

Attention!

Please make sure if there are applicable ABS legislations or regulatory requirements in provider countries prior to your access to genetic resources. The following acts, for example, may be covered by ABS measures in foreign countries:

- To bring an ownerless organism found in natural environment or by the roadside overseas into Japan for research purpose.
- To bring foreign samples of soil or water into Japan for the purpose of a biological survey.
- To receive foreign genetic resources unexpectedly which local research fellows gave you as a gift.
- To purchase commodity products (e.g. food crop) and bring them into Japan as research materials.
- A foreign student brings genetic resources from one's home country into Japan for research purpose.

In terms of risk management, it is strongly advisable to confirm whether samples you have, including those bought or received from distributors or research partners, had been lawfully accessed.

Implementation of the Nagoya Protocol in Japan

ABS Guidelines

Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

Contact details of relevant ministries for the ABS Guidelines

<p>Matters related to : general operation of the ABS Guidelines Ministry of the Environment (MOE) ⁶⁾ Office for Mainstreaming Biodiversity, Biodiversity Policy Division, Nature Conservation Bureau TEL: +1 3 5521 8150 E-mail: bio-abs@env.go.jp</p>	<p>Alcohols and tobacco Ministry of Finance (MOF) ¹⁾ Director (Analysis and Brewing Technology), Taxation Department, National Tax Agency TEL: +1 3 3581 4161 Email: sake.tech@nta.go.jp Tobacco and Salt Industries Office, Planning and Administration Division, Financial Bureau TEL: +81 3 3581 4111</p>	<p>Academic research Ministry of Education, Culture, Sports, Science and Technology (MEXT) ²⁾ Life Sciences Division, Research Promotion Bureau TEL: +81 3 6734 4378 E-mail: life@mext.go.jp</p>
<p>Pharmaceuticals and its equivalent Ministry of Health, Labour and Welfare (MHLW) ³⁾ Planning Unit, Economic Affairs Division, Health Policy Bureau TEL: +1 3 5521 8150 E-mail: bio-abs@mhlw.go.jp</p>	<p>Breeding or its equivalent and food industry Ministry of Agriculture, Forestry and Fisheries (MAFF) ⁴⁾ Environment Policy Office, Policy Planning Division, Minister's Secretariat TEL: +81 3 6744 2017 E-mail: info_abs@maff.go.jp</p>	<p>Mining and manufacturing industries (biochemical industry) Ministry of Economy, Trade and Industry (METI) ⁵⁾ Bio-Business Promotion Office, Bio-Industry Division, Commerce and Service Industry Policy Group, Commerce and Information Policy Bureau TEL: +81 3 3501 8625 E-mail: bio-abs@meti.go.jp</p>

MOE's ABS Website

The Ministry of the Environment has launched the ABS website.

<Contents>

- Introduction to the Nagoya Protocol and the ABS Guidelines
- Reporting procedures under the ABS Guidelines
- Publication of reports based on the ABS Guidelines
- Japanese translations of other countries' ABS legislations for reference
- Related links to ABS information sites



<http://www.env.go.jp/nature/biodic-abs/index.html>



Contact points for supporting ABS preparation

<Academic/Research sector>

ABS Task Force Team for Academia, National Institute of Genetics
 TEL: +81 55 981 5831 FAX: +81 55 981 5832
 E-mail: abs@nig.ac.jp

<Industrial sector>

Japan Bioindustry Association Research Institute
 Consultation Desk on Access to Foreign Genetic Resources
 TEL: +81 3 5541 2731 FAX: +81 3 5541 2737

ABS Guidelines, the domestic measures for the Nagoya Protocol

- Promoting Internationally Reliable Research and Development -

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The ABS Guidelines

Joint Public Notice issued by MOF¹⁾, MEXT²⁾, MHLW³⁾, MAFF⁴⁾, METI⁵⁾ and MOE⁶⁾
* For 1) ~ 6), see p. 4

(Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization)

On August 20 2017, Japan became a Party to the Nagoya Protocol⁷⁾, and its domestic measures “the ABS Guidelines” came into force.

