

The Guidance of Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 Use of Living Modified Organisms

(Tentative Translation)

[1] Object

This guidance stipulates necessary matters to ensure that the assessment of Adverse Effect on Biological Diversity to be performed by a person who wishes to obtain approval under the provisions of Article 4 paragraph 2 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (hereinafter “the Law”) can be performed scientifically and correctly and that the Biological Diversity Risk Assessment Report showing the result can be prepared correctly.

This guidance shall be reviewed as occasion demands, with future amplification of scientific knowledge on the adverse effects of living modified organisms on biological diversity and international trends concerning the assessment of the adverse effects of living modified organisms on biological diversity taken into account.

[2] Information Necessary for Assessment of Adverse Effect on Biological Diversity

The assessment of Adverse Effect on Biological Diversity shall be carried out by collecting information shown in Table 1 and using the collected information. Nevertheless, if there is a rational reason for not using part of the information shown in Table 1, such information need not be collected.

In case the need to collect other information than that shown in Table 1 arises during the process of the assessment in accordance with the procedure of assessment of Adverse Effect on Biological Diversity shown in Table 3, the assessment shall be carried only after additional collection of said information.

[3] Items and Procedure of Assessment of Adverse Effect on Biological Diversity

The assessment of Adverse Effect on Biological Diversity shall be carried out for each of the items listed in the left-hand column in Table 2 for the appropriate category of living modified organisms listed in the right-hand column in Table 2, in accordance with the procedure of assessment of Adverse Effect on Biological Diversity shown in Table 3, and it shall be judged comprehensively on the basis of the assessment of each item whether Adverse Effect on Biological Diversity could arise or not..

[4] Description in the Biological Diversity Risk Assessment Report

The Biological Diversity Risk Assessment Report shall be written in the order of items provided in Table 4.

Table 1 (Related to [2])

1. Information concerning a recipient organism (that is, a living organism in which nucleic acid, or its replicated product, obtained by using technology provided in Article 2 paragraph 2 subparagraph 1 of the Law is transferred; the same applies to the rest of this guidance) or the species to which the recipient organism belongs:

- (1) Taxonomical position and state of distribution in natural environment
- (2) History and present state of Use
- (3) Physiological and ecological properties
 - A. Basic properties
 - B. Environmental conditions allowing inhabiting or growth
 - C. Predacity or parasitism
 - D. Mode of propagation or reproduction
 - E. Pathogenicity
 - F. Productivity of harmful substances
 - G. Other information

2. Information concerning preparation of living modified organisms

- (1) Information concerning donor nucleic acid (that is, nucleic acid or replicated product thereof, obtained by using technology provided in Article 2 paragraph 2 subparagraph 1 of the Law, excluding nucleic acid and its replicated products which replicate, in the recipient organism transferred, the whole or a part thereof (hereinafter “vector”); the same applies to the rest of this guidance).
 - A. Composition and origins of component elements
 - B. Functions of component elements
- (2) Information concerning vector
 - A. Name and origin
 - B. Properties
- (3) Method of preparing living modified organisms
 - A. Structure of the entire nucleic acid transferred in recipient organism
 - B. Method of transferring nucleic acid transferred in recipient organism
 - C. Processes of rearing of living modified organisms
- (4) State of existence of nucleic acid transferred in cells and stability of expression of traits caused by the nucleic acid
- (5) Methods of detection and identification of living modified organisms and their sensitivity and reliability
- (6) Difference from the recipient organism or the species to which the recipient organism belongs

3. Information concerning the Use of living modified organisms

- (1) Content of the Use
- (2) Method of the Use
- (3) Method of collecting information by person who wishes to obtain approval after the start of Type 1 Use
- (4) Emergency measures which should be taken to prevent Adverse Effect on Biological Diversity in case Adverse Effect on Biological Diversity could arise
- (5) The results of Use in laboratory or Use in similar environment to the environment in which Type 1 Use is intended (in principle, to be carried out for an appropriate period that is commensurate with its life-cycle or generation time of the living modified organisms)
6. Information obtained from Use abroad

Table 2 (Related to [3])

