「第九条第一項」と読み替えるものとする。

(第一種使用等に関する措置命令)

第十条 主務大臣は、第四条第一項の規定に違反して遺伝子組換え生物等の第一種使用等をした者、又はしている者に対し、生物多様性影響を防止するため必要な限度において、遺伝子組換え生物等の回収を図ることその他の必要な措置を執るべきことを命ずることができる。

- 2 主務大臣は、第七条第一項（前条第四項において準用する場合を含む。）に規定する場合その他特別の事情が生じた場合において、生物多様性影響を防止するため緊急の必要があると認めるとき（次条第一項に規定する場合を除く。）は、生物多様性影響を防止するため必要な限度において、遺伝子組換え生物等の第一種使用等をしている者、若しくはした者又は

させた者（特に緊急の必要があると認める場合においては、国内管理人を含む。）に対し、当該第一種使用等を中止することその他の必要な措置を執るべきことを命ずることができる。

（第一種使用等に関する事故時の措置）

第十一条 遺伝子組換え生物等の第一種使用等をしている者は、事故の発生により当該遺伝子組換え生物等について承認された第一種使用規程に従うことができない場合において、生物多様性影響が生ずるおそれのあるときは、直ちに、生物多様性影響を防止するための応急の措置を執るとともに、速やかにその事故の状況及び執った措置の概要を主務大臣に届け出なければならない。

2 主務大臣は、前項に規定する者が同項の応急の措置を執っていないと認めるときは、その者に対し、同項に規定する応急の措置を執るべきことを命ずることができる。

第二節 遺伝子組換え生物等の第二種使用等

（主務省令で定める拡散防止措置の実施）

第十二条 遺伝子組換え生物等の第二種使用等をする者は、当該第二種使用等に当たって執るべき拡散防止措置が主務省令により定められている場合には、その使用等をする間、当該拡散防止措置を執らなければならない。

（確認を受けた拡散防止措置の実施）

第十三条 遺伝子組換え生物等の第二種使用等をする者は、前条の主務省令により当該第二種使用等に当たって執るべき拡散防止措置が定められていない場合（特定遺伝子組換え生物等の第二種使用等をする場合その他主務省令で定める場合を除く。）には、その使用等をする間、あらかじめ主務大臣の確認を受けた拡散防止措置を執らなければならない。

2 前項の確認の申請は、次の事項を記載した申請書を提出して、これをしなければならない。

- 一 氏名及び住所
- 二 第二種使用等の対象となる遺伝子組換え生物等の特性
- 三 第二種使用等において執る拡散防止措置
- 四 前三号に掲げるもののほか、主務省令で定める事項

3 前二項に規定するもののほか、第一項の確認に関して必要な事項は、主務省令で定める。

（第二種使用等に関する措置命令）

第十四条 主務大臣は、第十二条又は前条第一項の規定に違反して第二種使用等をしている者、又はした者に対し、第十二条の主務省令で定める拡散防止措置を執ることその他の必要な措置を執るべきことを命ずることができる。

2 主務大臣は、第十二条の主務省令の制定又は前条第一項の確認の日以降における遺伝子組換え生物等に関する科学的知見の充実により施設等の外への遺伝子組換え生物等の拡散を防止するため緊急の必要があると認めるに至ったときは、第十二条の主務省令により定められている拡散防止措置を執って第二種使用等をしている者、若しくはした者又は前条第一項の確認を受けた者に対し、当該拡散防止措置を改善するための措置を執ることその他の必要な措置を執るべきことを命ずることができる。

（第二種使用等に関する事故時の措置）

第十五条 遺伝子組換え生物等の第二種使用等をしている者は、拡散防止措置に係る施設等において破損その他の事故が発生し、当該遺伝子組換え生物等について第十二条の主務省令で定める拡散防止措置又は第十三条第一項の確認を受けた拡散防止措置を執ることができな

いときは、直ちに、その事故について応急の措置を執るとともに、速やかにその事故の状況及び執った措置の概要を主務大臣に届け出なければならない。

- 2 主務大臣は、前項に規定する者が同項の応急の措置を執っていないと認めるときは、その者に対し、同項に規定する応急の措置を執るべきことを命ずることができる。

第三節 生物検査

(輸入の届出)

第十六条 生産地の事情その他の事情からみて、その使用等により生物多様性影響が生ずるおそれがないとはいえない遺伝子組換え生物等をこれに該当すると知らないで輸入するおそれが高い場合その他これに類する場合であつて主務大臣が指定する場合に該当するときは、その指定に係る輸入をしようとする者は、主務省令で定めるところにより、その都度その旨を主務大臣に届け出なければならない。

(生物検査命令)

第十七条 主務大臣は、主務省令で定めるところにより、前条の規定による届出をした者に対し、その者が行う輸入に係る生物（第三項及び第五項において「検査対象生物」という。）につき、主務大臣又は主務大臣の登録を受けた者（以下「登録検査機関」という。）から、同条の指定の理由となった遺伝子組換え生物等であるかどうかについての検査（以下「生物検査」という。）を受けるべきことを命ずることができる。

- 2 主務大臣は、前項の規定による命令は、前条の規定による届出を受けた後直ちにしなければならない。
- 3 第一項の規定による命令を受けた者は、生物検査を受け、その結果についての通知を受けるまでの間は、施設等を用いることその他の主務大臣の指定する条件に基づいて検査対象生物の使用等を行わなければならない。また、検査対象生物を譲渡し、又は提供してはならない。
- 4 前項の通知であつて登録検査機関がするものは、主務大臣を経由してするものとする。
- 5 主務大臣は、第三項に規定する者が同項の規定に違反していると認めるときは、その者に対し、同項の条件に基づいて検査対象生物の使用等を行うことその他の必要な措置を執るべきことを命ずることができる。

(登録検査機関)

第十八条 前条第一項の登録（以下この節において「登録」という。）は、生物検査を行おうとする者の申請により行う。

- 2 次の各号のいずれかに該当する者は、登録を受けることができない。
 - 一 この法律に規定する罪を犯して刑に処せられ、その執行を終わり、又はその執行を受けることがなくなった日から起算して二年を経過しない者であること。
 - 二 第二十一条第四項又は第五項の規定により登録を取り消され、その取消しの日から起算して二年を経過しない者であること。
 - 三 法人であつて、その業務を行う役員のうち前二号のいずれかに該当する者があること。
- 3 主務大臣は、登録の申請をした者（以下この項において「登録申請者」という。）が次の各号のいずれにも適合しているときは、その登録をしなければならない。この場合において、登録に関して必要な手続は、主務省令で定める。
 - 一 凍結乾燥器、粉碎機、天びん、遠心分離機、分光光度計、核酸増幅器及び電気泳動装置を有すること。
 - 二 次のいずれかに該当する者が生物検査を実施し、その人数が生物検査を行う事業所ごと

に二名以上であること。

イ 学校教育法（昭和二十二年法律第二十六号）に基づく大学（短期大学を除く。）、旧大学令（大正七年勅令第三百八十八号）に基づく大学又は旧専門学校令（明治三十六年勅令第六十一号）に基づく専門学校において医学、歯学、薬学、獣医学、畜産学、水産学、農芸化学、応用化学若しくは生物学の課程又はこれらに相当する課程を修めて卒業した後、一年以上分子生物学的検査の業務に従事した経験を有する者であること。

