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ANNEX II

PROCEDURES AND MINIMUM ELEMENTS TO BE ADDRESSED IN AN ENVIRONMENTAL RISK ASSESSMENT AS FORESEEN UNDER ARTICLE 9

To evaluate risks associated with the introduction or translocation of aquatic organisms it is necessary to assess the probability that the organisms will become established and the consequences of that establishment.

The process addresses the major environmental components. It provides a standardised approach for evaluating the risk of genetic and ecological impacts as well as the potential for introducing a non-target species that might impact the native species of the proposed receiving waters.

During the review process, emphasis is not on the ratings but on the detailed biological and other relevant information statements that motivate them. In case of scientific uncertainty, the precautionary principle should be applied.

For the purpose of this Annex, where an application refers to a proposed translocation the terms 'introduction/introduced' are to be replaced by 'translocation/translocated'.

PART 1

ECOLOGICAL AND GENETIC RISK ASSESSMENT PROCESS

Step 1 Likelihood of establishment and spreading beyond the intended area of introduction

Event	Likelihood(H, M, L) ^a	Certainty(VC, RC, RU, VU) ^b	Comments in support of assessment ^c
The introduced or translocated species, escaped or dispersed, successfully colonises and maintains a population in the intended area of introduction beyond the control of the aquaculture facility.			
The introduced species or translocated, escaped or dispersed, spreads beyond the intended area of introduction.			
Final rating ^d			

a H = High, M = Medium, L = Low

b VC = Very certain, RC = Reasonably certain, RU = Reasonably uncertain, VU = Very uncertain

c The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

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- d** The final rating for the likelihood of establishment and spreading is assigned the value of the element with the lowest rating (for example, high and low ratings for the above elements would result in a final low rating). Again, both events — probability of the organism successfully colonising and maintaining a population in the intended area of introduction (be it a confined environment such as a facility, or a natural habitat) and the probability of spreading beyond the intended area of introduction (estimated as explained above) — need to occur in order to have establishment beyond the intended area of introduction.
- The final rating for the level of Certainty is assigned the value of the element with the lowest level of certainty (e.g. very certain and reasonably certain ratings would result in a final reasonably certain rating). The harmfulness of a establishment and spreading should be taken into account, together with risk/benefit ration, in arriving at the final rating.

Step 2 Consequences of establishment and spreading

Event	Likelihood(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment ^a
Genetic mixing with local populations leads to a loss of genetic diversity.			
Competition (food, space) with or predation on native populations leads to their extirpation.			
Other undesirable events of ecological nature			
Some of the abovementioned events persist even after removal of the introduced species.			
Final rating ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final rating for the consequences of establishment and spreading is assigned the value of the element (individual probability) with the highest rating and the final rating for the level of certainty is assigned the value of the element with the lowest level of certainty.

Step 3 Risk potential associated to the alien and locally absent species

A single value is given based on the assessments done in Steps 1 and 2:

Component	Risk potential(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment ^a
a	The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.		
b	The final categorisation of risk potential takes the value of the highest of the two probabilities when there is no probability increment between the two estimates (i.e. if the Risk of establishment and spreading is high and the risk of ecological consequences is medium, the final rating takes the value of the highest of the two probabilities which is high. When there is a probability increment between the two estimates (i.e. a mixture of high and low) the final value is medium.		

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Establishment and spreading (step 1)			
Ecological consequences (step 2)			
Final rating of overall risk potential ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final categorisation of risk potential takes the value of the highest of the two probabilities when there is no probability increment between the two estimates (i.e. if the Risk of establishment and spreading is high and the risk of ecological consequences is medium, the final rating takes the value of the highest of the two probabilities which is high. When there is a probability increment between the two estimates (i.e. a mixture of high and low) the final value is medium.

