



Dr. Cristiana Paşca Palmer

Executive Secretary

Secretariat of the Convention on Biological Diversity United Nations Environment Programme

413 Saint-Jacques Street, Suite 800, Montreal, QC, H2Y 1N9, Canada

7 September 2017

Subject: JPMA's Comments on Digital Sequence Information on Genetic Resources

Dear Dr. Cristiana Paşca Palmer,

The Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary organization established in 1968, and represents the R&D-oriented pharmaceutical companies in Japan. Counting 72 leading R&D-oriented pharmaceutical companies as members (as of January, 2017), the JPMA is devoted to contribute to the promotion of the health and welfare in the global population through development of innovative medicines prescribed in medical facilities including hospitals and clinics.

As for your invitation for the public to comment on “Digital Sequence Information on Genetic Resources”, we submit our comments especially on the important issues for JPMA's member companies. Your deep consideration on these matters would be appreciated.

1. Legal certainty of the institution

Legal certainty is essential for the implementation of the objectives of the Nagoya Protocol (the fair and equitable sharing of benefits arising from their utilization, the conservation of biological diversity, and the sustainable utilization of their composing elements). These objectives are to be attainable only if the framework of the institution is stable and transparent, and core procedures are clear and effective.

Serious negotiations and discussions were conducted to adopt the Nagoya Protocol, and yet a lot of ambiguity remains. The implementation of domestic measures based on the Protocol in the various countries requires a lot of work as well – many countries have not yet to implement it. Furthermore, in terms of domestic measures and their operation, discrepancies still exist among countries which have already implemented it.

Under these circumstances, expanding the definition/scope of genetic resources under the Nagoya Protocol to include additional digital sequence information may generate further substantial work, detract from legal certainty, and thereby impede access to such information. In addition,

ambiguous obligations based on unclear access and benefit sharing may arise, and thereby the check and monitoring burdens for user countries may increase substantially, or the implementation thereof may become practically impossible. Consequently, there will be a fear that the framework including digital sequence information would be unworkable.

2. Past discussion and present definition

The issue as to whether digital sequence information should be regarded as part of the definition of genetic resources was extensively discussed in the course of negotiations for the Nagoya Protocol; consequently, we have understood that digital sequence information was to be excluded from the definition of genetic resources.

As stipulated in Article 2 of the CDB and referred to in Article 2 of the Nagoya Protocol, the definition of “genetic resources” is “genetic material of actual or potential value” – they are materials of biological origin containing functional units of heredity. Genetic resources mean materials physically containing genes. Therefore, according to the definition of genetic materials, digital sequence information does not fall under the genetic resources defined by the CBD.

3. Influence on R&D

Freely accessible digital sequence information is indispensable for the objectives of Article 12 in the CBD: the promotion of scientific development in research on biological diversity; the development of programs for scientific and technological education; the promotion of technology transfers; research collaborations; and the development of competency. Accordingly, at least that digital sequence information which is in the public domain should be freely accessible.

In addition, allowing economic compensation for application of such digital sequence information in the public domain is not the intended objective of the CBD/Nagoya Protocol, but rather hinders the application of digital sequence information in the public domain which would otherwise enable scientific and technological development.

4. Conclusion

As mentioned above, expanding the definition of genetic resources to include digital sequence information detracts from the legal certainty of the Nagoya Protocol. Furthermore, through extensive past discussions, digital sequence information should not be added to the definition/scope of genetic resources and is irrelevant to the objectives of the CBD. Accordingly, we can't escape the conclusion that further discussion on digital sequence information is unnecessary.

Very truly yours,

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