ロ 学校教育法に基づく短期大学又は高等専門学校において工業化学若しくは生物学の課程又はこれらに相当する課程を修めて卒業した後、三年以上分子生物学的検査の業務に従事した経験を有する者であること。

ハ イ及びロに掲げる者と同等以上の知識経験を有する者であること。

三 登録申請者が、業として遺伝子組換え生物等の使用等をし、又は遺伝子組換え生物等を譲渡し、若しくは提供している者（以下この号において「遺伝子組換え生物使用業者等」という。）に支配されているものとして次のいずれかに該当するものでないこと。

イ 登録申請者が株式会社である場合にあっては、遺伝子組換え生物使用業者等がその親法人（会社法（平成十七年法律第八十六号）第八百七十九条第一項に規定する親法人をいう。）であること。

ロ 登録申請者の役員（持分会社（会社法第五百七十五条第一項に規定する持分会社をいう。）にあっては、業務を執行する社員）に占める遺伝子組換え生物使用業者等の役員又は職員（過去二年間にその遺伝子組換え生物使用業者等の役員又は職員であった者を含む。）の割合が二分の一を超えていること。

ハ 登録申請者（法人にあっては、その代表権を有する役員）が、遺伝子組換え生物使用業者等の役員又は職員（過去二年間にその遺伝子組換え生物使用業者等の役員又は職員であった者を含む。）であること。

4 登録は、登録検査機関登録簿に次に掲げる事項を記載してするものとする。

一 登録の年月日及び番号

二 登録を受けた者の氏名及び住所

三 前二号に掲げるもののほか、主務省令で定める事項

（遵守事項等）

第十九条 登録検査機関は、生物検査を実施することを求められたときは、正当な理由がある場合を除き、遅滞なく、生物検査を実施しなければならない。

2 登録検査機関は、公正に、かつ、主務省令で定める方法により生物検査を実施しなければならない。

3 登録検査機関は、生物検査を実施する事業所の所在地を変更しようとするときは、変更しようとする日の二週間前までに、主務大臣に届け出なければならない。

4 登録検査機関は、その生物検査の業務の開始前に、主務省令で定めるところにより、その生物検査の業務の実施に関する規程を定め、主務大臣の認可を受けなければならない。これを変更しようとするときも、同様とする。

5 登録検査機関は、毎事業年度経過後三月以内に、その事業年度の財産目録、貸借対照表及び損益計算書又は収支計算書並びに事業報告書（その作成に代えて電磁的記録（電子的方式、磁気的方式その他の人の知覚によっては認識することができない方式で作られる記録であって、電子計算機による情報処理の用に供されるものをいう。以下この項及び次項において

同じ。)の作成がされている場合における当該電磁的記録を含む。以下「財務諸表等」という。)を作成し、五年間事業所に備えて置かなければならない。

- 6 生物検査を受けようとする者その他の利害関係人は、登録検査機関の業務時間内は、いつでも、次に掲げる請求をすることができる。ただし、第二号又は第四号の請求をするには、登録検査機関の定めた費用を支払わなければならない。
 - 一 財務諸表等が書面をもって作成されているときは、当該書面の閲覧又は謄写の請求
 - 二 前号の書面の謄本又は抄本の請求
 - 三 財務諸表等が電磁的記録をもって作成されているときは、当該電磁的記録に記録された事項を主務省令で定める方法により表示したものの閲覧又は謄写の請求
 - 四 前号の電磁的記録に記録された事項を電磁的方法であって主務省令で定めるものにより提供することの請求又は当該事項を記載した書面の交付の請求
- 7 登録検査機関は、主務省令で定めるところにより、帳簿を備え、生物検査に関し主務省令で定める事項を記載し、これを保存しなければならない。
- 8 登録検査機関は、主務大臣の許可を受けなければ、その生物検査の業務の全部又は一部を休止し、又は廃止してはならない。

(秘密保持義務等)

第二十条 登録検査機関の役員若しくは職員又はこれらの職にあった者は、その生物検査に関し知り得た秘密を漏らしてはならない。

- 2 生物検査に従事する登録検査機関の役員又は職員は、刑法(明治四十年法律第四十五号)その他の罰則の適用については、法令により公務に従事する職員とみなす。

(適合命令等)

第二十一条 主務大臣は、登録検査機関が第十八条第三項各号のいずれかに適合しなくなったと認めるときは、その登録検査機関に対し、これらの規定に適合するため必要な措置を執るべきことを命ずることができる。

- 2 主務大臣は、登録検査機関が第十九条第一項若しくは第二項の規定に違反していると認めるとき、又は登録検査機関が行う第十七条第三項の通知の記載が適当でないとき、その登録検査機関に対し、生物検査を実施すべきこと又は生物検査の方法その他の業務の方法の改善に関し必要な措置を執るべきことを命ずることができる。
- 3 主務大臣は、第十九条第四項の規程が生物検査の公正な実施上不適当となったと認めるときは、その規程を変更すべきことを命ずることができる。
- 4 主務大臣は、登録検査機関が第十八条第二項第一号又は第三号に該当するに至ったときは、登録を取り消さなければならない。
- 5 主務大臣は、登録検査機関が次の各号のいずれかに該当するときは、その登録を取り消し、又は期間を定めて生物検査の業務の全部若しくは一部の停止を命ずることができる。
 - 一 第十九条第三項から第五項まで、第七項又は第八項の規定に違反したとき。
 - 二 第十九条第四項の規程によらないで生物検査を実施したとき。
 - 三 正当な理由がないのに第十九条第六項各号の規定による請求を拒んだとき。
 - 四 第一項から第三項までの規定による命令に違反したとき。
 - 五 不正の手段により登録を受けたとき。

(報告徴収及び立入検査)

第二十二条 主務大臣は、この節の規定の施行に必要な限度において、登録検査機関に対し、

その生物検査の業務に関し報告を求め、又はその職員に、登録検査機関の事務所に立ち入り、登録検査機関の帳簿、書類その他必要な物件を検査させ、若しくは関係者に質問させることができる。

2 前項の規定による立入検査をする職員は、その身分を示す証明書を携帯し、関係者に提示しなければならない。

3 第一項の規定による立入検査の権限は、犯罪捜査のために認められたものと解釈してはならない。

(公示)

第二十三条 主務大臣は、次に掲げる場合には、その旨を官報に公示しなければならない。

一 登録をしたとき。

二 第十九条第三項の規定による届出があったとき。

三 第十九条第八項の許可をしたとき。

四 第二十一条第四項若しくは第五項の規定により登録を取り消し、又は同項の規定により生物検査の業務の全部若しくは一部の停止を命じたとき。

(手数料)

第二十四条 生物検査を受けようとする者は、実費を勘案して政令で定める額の手数料を国(登録検査機関が生物検査を行う場合にあっては、登録検査機関)に納めなければならない。

2 前項の規定により登録検査機関に納められた手数料は、登録検査機関の収入とする。

第四節 情報の提供

(適正使用情報)

第二十五条 主務大臣は、第四条第一項又は第九条第一項の承認を受けた第一種使用規程に係る遺伝子組換え生物等について、その第一種使用等がこの法律に従って適正に行われるようにするため、必要に応じ、当該遺伝子組換え生物等を譲渡し、若しくは提供し、若しくは委託してその第一種使用等をさせようとする者がその譲渡若しくは提供を受ける者若しくは委託を受けてその第一種使用等をする者に提供すべき情報(以下「適正使用情報」という。)を定め、又はこれを変更するものとする。