The result of this assessment will be expressed in terms of the following risk levels:

A high-risk movement:

- (a) has a high risk of damaging biodiversity from spreading and other ecological consequences;
- (b) operates under farming conditions which would increase the risk of such damage;
- (c) involves an aquaculture facility which sells live aquatic animals for further farming or restocking;
- (d) as a consequence, the movement is of major concern (major mitigation measures are required). It is advised that the proposal be rejected unless mitigation procedures can be developed to reduce the risk to low.

A medium-risk movement:

- (a) has a medium risk of damaging biodiversity from spreading and other ecological consequences;
- (b) operates under farming conditions which would not necessarily increase the risk of such damage, taking account of the species and the containment conditions;
- (c) involves an aquaculture facility which sells its products mainly for human consumption;
- (d) as a consequence the movement is of moderate concern. It is advised that the proposal be rejected unless mitigation procedures can be developed to reduce the risk to low.

A low-risk movement:

- (a) has a low risk of damaging biodiversity from spreading and other ecological consequences.
- (b) operates under farming conditions which would not increase the risk of such damage;
- (c) involves an aquaculture facility which sells its products for human consumption only;
- (d) as a consequence the movement is of negligible concern. It is advised that the proposal be approved. Mitigation is not needed.

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The proposal can only be approved as presented (no mitigating measures required) if the overall estimated risk potential is low and if the overall certainty for which the overall risk has been estimated is very certain or reasonably certain.

If, as a result of a first analysis, a high or medium category is attributed to the overall risk, then containment or mitigation proposals are to be incorporated in the application, which will be subject to subsequent risk analysis until the final rating for the overall risk becomes low with a very certain or reasonably certain assessment. Descriptions of these additional steps, together with detailed specifications of the containment or mitigation measures, will become an integral part of the risk assessment.

PART 2

NON-TARGET SPECIES ASSESSMENT PROCESS

Step 1 Likelihood of establishment and spreading of non-target species beyond the intended area of introduction

Event	Likelihood(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment ^a
A non-target species is introduced as a consequence of the introduction or translocation of the aquatic organisms.			
The introduced non-target species encounters susceptible habitats or host organisms.			
Final rating ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final rating under likelihood is assigned the value of the element with the lowest risk rating and the final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

Step 2 Consequences of non-target species establishment and spreading

Event	Likelihood(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment ^a
The non-target species compete with or predate on native			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final rating for the consequences is assigned the value of the highest risk rating and final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

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populations, leading to their extirpation.			
Genetic mixing of the non-target species with local populations leads to a loss of genetic diversity.			
Other undesirable events of ecological or pathological nature			
Some of the abovementioned events persist even after removal of the non-target species.			
Final rating ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final rating for the consequences is assigned the value of the highest risk rating and final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

Step 3 Risk potential associated with non-target species

A single value is given based on the assessments performed in Steps 1 and 2:

Component	Risk potential(H, M, L)	Certainty(VC, RC, RU, VU)	Comments in support of assessment ^a
Establishment and spreading (step 1)			
Ecological consequences (step 2)			
Final rating ^b			

a The assessor is referred for guidance to Appendix A and Appendix B of the ICES Code of Practice.

b The final rating under risk potential is assigned the value of the element with the lowest risk rating and the final rating for the level of certainty is also assigned the value of the element with the lowest level of certainty.

The conditions applicable to the assessment of risk potential associated to the alien species (part 1) are to also apply, *mutatis mutandis*, to this risk potential associated with non-target species (part 2), including the obligation to introduce containment and mitigation measures.