⁷⁾ The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

Please be aware that hereafter a report on lawful access to genetic resources overseas is requested under the Guidelines

in order to increase reliability of the utilization and research activities of genetic resources in Japan through transparent reporting.

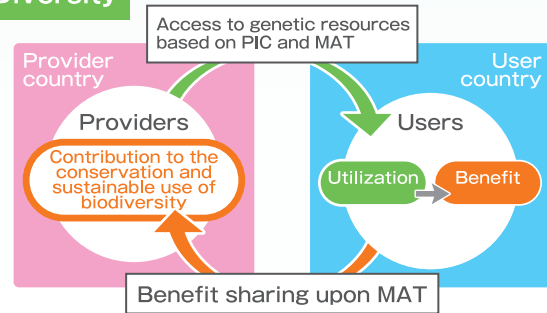
Background on the ABS Guidelines

The Convention on Biological Diversity

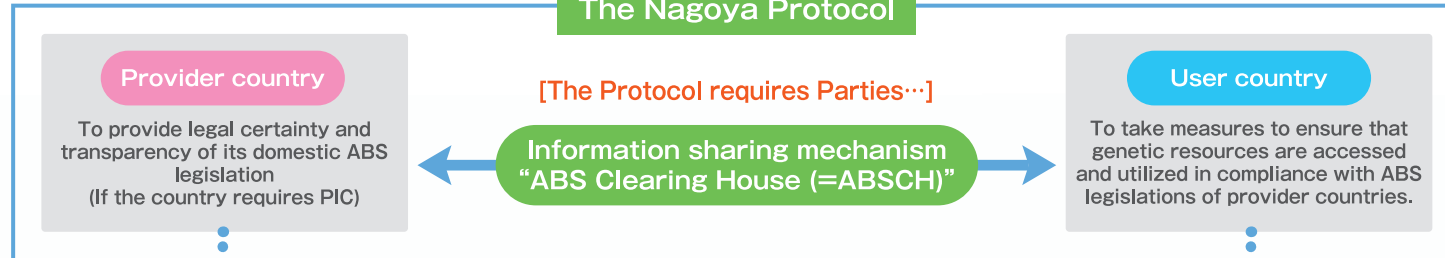
[Basic ABS rules provided in the Convention on Biological Diversity]

- Access to genetic resources shall be subject to PIC⁸⁾ and in compliance with ABS legislation of the provider country.⁹⁾
- MAT¹⁰⁾ with providers is to be established.
- Access to genetic resources and the benefit-sharing shall be upon MAT.

⁸⁾ PIC: prior informed consent
⁹⁾ Not needed if a provider country does not require PIC
¹⁰⁾ MAT: mutually agreed terms



The Nagoya Protocol



The ABS Guidelines (Domestic measures of Japan)

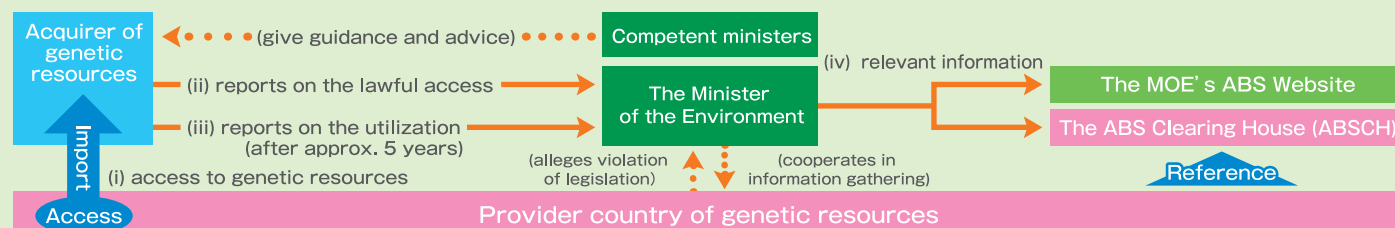
[Provider country measures]

- The Government of Japan does not require PIC for access to genetic resources in Japan.