2 主務大臣は、前項の規定により適正使用情報を定め、又はこれを変更したときは、主務省令で定めるところにより、遅滞なく、その内容を公表しなければならない。

3 前項の規定による公表は、告示により行うものとする。

(情報の提供)

第二十六条 遺伝子組換え生物等を譲渡し、若しくは提供し、又は委託して使用等をさせようとする者は、主務省令で定めるところにより、その譲渡若しくは提供を受ける者又は委託を受けてその使用等をする者に対し、適正使用情報その他の主務省令で定める事項に関する情報を文書の交付その他の主務省令で定める方法により提供しなければならない。

2 主務大臣は、前項の規定に違反して遺伝子組換え生物等の譲渡若しくは提供又は委託による使用等がなされた場合において、生物多様性影響が生ずるおそれがあると認めるときは、生物多様性影響を防止するため必要な限度において、当該遺伝子組換え生物等を譲渡し、若しくは提供し、又は委託して使用等をさせた者に対し、遺伝子組換え生物等の回収を図ることその他の必要な措置を執るべきことを命ずることができる。

第三章 輸出に関する措置

(輸出の通告)

第二十七条 遺伝子組換え生物等を輸出しようとする者は、主務省令で定めるところにより、輸入国に対し、輸出しようとする遺伝子組換え生物等の種類の名称その他主務省令で定める事項を通告しなければならない。ただし、専ら動物のために使用されることが目的とされている医薬品（医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律（昭和三十五年法律第百四十五号）第二条第一項の医薬品をいう。以下この条において同じ。）以外の医薬品を輸出する場合その他主務省令で定める場合は、この限りでない。

（輸出の際の表示）

第二十八条 遺伝子組換え生物等は、主務省令で定めるところにより、当該遺伝子組換え生物等又はその包装、容器若しくは送り状に当該遺伝子組換え生物等の使用等の態様その他主務省令で定める事項を表示したものでなければ、輸出してはならない。この場合において、前条ただし書の規定は、本条の規定による輸出について準用する。

（輸出に関する命令）

第二十九条 主務大臣は、前二条の規定に違反して遺伝子組換え生物等の輸出が行われた場合において、生物多様性影響が生ずるおそれがあると認めるときは、生物多様性影響を防止するため必要な限度において、当該遺伝子組換え生物等を輸出した者に対し、当該遺伝子組換え生物等の回収を図ることその他の必要な措置を執るべきことを命ずることができる。

第四章 雑則

（報告徴収）

第三十条 主務大臣は、この法律の施行に必要な限度において、遺伝子組換え生物等（遺伝子組換え生物等であることの疑いのある生物を含む。以下この条、次条第一項及び第三十二条第一項において同じ。）の使用等をしている者、又はした者、遺伝子組換え生物等を譲渡し、又は提供した者、国内管理人、遺伝子組換え生物等を輸出した者その他の関係者からその行為の実施状況その他必要な事項の報告を求めることができる。

（立入検査等）

第三十一条 主務大臣は、この法律の施行に必要な限度において、その職員に、遺伝子組換え生物等の使用等をしている者、又はした者、遺伝子組換え生物等を譲渡し、又は提供した者、国内管理人、遺伝子組換え生物等を輸出した者その他の関係者がその行為を行う場所その他の場所に立ち入らせ、関係者に質問させ、遺伝子組換え生物等、施設等その他の物件を検査させ、又は検査に必要な最少限度の分量に限り遺伝子組換え生物等を無償で収去させることができる。

2 当該職員は、前項の規定による立入り、質問、検査又は収去（以下「立入検査等」という。）をする場合には、その身分を示す証明書を携帯し、関係者に提示しなければならない。

3 第一項の規定による立入検査等の権限は、犯罪捜査のため認められたものと解釈してはならない。

（センター等による立入検査等）

第三十二条 農林水産大臣、経済産業大臣又は厚生労働大臣は、前条第一項の場合において必要があると認めるときは、独立行政法人農林水産消費安全技術センター、独立行政法人家畜改良センター、国立研究開発法人農業・食品産業技術総合研究機構、国立研究開発法人水産研究・教育機構、独立行政法人製品評価技術基盤機構又は独立行政法人医薬品医療機器総合機構（以下「センター等」という。）に対し、次に掲げるセンター等の区分に応じ、遺伝子組換え生物等の使用等をしている者、又はした者、遺伝子組換え生物等を譲渡し、又は提供

した者、国内管理人、遺伝子組換え生物等を輸出した者その他の関係者がその行為を行う場所その他の場所に立ち入らせ、関係者に質問させ、遺伝子組換え生物等、施設等その他の物件を検査させ、又は検査に必要な最少限度の分量に限り遺伝子組換え生物等を無償で取去させることができる。

一 独立行政法人農林水産消費安全技術センター、独立行政法人家畜改良センター、国立研究開発法人農業・食品産業技術総合研究機構及び国立研究開発法人水産研究・教育機構
農林水産大臣

二 独立行政法人製品評価技術基盤機構 経済産業大臣

三 独立行政法人医薬品医療機器総合機構 厚生労働大臣

2 農林水産大臣、経済産業大臣又は厚生労働大臣は、前項の規定によりセンター等に立入検査等を行わせる場合には、同項各号に掲げるセンター等の区分に応じ、センター等に対し、立入検査等を行う期日、場所その他必要な事項を示してこれを実施すべきことを指示するものとする。

3 センター等は、前項の規定による指示に従って第一項の規定による立入検査等をする場合には、遺伝子組換え生物等に関し知識経験を有する職員であつて、同項各号に掲げるセンター等の区分に応じ当該各号に定める大臣が発する命令で定める条件に適合するものに行わなければならない。

4 センター等は、第二項の規定による指示に従って第一項の規定による立入検査等を行ったときは、農林水産省令、経済産業省令又は厚生労働省令で定めるところにより、同項の規定により得た検査の結果を同項各号に掲げるセンター等の区分に応じ、農林水産大臣、経済産業大臣又は厚生労働大臣に報告しなければならない。

5 第一項の規定による立入検査等については、前条第二項及び第三項の規定を準用する。
(センター等に対する命令)

第三十三条 農林水産大臣、経済産業大臣又は厚生労働大臣は、前条第一項の規定による立入検査等の業務の適正な実施を確保するため必要があると認めるときは、同項各号に掲げるセンター等の区分に応じ、センター等に対し、当該業務に関し必要な命令をすることができる。
(科学的知見の充実のための措置)

第三十四条 国は、遺伝子組換え生物等及びその使用等により生ずる生物多様性影響に関する科学的知見の充実を図るため、これらに関する情報の収集、整理及び分析並びに研究の推進その他必要な措置を講ずるよう努めなければならない。
(国民の意見の聴取)

第三十五条 国は、この法律に基づく施策に国民の意見を反映し、関係者相互間の情報及び意見の交換の促進を図るため、生物多様性影響の評価に係る情報、前条の規定により収集し、整理し及び分析した情報その他の情報を公表し、広く国民の意見を求めるものとする。
(主務大臣等)

