Japan Bioindustry Association

Domestic Implementation of the Nagoya Protocol in Japan: General Observations and Opinions of Japan's Bioindustry

Submitted to the Japanese Government for "the Amendment to the National Biodiversity Strategy of Japan (Draft)"

In July –August 2012, the government of Japan was seeking public comments on "the Amendment to the National Biodiversity Strategy of Japan (Draft)" which stated that Japan plans to advance the formulation of Japan's domestic measures and aims at the ratification of the Nagoya Protocol (NP) and its implementation in Japan as soon as possible. The ABS Committee of JBA member companies submitted its opinion to the government in August 2012. The following is excerpted from the Committee's opinion.

I. General observations

A diverse range of industry sectors utilize genetic resources (GRs). They create value from GRs in various forms. Industry plays an essential role in generating social as well as economic benefits from GRs.

To access GRs in compliance with the Convention on Biological Diversity (CBD), we have invested the necessary financial, human, and time resources in our activities. We also have been conscientiously complying with the "Japan's Guidelines on Access to GRs for Users" which the Ministry of Economy, Trade and Industry put in place in 2005, in cooperation with Japan Bioindustry Association.

We hope that the government will acknowledge the activities that Japanese companies have been carrying out to comply with the CBD. We will welcome rules that are transparent, consistent, pragmatic, science-based and able to provide sound justification for investment in business. However, the domestic compliance measures under the NP should not impose unrealistic obstacles on research, development and business.

We propose that the government will provide opportunities for dialogue with the bioindustry sector with a view to sharing opinion and experiences, from early stages of the government's policy making process. Such dialogue will be useful in achieving practicable and cost-effective compliance measures under the NP. We look forward to having such opportunities.

Our opinions are given in the following section. We hope that the government will take them into consideration.

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II. Opinions

1. Certainty of measures

- 1) Certainty is essential to domestic compliance measures under the NP. However, there are a number of ambiguous points in major provisions of the NP with regard to their interpretation. This seems to be a major issue not only domestically, but also in other countries. This is an international issue. Under these circumstances, the government should not act too hastily. The government needs to keep track of international trends on this matter carefully, and to bear them in mind when formulating the domestic compliance measures.
- 2) Domestic compliance measures under the NP should be simple and pragmatic so that all the companies utilizing GRs can, regardless of their size and nature of business, comply with the measures without difficulty. Therefore, it is desirable for the domestic compliance measures under the NP to take a form of voluntary system.
- 3) The scope of domestic compliance measures should be clearly defined. For example:
 - a) Domestic compliance measures under the NP should be applicable only to those GRs accessed after the NP has entered into force in the country that provides the GRs.
 - b) Human GRs should be exempt.
 - c) Commodities generally traded in commercial distribution should in principle be exempt. For example, GRs, such as industrial raw materials and agricultural produce that are in general distribution, should be outside the scope of the domestic compliance measures.
 - d) It is important for user countries to verify to what extent the domestic access and benefit-sharing (ABS) legislation or regulatory requirements of providing countries comply with the NP. Depending on the extent of compliance, there may be a need to consider differential treatments for different providing countries. Domestic compliance measures under the NP of user countries should be applicable only to those providing countries whose domestic ABS legislation or regulatory requirements not only comply with the NP (e.g., Article 6.3), but also are made available to the ABS Clearing-house (ABS-CH) (e.g., Article 14.2).
 - e) Domestic compliance measures under the NP should not interfere with domestic intellectual property systems and product licensing systems.
- 4) The government should not force companies to disclose their confidential information in the course of implementing domestic compliance measures under the NP. No disclosure of information besides what is disclosed on ABS-CH should be mandated.

2. Important points to consider when setting up checkpoint(s)

- 1) The objective of checkpoint(s) is to support compliance by taking measures to monitor and to enhance transparency about utilization of GRs (NP Article 17.1). If a checkpoint(s) imposes a heavy bureaucratic burden, the vast majority of honest and compliant GRs users would be victimized because of ill-willed users who are an extremely small fraction of the society. The function of checkpoint(s) should never be a "policing mechanism."
- 2) The establishment of checkpoint(s) means an additional burden for the companies and researchers. Therefore, checkpoint(s) should be a pragmatic mechanism that functions effectively, but should not hinder research, development and business operation. Checkpoint(s) should meet all the points given above (Section 1: Certainty of Measures).
- 3) Checkpoint(s) should constantly study the domestic ABS legislation or regulatory requirements of the providing countries made available to the ABS-CH, and have the capability to make balanced and objective judgments to allegations from providing countries.

3. Simultaneous implementation of "domestic compliance measures" and "measures to facilitate access to genetic resources"

"Domestic compliance measures under the NP" and "measures to facilitate access to GRs" are like the two wheels of a bicycle. Only when the two work together, the bicycle can function properly. By promoting this approach, both providers and users of GRs will benefit, and the ABS system function. The Ministry of Economy, Trade and Industry (METI) has been promoting this approach in cooperation with JBA, since 2005, by implementing, e.g., "Japan's Guidelines on Access to Genetic Resources for Users", "nationwide awareness-raising seminars", "specialized website", and "help desk". Bilateral approach through microbial resource centers has also been beneficial to both providers and users (e.g. research cooperation between the National Institute of Technology and Evaluation of Japan and Asian counterparts). We hope that the government will further reinforce this sort of measures under the NP.

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