[User country measures]

- **Reports on lawful access**
 Reports on lawful access are to be submitted if one obtained access to genetic resources in a country, which had made its ABS measures available on the ABSCH. Only such an access whose Internationally Recognized Certificate of Compliance (=IRCC) has been posted on the ABSCH as an evidence of PIC and MAT is to be covered by the reports.
- **Monitoring**
 Users are asked to submit the information on the utilization of genetic resources five years after submitting report on lawful access.
- **Publication of the reported lawful accesses on the MOE's ABS website**
 Information collected through access reports and user reports is to be posted on the MOE's website and the ABSCH.

Operating procedure of Japan's compliance measures



Terms and Scope of the ABS Guidelines

Genetic resources

Genetic material of actual or potential value, where genetic material is material of plant, animal, microbial or other origin containing functional units of heredity

Utilization of genetic resources

To conduct research and development on the genetic and/or biochemical composition of genetic resources

not applicable to

- Information concerning genetic resources (ex. DNA base)
- Synthetic nucleic acids
- Biochemical compounds that lack functional units of heredity
- Human genetic resources
- Genetic resources of a provider country accessed before August 20, 2017
- Commodities purchased not for the purpose of utilization of genetic resources

not applicable to

- Utilization of genetic resources to which the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR-FA) applies
- Utilization of genetic resources specified in the Pandemic Influenza Preparedness Framework (PIPF)
- Incubation, domestication or cultivation.
- Manufacturing products using biological resources as raw materials; adding extract of biological resources, etc.

The Guidelines are not applicable to:

The ABS Guidelines are not applicable to those which fall outside the scope of the Nagoya Protocol.

! Please note:

the scope of access measures of a provider country is not always identical with that of the ABS Guidelines of Japan. Regardless of whether an access to genetic resources overseas falls within the scope of the ABS Guidelines and thus calls for reporting, one should always be in compliance with legislation and regulatory requirements of the provider country, as far as the said access is covered by them.

Reports concerning lawful access and utilization of genetic resources

Report on lawful access

One is to submit a report using Form 1¹¹⁾ when both (i) and (ii) apply:

- obtained access to genetic resources covered by the legislation of the provider country and **imported them into Japan by oneself**
- the IRCC for the said access is posted on the ABSCH.

¹¹⁾ Form 1, 2 and 3 are prescribed reporting forms attached to the Annex of the ABS Guidelines.

Voluntary reporting

One may submit a voluntary report in the following cases, even if (i) and (ii) do not apply:

- obtained a permit or its equivalent in accordance with the legislation of the provider country, but the IRCC for the said access has not appeared on the ABSCH yet (use Form 2)
- received genetic resources in a foreign country from a person, who had acquired them in accordance with the legislation of the country, and imported them into Japan, or received genetic resources in Japan which had been lawfully accessed overseas and then imported into Japan (use Form 1 or 2)

● How to check “legislations in provider countries”:

In the ABS Guidelines “legislations in provider countries” mean domestic legislations or regulatory requirements of a provider country which are posted on the ABSCH.

● Report concerning lawful access to traditional knowledge associated with genetic resources:

Among persons who are to submit a report above, those who obtained access to and imported traditional knowledge associated to the said genetic resources held by indigenous and local communities, one is to report on lawful access to the traditional knowledge as well.

Reports on lawful access are to be submitted to the Minister of the Environment within six months from the date of the publication of the IRCC

<Subject matter>

- The unique identifier of the IRCC (for Form 1)
- Information related to the permit or its equivalent (for Form 2)
- Whether the associated traditional knowledge was accessed based on PIC (or approval and involvement) of indigenous or local communities and establishment of MAT (if applicable)
- Whether the genetic resources are going to be utilized by the reporter oneself or passed on to others etc.

* Information one does not wish to provide to the ABSCH or to the MOE website will be kept confidential.

More information about each Form and reporting procedures are available on the MOE's ABS website: <http://www.env.go.jp/nature/biodic-abs/index.html>

Five years later

Submission of relevant information related to the utilization of genetic resources

<Subject matter> (cf. Form 3)

- A short description of genetic resources concerned
- Situation of the utilization of genetic resources
- Area of the utilization of genetic resources

* Information one does not wish to provide to the ABSCH or to the MOE website will be kept confidential.

Information designated as confidential by the reporter will not be posted on the ABSCH or MOE website.