第三十六条 この法律における主務大臣は、政令で定めるところにより、財務大臣、文部科学大臣、厚生労働大臣、農林水産大臣、経済産業大臣又は環境大臣とする。

2 この法律における主務省令は、主務大臣が発する命令とする。
(権限の委任)

第三十六条の二 この法律に規定する主務大臣の権限は、主務省令で定めるところにより、地方支分部局の長に委任することができる。

(経過措置)

第三十七条 この法律の規定に基づき命令を制定し、又は改廃する場合においては、その命令で、その制定又は改廃に伴い合理的に必要と判断される範囲内において、所要の経過措置(罰則に関する経過措置を含む。)を定めることができる。

第五章 罰則

第三十八条 第十条第一項若しくは第二項、第十一条第二項、第十四条第一項若しくは第二項、第十五条第二項、第十七条第五項、第二十六条第二項又は第二十九条の規定による命令に違反した者は、一年以下の懲役若しくは百万円以下の罰金に処し、又はこれを併科する。

第三十九条 次の各号のいずれかに該当する者は、六月以下の懲役若しくは五十万円以下の罰金に処し、又はこれを併科する。

- 一 第四条第一項の規定に違反して第一種使用等をした者
- 二 偽りその他不正の手段により第四条第一項又は第九条第一項の承認を受けた者

第四十条 次の各号のいずれかに該当する者は、六月以下の懲役又は五十万円以下の罰金に処する。

- 一 第四条第六項又は第七条第三項(これらの規定を第九条第四項において準用する場合を含む。)の規定に違反した者
- 二 第二十条第一項の規定に違反した者

第四十一条 第二十一条第五項の規定による生物検査の業務の停止の命令に違反したときは、その違反行為をした登録検査機関の役員又は職員は、六月以下の懲役又は五十万円以下の罰金に処する。

第四十二条 次の各号のいずれかに該当する者は、五十万円以下の罰金に処する。

- 一 第十三条第一項の規定に違反して確認を受けずに第二種使用等をした者
- 二 偽りその他不正の手段により第十三条第一項の確認を受けた者
- 三 第十六条の規定による届出をせず、又は虚偽の届出をして輸入した者
- 四 第二十六条第一項の規定による情報の提供をせず、又は虚偽の情報を提供して遺伝子組換え生物等を譲渡し、若しくは提供し、又は委託して使用等をさせた者
- 五 第二十七条の規定による通告をせず、又は虚偽の通告をして輸出した者
- 六 第二十八条の規定による表示をせず、又は虚偽の表示をして輸出した者

第四十三条 次の各号のいずれかに該当する者は、三十万円以下の罰金に処する。

- 一 第三十条に規定する報告をせず、又は虚偽の報告をした者
- 二 第三十一条第一項又は第三十二条第一項の規定による立入り、検査若しくは収去を拒み、妨げ、若しくは忌避し、又は質問に対して陳述をせず、若しくは虚偽の陳述をした者

第四十四条 次の各号のいずれかに該当するときは、その違反行為をした登録検査機関の役員又は職員は、三十万円以下の罰金に処する。

- 一 第十九条第七項の規定に違反して、同項に規定する事項の記載をせず、若しくは虚偽の記載をし、又は帳簿を保存しなかったとき。
- 二 第十九条第八項の許可を受けずに生物検査の業務の全部を廃止したとき。
- 三 第二十二條第一項に規定する報告をせず、若しくは虚偽の報告をし、又は同項の規定による立入り若しくは検査を拒み、妨げ、若しくは忌避し、若しくは質問に対して陳述をせず、若しくは虚偽の陳述をしたとき。

第四十五条 法人の代表者又は法人若しくは人の代理人、使用人その他の従業者が、その法人

又は人の業務に関し、第三十八条、第三十九条、第四十二条又は第四十三条の違反行為をしたときは、行為者を罰するほか、その法人又は人に対しても、各本条の罰金刑を科する。

第四十六条 第六条第一項（第九条第四項において準用する場合を含む。）の規定による届出をせず、又は虚偽の届出をした者は、二十万円以下の過料に処する。

第四十七条 次の各号のいずれかに該当するときは、その違反行為をした登録検査機関の役員又は職員は、二十万円以下の過料に処する。

一 第十九条第五項の規定に違反して財務諸表等を備えて置かず、財務諸表等に記載すべき事項を記載せず、又は虚偽の記載をしたとき。

二 正当な理由がないのに第十九条第六項各号の規定による請求を拒んだとき。

第四十八条 第三十三条の規定による命令に違反した場合には、その違反行為をしたセンター等の役員は、二十万円以下の過料に処する。

附 則

（施行期日）

第一条 この法律は、議定書が日本国について効力を生ずる日〔平成一六年二月一九日〕から施行する。ただし、次の各号に掲げる規定は、当該各号に定める日から施行する。

一 次条から附則第六条まで及び附則第十五条の規定（次号に掲げる改正規定を除く。）公布の日

二 附則第十五条の規定（独立行政法人医薬品医療機器総合機構法（平成十四年法律第百九十二号）第十五条第二項の改正規定に係る部分に限る。）この法律の施行の日（以下「施行日」という。）又は独立行政法人医薬品医療機器総合機構法の施行の日のいずれか遅い日〔平成一六年四月一日〕

（経過措置）

第二条 第四条第一項又は第九条第一項の承認を受けようとする者は、施行日前においても、第四条又は第九条の規定の例により、その承認の申請をすることができる。

2 主務大臣は、前項の規定により承認の申請があった場合には、施行日前においても、第四条又は第九条の規定の例により、その承認をすることができる。この場合において、これらの規定の例により承認を受けたときは、施行日において第四条第一項又は第九条第一項の規定により承認を受けたものとみなす。

3 この法律の施行の際現に遺伝子組換え生物等の第一種使用等をしている者であって、当該第一種使用等について第四条第一項又は第九条第一項の承認がなされていないものは、施行日から六月間は、当該第一種使用等に係る承認がなされたものとみなす。その期間が満了するまでに当該第一種使用等に係る第一種使用規程の承認の申請がなされた場合において、その期間を経過したときは、その申請に係る承認又は承認の申請の却下若しくは承認の拒否の処分がある日まで、同様とする。

第三条 第十三条第一項の確認を受けようとする者は、施行日前においても、同条の規定の例により、その確認の申請をすることができる。

2 主務大臣は、前項の規定により確認の申請があった場合には、施行日前においても、第十三条の規定の例により、その確認をすることができる。この場合において、同条の規定の例により確認を受けたときは、施行日において同条第一項の規定により確認を受けたものとみなす。

3 この法律の施行の際現に第十三条第一項に規定する第二種使用等をしている者であって、

同項の確認を受けた拡散防止措置を執っていないものは、施行日から六月間は、当該確認を受けた拡散防止措置を執っているものとみなす。その者がその期間が満了するまでに当該確認の申請をした場合において、その期間を経過したときは、その申請に基づく確認又は確認の拒否の処分がある日まで、同様とする。

第四条 第十八条第一項の登録を受けようとする者は、施行日前においても、その申請を行うことができる。

2 主務大臣は、前項の規定により申請があった場合には、施行日前においても、第十八条の規定の例により、登録をすることができる。この場合において、同条の規定の例により登録を受けたときは、施行日において同条第一項の規定によりその登録を受けたものとみなす。