PART 3

OVERALL ENVIRONMENTAL RISK ASSESSMENT — SUMMARY REPORT

- History, background and rationale for the request:
 - risk assessment summary information

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- summary of the ecological and genetic risk assessment
- summary of the non-target species risk assessment
- Comments:
- Mitigation measures:
- Concluding statement on total organism potential risk:
- Advice to competent authority:

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/451 reg. 9\(16\)](#)
- Art. 3(1) substituted by [S.I. 2019/451 reg. 9\(3\)\(a\)](#)
- Art. 3(8) words inserted by [S.I. 2019/451 reg. 9\(3\)\(b\)](#)
- Art. 3(18) substituted by [S.I. 2019/451 reg. 9\(3\)\(c\)](#) (This amendment not applied to legislation.gov.uk. [S.I. 2019/451, reg. 9\(3\)\(c\)\(d\)](#) substituted immediately before IP completion day by [S.I. 2020/1463, regs. 1\(2\)\(a\), 2\(b\)](#))
- Art. 3(18) substituted by [S.I. 2019/451, reg. 9\(3\)\(c\)](#) (as substituted) by [S.I. 2020/1463 reg. 2\(2\)\(b\)](#)
- Art. 3(19) substituted by [S.I. 2019/451 reg. 9\(3\)\(d\)](#) (This amendment not applied to legislation.gov.uk. [S.I. 2019/451, reg. 9\(3\)\(c\)\(d\)](#) substituted immediately before IP completion day by [S.I. 2020/1463, regs. 1\(2\)\(a\), 2\(b\)](#))
- Art. 3(19) substituted by [S.I. 2019/451, reg. 9\(3\)\(d\)](#) (as substituted) by [S.I. 2020/1463 reg. 2\(2\)\(b\)](#)
- Art. 13(a) words inserted by [S.I. 2019/451 reg. 9\(10\)\(b\)](#)
- Art. 13(b) words inserted by [S.I. 2019/451 reg. 9\(10\)\(c\)](#)
- Art. 19(a) words inserted by [S.I. 2019/451 reg. 9\(12\)\(b\)](#)
- Art. 19(b) words inserted by [S.I. 2019/451 reg. 9\(12\)\(b\)](#)
- Art. 21(1)(2) substituted for words in Art. 21 by [S.I. 2019/451, reg. 9\(13\)](#) (as substituted) by [S.I. 2020/1463 reg. 2\(2\)\(f\)](#)
- Art. 24(1)(1A) substituted for Art. 24(1) by [S.I. 2019/753 reg. 42\(2\)\(a\)](#)
- Art. 24(1A)(c) inserted in earlier amending provision [S.I. 2019/753, reg. 42\(2\)\(a\)](#) by [S.I. 2020/1463 reg. 4\(3\)](#)
- Art. 24(3)(c) omitted in earlier amending provision [S.I. 2019/753, reg. 42\(4\)](#) by [S.I. 2020/1463 reg. 4\(4\)\(b\)\(ii\)](#)
- Art. 24(3A) inserted by [S.I. 2019/753 reg. 42\(2\)\(d\)](#)
- Art. 24d24e inserted by [S.I. 2019/753 reg. 42\(4\)](#)
- Art. 24d(1) words substituted in earlier amending provision [S.I. 2019/753, reg. 42\(4\)](#) by [S.I. 2020/1463 reg. 4\(4\)\(a\)\(i\)](#)
- Art. 24d(4) omitted in earlier amending provision [S.I. 2019/753, reg. 42\(4\)](#) by [S.I. 2020/1463 reg. 4\(4\)\(a\)\(ii\)](#)
- Art. 24d(8) omitted in earlier amending provision [S.I. 2019/753, reg. 42\(4\)](#) by [S.I. 2020/1463 reg. 4\(4\)\(a\)\(ii\)](#)
- Art. 24e(2) words substituted in earlier amending provision [S.I. 2019/753, reg. 42\(4\)](#) by [S.I. 2020/1463 reg. 4\(4\)\(b\)\(i\)](#)
- Art. 24e(4) word substituted in earlier amending provision [S.I. 2019/753, reg. 42\(4\)](#) by [S.I. 2020/1463 reg. 4\(4\)\(b\)\(iii\)\(aa\)](#)
- Art. 24e(4) words substituted in earlier amending provision [S.I. 2019/753, reg. 42\(4\)](#) by [S.I. 2020/1463 reg. 4\(4\)\(b\)\(iii\)\(bb\)](#)