Position paper of

Japanese bio-business sector for submission to the WGDSI-2

Japan Bioindustry Association (JBA) Japan Cosmetic Industry Association (JCIA) Japan Pharmaceutical Manufacturers Association (JPMA) Japan Seed Trade Association (JASTA) KEIDANREN (Japan Business Federation)





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Japanese bio-business believes that the conservation and sustainable use of biodiversity is a challenge to be addressed by the international community as a whole, since all societies, including our own, depend on biodiversity. Since DSI and its use is now indispensable for solving these challenges and is also one of important sources of benefit-sharing, we strongly hope that the benefit-sharing mechanism, rather than imposing benefit sharing obligations on specific users, will be designed in such a way as to facilitate the use of DSI, together with physical genetic resources, and to create a broad contribution base by building into the system incentives that are simple, easy to comply with, and ensure legal certainty.

1. General comments on the multilateral mechanism for benefit-sharing from the use of DSI;

We believe that benefit sharing from DSIs should meet the following conditions;

(i) Putting restrictions on the free exchange and use of DSI should be avoided;

In order to create value as a source of benefit-sharing, innovation should not be slow down or stifled. Recent innovations/R&D depend on collecting, exchanging, analyzing large amounts of data and using it as learning material. The free exchange and use of DSI makes this possible. If innovations/R&D are delayed or suppressed by restrictions on the free traffic of information, people/citizens in the world cannot enjoy achievements/fruits that would have been obtained through innovation/R&D in a timely manner. Therefore, any benefitsharing mechanism that places restrictions on the free exchange and use of DSI must be avoided.

(ii) Linking the use of DSI to monetary benefit should be avoided;

Linking the use of DSI to financial benefits not only requires impractical tracking and tracing, but also induces the falsification of (meta)data based on malicious attempt to artificially control benefit-sharing, and may jeopardize the credibility of public databases. This would also lead to putting benefit-sharing obligations only on users of specific DSIs and related technologies, thereby encouraging avoidance of their use, limiting the flow of funds, and eventually impeding bioeconomy-centered social transformation.

(iii) Do not bring bilateral mechanisms into the system;

If bilateral mechanisms are introduced into the system, in addition to the track and trace requirements, there will be a risk of double payments and reduced legal clarity. Many companies, constantly looking for cost reduction and a legally stable business environment, will be forced to spend their valuable efforts on jurisdiction shopping. This is not a world we want to live in.

(iv) The system should ensure legal certainty regarding the fulfillment of benefit sharing obligations and the use of DSI:

We believe that contributions to the fund should be recognized by all countries as fulfilling their benefit-sharing obligations under the CBD, and should provide assurance that there are no other ABS requirements with respect to the use of DSI. This is extremely important for businesses that value legal certainty and could be a strong and essential incentive for voluntary contributions to the fund.

(v) A fair business environment should not be distorted by DSI benefit-sharing schemes: We also compete in some areas with companies that do not use DSI. How can we gain internal understanding of contributions to the fund if it is clear that we are losing business competitiveness to companies which do not use DSI or are outside the benefit-sharing framework, while all companies benefit to a greater or lesser extent from biodiversity? We believe that international efforts are needed to ensure that the implementation of benefitsharing obligations does not unfairly distort the level playing field.

(vi) We call for a transparent management of the fund in coordination with other international ABS frameworks:

We believe that our contributions must be used for conservation and sustainable use of biodiversity. Purposes and plans for using funds shall be clarified, and annual review for status and update of using funds shall become mandatory. We also call for a high level of transparency and international coordination in the management of the fund, as it would be inefficient for other international ABS instruments to establish their own funds and operate under different rules, creating confusion in R&D and risking stacking of benefit-sharing obligations.

2. Specific comments on the "Synthesis of information for the further development of the multilateral mechanism established under decision 15/9, including elements of a draft recommendation" (CBD/WGDSI/2/2)

While Japanese bio-business hopes that the proposals from the CBD Secretariat and Co-Chairs will play an important role in advancing future discussions leading up to COP16, we would like to share some of our concerns:

- 1). The method for determining which products and sectors are subject to benefit-sharing must be based on information that accurately reflects business reality and is easily understood by all potential contributors:
 - The idea of not daring to define the scope of "DSI" or the definition of "use of DSI" may be a compromise to have as many contributors as possible and to minimize each financial burden, but it is not acceptable to impose benefit-sharing obligations on specific products or sectors without defining them.
 - Even if a list of "products subject to benefit-sharing" or "sectors highly dependent on DSI" were somehow created at this moment, such a list would not be future-proof to keep up with future technological developments.
 - If users were required to identify their own products benefiting from the use of DSI, the resulting requirements to track and trace the use of DSI throughout the supply chain will be extremely difficult and virtually impossible to identify.
 - There are many questions about the "sectors with high reliance on DSI" cited as examples; the study report commissioned by the CBD does not provide a clear reason why these sectors were identified. We and other related organizations have pointed out in our peer review of the study report that while the companies comprising the sectors are extremely diverse, it is questionable to identify them as subject to the benefit-sharing obligation on the basis of only a few examples.

2). The method of determining the amount of benefit-sharing must also be satisfactory to the contributors:

- If companies are required to contribute X% of their revenue, depending on the business portfolio, the profitability and/or growth potential of the business concerned, many companies may use the implementation of the system as an opportunity to make a business decision to divest, close or withdraw from DSI-related businesses.
- Given that the average ratio of operating profit to sales in the Japanese manufacturing industry is about 4%, it is clear that if levies were imposed on 1% of sales, there could be significant obstacles to business sustainability or continuity. It is a common perception in the industry that the levy would inevitably be passed on to product prices, which could result in a new inflationary pressure.
- In addition to being a high-risk, high-return business, the pharmaceutical industry is an industry in which it is virtually impossible to pass on the cost of benefit-sharing to the politically determined drug price, as is the case in Japan and many other countries. A levy on sales in such a business model does not take into account the reality of the industry and could threaten the continuity of the business. Further encouraging companies to exit the business of using DSI raises concerns about increasing health security risks in areas such as infectious diseases, where many companies have already exited due to the high business risks involved.

- It is questionable to determine contributors and contribution targets based on numerical data that do not correctly represent the profits generated by the DSI that are subject to CBD benefit-sharing, including sales of products developed using human DSI and that not even using DSI, for example. We are concerned that a system designed using such inappropriate numerical data will lead to over-inflated expectations of benefit-sharing from DSI. We should bear in mind that the Target 19 of the GBF indicates the need to close the financial gap by utilizing all resource mobilization mechanisms, not solely relying on benefit-sharing from the use of DSI.
- **3).** Contributions to the Multilateral Benefit-Sharing Fund should be considered in conformity not only with benefit-sharing obligations from DSI under the CBD, but also with the requirements of countries with relevant national laws and other international ABS fora:
 - It is common practice in current R&D today to treat DSI as big data. Grouping DSI of different international ABS instruments treaty by treaty, which leads to fragmentation of DSI, cannot be allowed. All DSI should be treated across treaties and on a unified basis for such purpose.
 - This would not only provide a strong incentive for contributors to the fund, but should also help to avoid stacking of benefit-sharing obligations and promote international collaborative research and co-development projects.

4). Disbursement from the Multilateral Benefit-Sharing Fund:

• Funding will be disbursed on the basis of projects (Option A, Annex para12, CBD/WGDSI/2/2) and should be explicitly used for the conservation and the restoration of biodiversity.