第五条 第十九条第四項の規程の認可を受けようとする者は、施行日前においても、その申請を行うことができる。

2 主務大臣は、前項の規定により申請があった場合には、施行日前においても、第十九条第四項の規定の例により、認可をすることができる。この場合において、同項の規定の例により認可を受けたときは、施行日において同項の規定によりその認可を受けたものとみなす。
(政令への委任)

第六条 第二条から前条に定めるもののほか、この法律の施行に関して必要な経過措置は、政令で定める。

(検討)

第七条 政府は、この法律の施行後五年を経過した場合において、この法律の施行の状況について検討を加え、必要があると認めるときは、その結果に基づいて所要の措置を講ずるものとする。

(独立行政法人農林水産消費技術センター法の一部改正)

第八条 独立行政法人農林水産消費技術センター法（平成十一年法律第百八十三号）の一部を次のように改正する。

[次のよう略]

(独立行政法人種苗管理センター法の一部改正)

第九条 独立行政法人種苗管理センター法（平成十一年法律第百八十四号）の一部を次のように改正する。

[次のよう略]

(独立行政法人家畜改良センター法の一部改正)

第十条 独立行政法人家畜改良センター法（平成十一年法律第百八十五号）の一部を次のように改正する。

[次のよう略]

(独立行政法人肥飼料検査所法の一部改正)

第十一条 独立行政法人肥飼料検査所法（平成十一年法律第百八十六号）の一部を次のように改正する。

[次のよう略]

(独立行政法人農薬検査所法の一部改正)

第十二条 独立行政法人農薬検査所法（平成十一年法律第百八十七号）の一部を次のように改正する。

[次のよう略]

(独立行政法人水産総合研究センター法の一部改正)

第十三条 独立行政法人水産総合研究センター法（平成十一年法律第百九十九号）の一部を次のように改正する。

〔次のよう略〕

(独立行政法人製品評価技術基盤機構法の一部改正)

第十四条 独立行政法人製品評価技術基盤機構法（平成十一年法律第二百四号）の一部を次のように改正する。

〔次のよう略〕

(独立行政法人医薬品医療機器総合機構法の一部改正)

第十五条 独立行政法人医薬品医療機器総合機構法の一部を次のように改正する。

〔次のよう略〕

附 則〔平成一四年一二月二〇日法律第一九二号抄〕

(施行期日等)

第一条 この法律は、平成十六年四月一日から施行する。〔後略〕

(政令への委任)

第三十三条 附則第三条、附則第四条、附則第六条から第二十条まで、附則第二十二条から第二十四条まで及び附則第二十七条に定めるもののほか、機構の設立に伴い必要な経過措置その他この法律の施行に関し必要な経過措置は、政令で定める。

附 則〔平成一七年四月二七日法律第三三号抄〕

(施行期日)

第一条 この法律は、平成十七年十月一日から施行する。

(経過措置)

第二十四条 この法律による改正後のそれぞれの法律の規定に基づき命令を制定し、又は改廃する場合においては、その命令で、その制定又は改廃に伴い合理的に必要と判断される範囲内において、所要の経過措置（罰則に関する経過措置を含む。）を定めることができる。

〔平成一七年七月二六日法律第八七号抄〕

第十二章 罰則に関する経過措置及び政令への委任

(罰則に関する経過措置)

第五百二十七条 施行日前にした行為及びこの法律の規定によりなお従前の例によることとされる場合における施行日以後にした行為に対する罰則の適用については、なお従前の例による。

(政令への委任)

第五百二十八条 この法律に定めるもののほか、この法律の規定による法律の廃止又は改正に伴い必要な経過措置は、政令で定める。

附 則〔平成一七年七月二六日法律第八七号〕

この法律は、会社法〔平成一七年七月法律第八六号〕の施行の日〔平成一八年五月一日〕から施行する。〔後略〕

附 則〔平成一九年三月三〇日法律第八号抄〕

(施行期日)

第一条 この法律は、平成十九年四月一日から施行する。ただし、附則第四条第二項及び第三項、第五条、第七条第二項並びに第二十二条の規定は、公布の日から施行する。

(罰則に関する経過措置)

第二十一条 施行日前にした行為及び附則第十条の規定によりなお従前の例によることとされる場合における施行日以後にした行為に対する罰則の適用については、なお従前の例による。

(政令への委任)

第二十二条 この附則に規定するもののほか、この法律の施行に関し必要な経過措置は、政令で定める。

附 則〔平成二五年十一月二七日法律第八四号抄〕

沿革

平成二五年一月一三日号外法律第一〇三号〔薬事法及び薬剤師法の一部を改正する法律附則一七条による改正〕

(施行期日)

第一条 この法律は、公布の日から起算して一年を超えない範囲内において政令で定める日から施行する。ただし、附則第六十四条、第六十六条及び第百二条の規定は、公布の日から施行する。

〔平成二六年七月政令二六八号により、平成二六・一一・二五から施行〕

(処分等の効力)

第百条 この法律の施行前に改正前のそれぞれの法律（これに基づく命令を含む。以下この条において同じ。）の規定によってした処分、手続その他の行為であって、改正後のそれぞれの法律の規定に相当の規定があるものは、この附則に別段の定めがあるものを除き、改正後のそれぞれの法律の相当の規定によってしたものとみなす。

(罰則に関する経過措置)

第百一条 この法律の施行前にした行為及びこの法律の規定によりなお従前の例によることとされる場合におけるこの法律の施行後にした行為に対する罰則の適用については、なお従前の例による。

(政令への委任)

第百二条 この附則に規定するもののほか、この法律の施行に伴い必要な経過措置（罰則に関する経過措置を含む。）は、政令で定める。

附 則〔平成二五年一月一三日法律第一〇三号抄〕

(施行期日)

第一条 この法律は、公布の日から起算して六月を超えない範囲内において政令で定める日から施行する。ただし、次の各号に掲げる規定は、当該各号に定める日から施行する。

一 〔略〕

二 附則第十七条の規定 薬事法等の一部を改正する法律（平成二十五年法律第八十四号）の公布の日〔平成二五年十一月二七日〕又はこの法律の公布の日のいずれか遅い日

附 則〔平成二六年六月一三日法律第六七号抄〕

(施行期日)

第一条 この法律は、独立行政法人通則法の一部を改正する法律（平成二十六年法律第六十六号。以下「通則法改正法」という。）の施行の日〔平成二七年四月一日〕から施行する。ただし、次の各号に掲げる規定は、当該各号に定める日から施行する。

一 附則第十四条第二項、第十八条及び第三十条の規定 公布の日

二 〔略〕

(処分等の効力)

第二十八条 この法律の施行前にこの法律による改正前のそれぞれの法律（これに基づく命令を含む。）の規定によってした又はすべき処分、手続その他の行為であってこの法律による改正後のそれぞれの法律（これに基づく命令を含む。以下この条において「新法令」という。）に相当の規定があるものは、法律（これに基づく政令を含む。）に別段の定めのあるものを除き、新法令の相当の規定によってした又はすべき処分、手続その他の行為とみなす。

(罰則に関する経過措置)

第二十九条 この法律の施行前にした行為及びこの附則の規定によりなおその効力を有することとされる場合におけるこの法律の施行後にした行為に対する罰則の適用については、なお従前の例による。

(その他の経過措置の政令等への委任)