Category of Living Modified Organisms	Assessment Items (Property of living modified organisms which might cause Adverse Effect on Biological Diversity)
Plants (living organisms belonging to Plantae and mushroom belonging to Fungi)	Competitiveness (Property of competing against wild plants for resources such as nutrients, sunshine, habitat, etc. and interfering with their growth)
	Productivity of harmful substances (Property of producing substances interfering with the living and growth of wild plants or animals, or microorganisms (hereinafter “wildlife”))
	Crossability (Property of hybridizing with related wild plants and transmitting nucleic acid transferred by the technologies regulated by the Law to them)
	Other properties (Properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of the ecosystem, which are considered to require an assessment of Adverse Effect on Biological Diversity)
Animals (living organisms belonging to Animalia)	Competitiveness (Property of competing against wild animals for resources such as food, nesting places and habitats, etc. and interfering with their living)
	Predacity or parasitism (Property of interfering with living or growth of wildlife by preying upon them or by being parasitic on them)
	Productivity of harmful substances (Property of producing substances interfering with living or growth of wildlife)
	Crossability (Property of hybridizing with related wild animals and transmitting nucleic acid transferred by the technologies regulated by the Law to them)
	Other properties (Properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of the ecosystem, which are considered to require an assessment of Adverse Effect on Biological Diversity)
Microorganisms (living organisms belonging to Fungi [excluding mushroom], those belonging to the Protista, viruses and viroids)	Property of reducing other microorganisms (Property of reducing other microorganisms by competition, productivity of harmful substances, etc.)
	Pathogenicity (Property of interfering with living or growth of wild plants or animals by infecting them)
	Productivity of harmful substances (Property of producing substances interfering with living or growth of wild plants or animals)
	Property of transmitting nucleic acid horizontally (Property of transmitting nucleic acid being transferred by the technologies regulated by the Law to wild plants and animals and other microorganisms)

	Other properties (Properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of the ecosystem, which are considered to require an assessment of Adverse Effect on Biological Diversity)
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Table 3 (Related to [3])

Procedure of Assessment of Adverse Effect on Biological Diversity	Method of Implementing the Assessment
1. Identification of wildlife likely to be affected	<p>Types of wildlife assumed to be affected by the properties of living modified organisms mentioned under assessment items in the right-hand column of Table 2 shall be identified by taxonomical categories and other genetic characters.</p> <p>If the species of pertinent wildlife are large in number, some species of wildlife deemed to be appropriate as the subject in carrying out the assessment shown in Procedure 2-4 may be selected in consideration of the growth and living environment of those species, their sensitivity to harmful substances produced by living modified organisms for Type 1 Use, relatedness to living modified organisms, etc.</p> <p>Nevertheless, if Japan has experience in the long-term use of the recipient organism of the living modified organism or the species to which the recipient organism belongs, and if there is no difference between the properties of the living modified organism mentioned under the assessment item in the right-hand column of Table 1 and those of the host or the species to which the host belongs, the wildlife likely to be affected need not be specified.</p>
2. Evaluation of concrete details of adverse effect	Concrete details of adverse effect of living modified organism on wildlife identified or selected in Procedure 1 shall be evaluated, for example, by conducting experiments on reaction of individuals of the wildlife and collecting relevant information.
3. Evaluation of likelihood of adverse effect	The likelihood of adverse effect on wildlife identified or selected in Procedure 1 caused by living modified organism in carrying out Type 1 Use in accordance with Type 1 Use regulations shall be evaluated while collecting information on the places or periods of time of living or growth of said wildlife and other pertinent matters.
4. Judgment of existence of Adverse Effect on Biological Diversity	<p>Whether the preservations of the species or population of the wildlife might be impaired or not shall be judged.</p> <p>If Japan has experience in the long-term use of the recipient organism of living modified organisms or the species to which the recipient organism belongs, judgment may be based on whether the degree of adverse effect is higher compared to that of the recipient organism or the species to which the recipient organism belongs.</p>

Table 4 (Related to [4])

1. Information collected prior to assessing Adverse Effect on Biological Diversity

Information collected under the provisions of [2] shall be mentioned according to the items shown in Table 1. When this is done, sources of the information shall be indicated clearly (if the information is based on knowledge or experience of experts or persons performing assessment, such fact should be mentioned).

2. Item-by-item Assessment of Adverse Effect on Biological Diversity

The content of assessment carried out according to the procedure of assessment of Adverse Effect on Biological Diversity as set forth in Table 3 shall be described for each assessment item shown in Table 2. When this is done, sources of information used in carrying out the assessment shall be indicated clearly (if the information is based on knowledge or experience of experts or persons performing assessment, such fact should be mentioned clearly). For any judgment made by a person who performs assessment, the grounds for said judgment should be clarified.

3. Comprehensive assessment of Adverse Effect on Biological Diversity

An outline of the result of assessment for each item of Table 2 and the result of comprehensive judgment that takes such assessment results into account shall be mentioned.