

Supplement 2. Safe Handling of Life Science Experiments

Appendix 2-1 Regarding the [Legislation draft for ensuring biodiversity by regulation of the use of genetically-modified living organisms, etc.]

(1) Background

- In January, 2000, the [Treaty on Biological Diversity, ‘Cartagena Protocol on Bio-safety’] was adopted. The treaty was made to prevent harmful effects caused by genetically-modified living organisms on biological diversity.
- The protocol became effective 90 days after the conclusion of 50 countries signed it. 44 countries and EC (European Community) concluded the protocol on March 4, 2003.

(2) Principal Outlines of the Legislation

1. Purpose of the Legislation

To ensure the biological diversity through international cooperation, the legislation is aimed at retaining the proper and smooth enforcement of the protocol by taking measures regarding the restricted use of genetically-modified living organisms, etc. The legislation will also contribute to the welfare of humankind as well as the security of the people’s healthy and cultural lives both at present and in the future.

2. Declaration of the Basic Issues

The Minister in charge announces the basic issues to the public regarding the use of genetically-modified living organisms, etc. in order to promote the proper and smooth enforcement of the protocol.

3. Procedures for Usage Type 1 (Use without preventing spreading to the environment)

- Those who use Usage Type 1 for making or importing genetically-modified living organisms, etc. and intend to use other Usage Type 1 must submit Usage Type 1 Regulations and receive the approval of the minister in charge before using Usage Type 1. However, the before-mentioned procedure is not necessary when using Usage Type 1 in accordance with the Approved Usage Type 1 Regulations.
- When applying for approval, an evaluation report of biodiversity effects must be attached.
- Regarding the Approved Usage Type 1 Regulations, the minister in charge will announce them.
- Not only those who intend to import from abroad to Japan but other persons who intend to make personal use of Usage Type 1 of genetically-modified living organisms can apply for approval for Usage Type 1 Regulations.

4. Procedures for Usage Type 2 (Use of genetically-modified living organisms and preventing them spreading to the environment)

- Those who intend to use Usage Type 2 must take prevention measures to stop them spreading if

any prevention measures to be taken have been established by the ministry in charge of using Usage Type 2.

- If the prevention measures to be taken have not been established by the ministry in charge of using Usage Type 2, take the prevention measures preliminarily approved by the minister in charge.

5. Inspection of Living Organisms Imported from Other Countries

- Those who wish to import genetically-modified living organisms that may cause biodiversity effects (unapproved genetically-modified living organisms) and have high risk of being imported without such a recognition must submit a notification to the minister in charge of this matter.
- The minister in charge can order the notification submitter to undergo an inspection performed by either the minister or a person registered by the minister regarding the living organism the submitter imports.

6. Provision of Information

- Regarding the genetically-modified living organisms etc. relating to the Approved Usage Type 1 Regulations, establish [Information for Appropriate Usage] to be delivered to the alienee for appropriate use of Usage Type 1 if necessary.
- When delivering, providing, or relegating the use of genetically-modified living organisms, etc. (exclude the case without established Information for Appropriate Usage by the ministerial ordinance), necessary information must be provided.

7. Procedures relating to Export

- Those who intend to export genetically-modified living organisms, etc. (excluding pharmaceutical products for human consumption and the use of Usage Type 2 by the ministerial ordinance) must notify the importing country.
- Establish rules that prohibit the genetically-modified living organisms, etc. without usage embodiment indication from exporting.

8. Other

- The minister in charge conducts necessary debriefing, on-site inspection, and orders measures to take.
- Establish rules relating to necessary penalties, transitional measure, etc.

(3) Enforcement Date

This legislation shall be put into force as of the date the Protocol becomes effective in Japan.

(4) Reference

- Through the [Koizumi Conception] announced last summer by the then Prime Minister Koizumi for the Earth Summit, the Minister expressed a desire to strive for an early conclusion of the Protocol.

- [Koizumi Conception] (specific actions by the Japanese Government for [Sustainable Development] – toward Global Sharing) 2. Priority Areas and Specific Efforts (3) Today's complacency, Tomorrow's plight – Environment – “Striving for an early conclusion of the Biodiversity Treaty [Cartagena Protocol on Bio-safety]”
- Regarding the basic action plan of the Biotechnology Strategy Seine established in December last year, the overhaul of the Legislation was positioned for an early conclusion of the ‘Cartagena Protocol’.
- Biotechnology Strategy Seine **【Environment / Energy Field (Improve day-to-day life)】** [1] Prevent the harmful effect of Living Modified Organisms on the safety of biodiversity and the environment.
- <Basic Action Plan>
To conclude the [Cartagena Protocol on Bio-safety], an international framework to prevent the harmful effect that Living Modified Organisms have on the conservation of biodiversity and its sustainable use, we must provide necessary domestic law. In addition to this, conduct research developments regarding the method of risk management / risk evaluation to carry out appropriate restrictions relating to the intentional introduction of Living Modified Organisms to the environment. Furthermore, investigate the effect on biodiversity.