第三十条 附則第三条から前条までに定めるもののほか、この法律の施行に関し必要な経過措置（罰則に関する経過措置を含む。）は、政令（人事院の所掌する事項については、人事院規則）で定める。

附 則〔平成二七年九月一八日法律第七〇号抄〕

(施行期日)

第一条 この法律は、平成二十八年四月一日から施行する。〔後略〕

日本の国立公園

環境省自然環境局 Nature Conservation Bureau, Ministry of the Environment



自然環境保全法上の原生自然環境保全地域及び自然環境保全地域



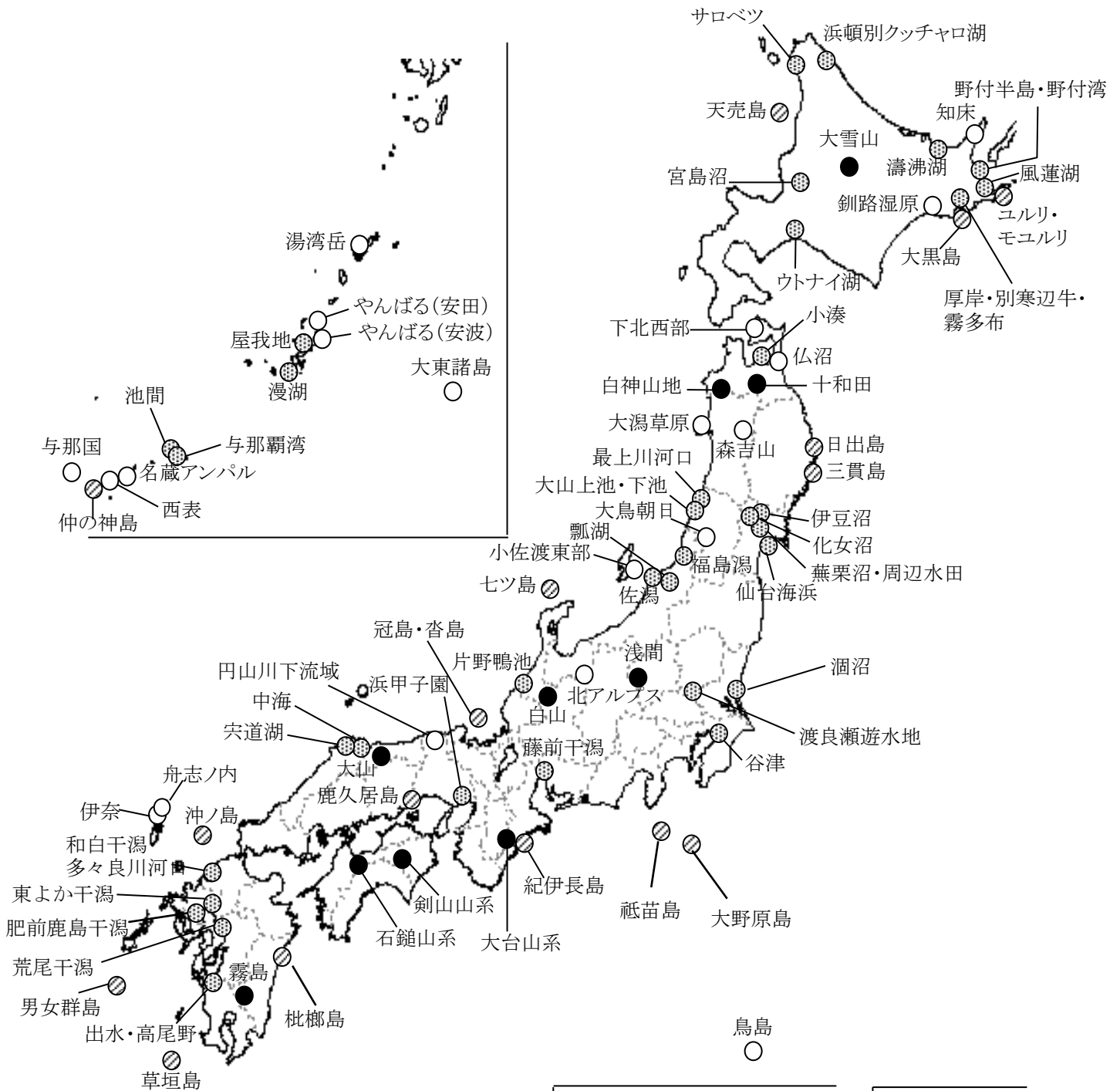
原生自然環境保全地域

- ① 遠音別岳原生自然環境保全地域
- ② 十勝川源流部原生自然環境保全地域
- ③ 南硫黄島原生自然環境保全地域
- ④ 大井川源流部原生自然環境保全地域
- ⑤ 屋久島原生自然環境保全地域

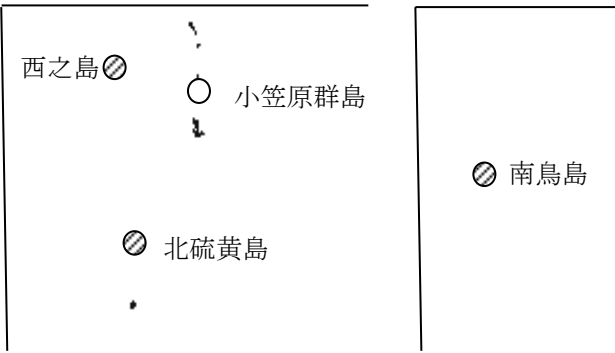
自然環境保全地域

- ⑥ 太平山自然環境保全地域
- ⑦ 白神山地自然環境保全地域
- ⑧ 早池峰自然環境保全地域
- ⑨ 和賀岳自然環境保全地域
- ⑩ 大佐飛山自然環境保全地域
- ⑪ 利根川源流部自然環境保全地域
- ⑫ 笹ヶ峰自然環境保全地域
- ⑬ 白鬘岳自然環境保全地域
- ⑭ 稲尾岳自然環境保全地域
- ⑮ 崎山湾自然環境保全地域

国指定鳥獣保護区的位置図 (平成27年5月1日現在)



凡 例	
●	大規模生息地
⊙	集団渡来地
⊘	集団繁殖地
○	希少鳥獣生息地



生息地等保護区一覧



名称	設定年月日	面積 (ha) ()は管 理地区	指定地の概要	保護に関する方針 (概要)
羽田ミヤコ タナゴ 生息地保護 区 (栃木県大 田原市)	平成 6 年 12 月 26 日	60.6 (12.8)	<ul style="list-style-type: none"> ・栃木県北部的那須野ヶ原扇状地東部に位置する丘陵地。 ・羽田沼と同沼を水源とする農業用水路及びそれらを取り巻く水田等。 	<ul style="list-style-type: none"> ・ミヤコタナゴの生息には、用水路の水質・形質維持及び餌条件、産卵母貝であるマツカサガイの生息の確保が必要。 ・当該区域における各種行為は、用水路の水質・形質等の生息環境への影響について特に配慮が必要。・マツカサガイの捕獲を規制。
北岳キタダ ケソウ 生育地保護 区 (山梨県南 アルプス市)	平成 6 年 12 月 26 日	38.5 (38.5) 全域	<ul style="list-style-type: none"> ・南アルプス北岳山頂部南東斜面。 ・標高 2,750m 以上の高山帯で、高山植物群落地帯。 	<ul style="list-style-type: none"> ・キタダケソウの生育には、生育基盤である地形・地質の維持並びにキタダケソウ群落及び周辺植生の確保が必要。 ・当該区域における各種行為は、地形、地質、植生等の生育環境への影響について特に配慮が必要。 ・積雪期以外の期間 (毎年 6 月 1 日から 11 月 30 日まで) について登山道を除く全域を立入制限地区に指定。

善王寺長岡 アベサンシ ョウウオ 生息地保護 区(京都府京 丹後市)	平成 18 年 7 月 3 日	13.1 (3.9)	・丹後半島のほぼ中央部の丘陵地に位置する標高 30~60m の小丘陵。 ・主に落葉広葉樹二次林で、一部竹が優占している。	・繁殖場所、幼生の生息環境となる池、水路、それらの湧水源並びに成体の生息環境となる水辺周辺の森林の保護が必要。 ・各種行為は、生息環境に影響を及ぼさないよう配慮が必要。
大岡アベサ ンショウウ オ 生息地保護 区(兵庫県豊 岡市)	平成 10 年 11 月 4 日	3.1 (3.10) 全域	・兵庫県北部の大岡山(標高 663.6m)の東南斜面。 ・ヤブツバキ、アラカシ等の常緑広葉樹及びヒノキ、スギや竹林の混交林。	・水路等の水質、底質等の保全、水量の安定的な供給、うっ閉し森林の湿潤な林床の保全が必要。 ・当該区域における各種行為は、生息環境に影響を及ぼすことのないよう配慮が必要。
山迫ハナシ ノブ 生育地保護 区(熊本県阿 蘇郡高森町)	平成 8 年 6 月 3 日	1.13 (1.13) 全域	・阿蘇山の東外輪上に位置する北向きの緩斜面で、標高は約 800m。 ・採草地として利用されてきた草地。・周囲の土地はスギ、クヌギの造林地となっている。	・刈取り等の実施により植生の遷移を抑制することが必要。 ・当該区域における各種行為は、地形、地質、植生等の生育環境の維持について配慮が必要。
北伯母様ハ ナシノブ 生育地保護 区(熊本県阿 蘇郡高森町)	平成 8 年 6 月 3 日	7.05 (1.94)	・阿蘇山の東外輪上に位置する北向きの緩斜面で、標高は約 800m。 ・高さ数メートル程度のヒノキの若齢造林地。 ・周囲の土地はスギ、クヌギの造林地となっている。	・刈取り等の実施により植生の遷移を抑制すること、及び間伐等の森林管理を適切に実施し造林木の被陰による生育への影響を最小限とすることが必要。 ・当該区域における各種行為は、地形、地質、植生等の生育環境の維持について配慮が必要。
蘭牟田池ベ ッコウトン ボ 生息地保護 区(鹿児島県 薩摩川内市)	平成 8 年 6 月 3 日	153 (60)	・蘭牟田池は、標高 300m に位置する火口湖で、池の北西部は泥炭からなる湿原となっている。 ・蘭牟田池の周囲は、水田、畑地等として利用されているほか、宿泊施設、キャンプ場等が整備されている。	・池は、産卵、幼虫の生息、羽化の場として重要であり、当該区域における各種行為は、池の水位、水質、底質及び湿原植生の維持について配慮が必要。 ・池周辺の草地は、成虫の採餌の場として利用されており、草地植生を維持することが必要。

<p>宇江城岳キクザトサワヘビ</p> <p>生息地保護区（沖縄県久米島町）</p>	<p>平成 10 年 6 月 15 日</p>	<p>600 (255)</p>	<ul style="list-style-type: none"> ・ 沖縄県久米島北部の宇江城岳を中心とする山地周辺の地域。 ・ 複数の沢の源流となっており、イタジイなどの広葉樹林が広がっている。 	<ul style="list-style-type: none"> ・ キクザトサワヘビは、水環境への依存度が高く、水質の保全、集水域の地形及び森林の維持、水量の安定的な確保が必要。 ・ 各種行為は、生息環境に影響を及ぼさないよう配慮が必要。
<p>米原イシガキニイニイ</p> <p>生息地保護区（沖縄県石垣市）</p>	<p>平成 15 年 11 月 11 日</p>	<p>9.0 (9.0)全域</p>	<ul style="list-style-type: none"> ・ 沖縄県石垣島北部のヤエヤマヤシ群落と一体となって成立している湿潤な広葉樹林及びその周辺地域。 	<ul style="list-style-type: none"> ・ 生息基盤である広葉樹林内の環境及びヤエヤマヤシ群落の一体的維持が必要。 ・ 幼虫が成育する地域においては、土壌の乾燥化、踏み固め及び流失を避けるため立入制限地区に指定。

国内希少野生動植物種一覽表

平成28年6月1日現在(全175種)

* 鳥類(37種)

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
かも科	シジュウカラガン	平成5年		
うみすずめ科	エトビリカ	〃		(平成13年)
	ウミガラス	〃		(平成13年)
しぎ科	アマミヤマシギ	〃		(平成11年) 平成27年改定
	カラフトアオアシシギ	〃		
こうのとり科	コウノトリ	〃		
とき科	トキ	〃		(平成5年) 平成16年改定
はと科	キンバト	〃		
	アカガシラカラスバト	〃		(平成18年)
	ヨナクニカラスバト	〃		
たか科	オオタカ	〃		
	イヌワシ	〃		(平成8年)
	オガサワラノスリ	〃		
	オジロワシ	〃		(平成17年)
	オオワシ	〃		(平成17年)
	カンムリワシ	〃		
	クマタカ	〃		
はやぶさ科	シマハヤブサ	〃		
	ハヤブサ	〃		
きじ科	ライチョウ	〃		(平成24年)
つる科	タンチョウ	〃		(平成5年)
くいな科	ヤンバルクイナ	〃		(平成16年) 平成27年改定
あとり科	オガサワラカワラヒワ	〃		
みつすい科	ハハジマメグロ	〃		
ひたき科	アカヒゲ	〃		
	ホントウアカヒゲ	〃		
	ウスアカヒゲ	〃		
	オオセッカ	〃		
	オオトラツグミ	〃		(平成11年) 平成27年改定
やいろちょう科	ヤイロチョウ	〃		
う科	チシマウガラス	〃		
きつつき科	オーストンオオアカゲラ	〃		
	ミユビゲラ	〃		
	ノグチゲラ	〃		(平成10年) 平成27年改定
あほうどり科	アホウドリ	〃		(平成5年) 平成18年改定
ふくろう科	ワシミミズク	平成9年		
	シマフクロウ	平成5年		(平成5年)

* 哺乳類(9種)

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
ねずみ科	ケナガネズミ	平成28年		
	オキナワトゲネズミ	〃		
	アマミトゲネズミ	〃		
	トクノシマトゲネズミ	〃		
ねこ科	ツシマヤマネコ	平成6年		(平成7年)
	イリオモテヤマネコ	〃		(平成7年)
おおこうもり科	ダイトウオオコウモリ	平成16年		
	オガサワラオオコウモリ	平成21年		(平成22年)
うさぎ科	アマミノクロウサギ	平成16年		(平成16年) 平成27年改定

* 爬虫類（7種）

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
とかげもどき科	クロイトカゲモドキ	平成27年		
	マダラトカゲモドキ	〃		
	オビトカゲモドキ	〃		
	イヘヤトカゲモドキ	〃		
	クメトカゲモドキ	〃		
かなへび科	ミヤコカナヘビ	平成28年		
なみへび科	キクザトサウヘビ	平成7年		

* 両生類（11種）

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
あかがえる科	ホルストガエル	平成28年		
	オットンガエル	〃		
	ナミエガエル	〃		
	オキナワイシカワガエル	〃		
	アマミシカワガエル	〃		
さんしょうお科	アベサンショウウオ	平成7年		(平成8年) 平成27年改定
	アマクササンショウウオ	平成27年		
	オオスミサンショウウオ	〃		
	ソボサンショウウオ	〃		
いもり科	ツクバハコネサンショウウオ	〃		
	イボイモリ	平成28年		

* 魚類（4種）

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
どじょう科	アユモドキ	平成16年		(平成16年) 平成27年改定
こい科	イタセンバラ	平成7年		(平成8年) 平成27年改定
	スイゲンゼニタナゴ	平成14年		(平成16年)
	ミヤコタナゴ	平成6年		(平成7年)

* 昆虫類（39種）

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
たまむし科	オガサワラナガタマムシ	平成27年		
	シラフオガサワラナガタマムシ	〃		
	オガサワラムツボシタマムシ父島列島亜種	〃		
	オガサワラムツボシタマムシ母島亜種	〃		
	ツヤヒメマルタマムシ	〃		
	ツマベニタマムシ父島・母島列島亜種	〃		
おさむし科	オガサワラハンミョウ	平成20年		(平成21年) 平成27年改定
かみきりむし科	フサヒゲルリカミキリ	平成28年		
	オガサワラトビロカミキリ	平成27年		
	オガサワラトラカミキリ	〃		
	オガサワラキイロトラカミキリ	〃		
	オガサワラモモフトコバネカミキリ	〃		
	フタモンアメイロカミキリ父島列島亜種	〃		
	オガサワライカリモントラカミキリ	〃		
げんごろう科	ヤシャゲンゴロウ	平成8年		(平成17年)
	マルコガタノゲンゴロウ	平成23年		
	フチトリゲンゴロウ	〃		
	シャープゲンゴロウモドキ	〃		
	マダラシマゲンゴロウ	平成28年		

くわがたむし科	ヨナグニマルバネクワガタ オキナワマルバネクワガタ ウケジマルバネクワガタ	平成23年 平成28年 "		
はなのみ科	クスイキボシハナノミ キネムキボシハナノミ オガサワラキボシハナノミ オガサワラモンハナノミ	平成27年 " " "		
こがねむし科	ヤンバルテナゴコガネ	平成8年		(平成9年) 平成27年改定
せみ科	イシガキニイニイ	平成14年		
しじみちょう科	オガサワラシジミ ゴマシジミ本州中部亜種 アサマシジミ北海道亜種 ゴイシツバメシジミ	平成20年 平成28年 " 平成8年		(平成21年) (平成9年)
たてはちょう科	ウスイロヒョウモンモドキ ヒョウモンモドキ	平成28年 平成23年		
ばった科	アカハネバッタ	平成28年		
えぞとんぼ科	オガサワラトンボ	平成20年		(平成21年) 平成27年改定
あおいととんぼ科	オガサワラアオイトトンボ	"		(平成21年) 平成27年改定
はなだかとんぼ科	ハナダカトンボ	"		(平成21年) 平成27年改定
とんぼ科	ベッコウトンボ	平成6年		(平成8年)

* 陸産貝類 (14種)

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
なんばんまい科	アニジマカタマイマイ	平成27年		
	コガネカタマイマイ	"		
	チチジマカタマイマイ	"		
	ヒシカタマイマイ	"		
	ヒメカタマイマイ	"		
	フタオビカタマイマイ	"		
	アナカタマイマイ	"		
	オトメカタマイマイ	"		
	カタマイマイ	"		
	アケボノカタマイマイ	"		
	ヌノメカタマイマイ	"		
	キノボリカタマイマイ	"		
	コハクアナカタマイマイ	"		
	ミスジカタマイマイ	"		

* 植物 (54種、うち特定国内希少野生動植物種11種)

科名	種名	指定年	特定国内希少野生動植物種(指定年)	保護増殖事業計画(策定年)
さといも科	サキシマハブカズラ	平成28年		
	ヒメハブカズラ	平成28年		
ちゃせんしだ科	マキノシダ	平成28年		
	フササザラン	平成28年		
	ヒメタニワタリ	平成20年		(平成21年)
めしだ科	ヤクシマタニイヌワラビ	平成28年		
	ホソバシケチシダ	平成28年		
	アオイガワラビ	平成28年		
きく科	コヘラナレン	平成20年		(平成21年)
こばのいしかぐま科	ホソバコウシュンシダ	平成28年		
おしだ科	アマミデング	平成11年	(平成11年)	
つつじ科	ムニンツツジ	平成16年		(平成16年)
	ウラジロヒカゲツツジ	平成24年		
	ヤドリコケモモ	平成11年		

りんどう科	ヤクシマリンドウ	平成28年	(平成28年)	
いわたばこ科	ナガミカズラ	平成27年		
しそ科	シマカコソウ	平成20年		(平成21年)
ひかげのかずら科	ヒモスギラン	平成28年		
	ヒメヨウラクヒバ	平成27年		
のぼたん科	ムニンノボタン	平成16年		(平成16年)
すいれん科	シモツケコウホネ	平成24年		
らん科	キバナシュスラン	平成28年	(平成28年)	
	コウシュンシュスラン	平成28年		
	アサヒエビネ	平成16年		(平成16年)
	ホシツルラン	平成16年		(平成16年)
	オオスズムシラン	平成28年		
	タカオオオスズムシラン	平成27年		
	チョウセンキバナアツモリソウ	平成14年		(平成16年)
	ホテイアツモリ	平成9年	(平成9年)	
	レブンアツモリソウ	平成6年	(平成6年)	(平成8年)
	アツモリソウ	平成9年	(平成9年)	
	オキナワセッコク	平成14年	(平成20年)	
	ヒメクリソラン	平成28年		
	コゴメキノエラン	平成11年		
	ナンバンカモメラン	平成28年	(平成28年)	
	シマホザキラン	平成16年		(平成16年)
	ヒメカクラン	平成28年		
	クニガミトンボソウ	平成14年		
	イリオモテトンボソウ	平成27年		
	ハガクレナガミラン	平成28年		
	ミソボシラン	平成27年		
きじのおしだ科	リュウキュウキジノオ	平成27年		
こしょう科	タイヨウフウトウカズラ	平成16年		(平成16年)
とべら科	コバトベラ	"		(平成16年)
はなしのぶ科	ハナシノブ	平成7年	(平成7年)	(平成8年)
さくらそう科	カッコソウ	平成24年		
きんぼうげ科	キタダケソウ	平成6年	(平成6年)	(平成7年)
ゆきのした科	ヤエヤマヒメウツギ	平成28年		
はいのき科	ウチダシクロキ	平成20年		(平成21年)
ななばけしだ科	コモチナナバケシダ	平成28年	(平成28年)	
	ナガバウスシダ	平成28年		
ひめしだ科	シマヤワラシダ	平成28年		
おみえなし科	シマキンレイカ	平成28年		
くまつづら科	ウラジロコムラサキ	平成16年		(平成16年)