Personal Care Products Council
Committed to Safety, Quality & Innovation

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Ms. Cristiana Paşca Palmer, PhD
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, QC, H2Y 1N9, Canada
via email: secretariat@cbd.int

Dear Dr. Palmer,

On behalf of the U.S. Personal Care Products Council (PCPC) I am pleased to share with you the following comments regarding the inclusion of the use of digital sequence information, also known as genetic sequence data (GSD), on genetic resources (DSI) under the provisions of the UN Convention on Biodiversity.

PCPC is the leading national industry association representing the cosmetics and personal care products industry in the United States. Our organization has over 600 member companies, including all major global brands, as well as many small and medium sized companies that manufacture and distribute finished products, and suppliers of ingredients and raw materials used in the production of finished products. Our member companies consistently strive to uphold and surpass the most stringent regulatory and product integrity standards worldwide.

As you may know, our organization has been actively engaged in matters related to the UN Convention on Biodiversity and the Nagoya Protocol on Access and Benefit Sharing for a number of years. We find that, overall, the lack of clarity and continued ambiguity around many of the concepts and definitions in the Nagoya Protocol (NP) has led to differing interpretations and implementing policies around the world. This has created a great deal of confusion and uncertainty in the business community, creating disincentives for R&D on genetic resources (GR) and, ultimately, undermining innovation and sustainable development. We believe that the inclusion of Digital Sequence Information (DSI) into the concept of GR would be inconsistent with the spirt of the CBD and Nagoya Protocol, and would hamper further the continued sustainable use of GRs.

Furthermore, we believe that a single umbrella policy to cover all situations where DSI may be used would be unrealistic in light of the very complex nature of the issues; rather, we believe treatment of DSI would be more appropriately considered as part of individual Mutually Agreed Terms (MAT).

Utilization

Guidance on how to interpret R&D with respect to DSIs should be consistent with current definitions, and we can refer to the definition of utilization in Article 2 of the Nagoya Protocol:

"Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention."

Given this definition, it is important to acknowledge that research and development is more than just gathering knowledge or merely describing (certain) features of the genetic resource; it requires further use (developed) from that knowledge. Creating knowledge or insight into characteristics of potential benefit (research) is not complete utilization of the genetic resource.

Genetic resources are often used for a multitude of experimental studies. However, most of these studies do not target the genetic and/or biochemical composition of the genetic resources. The ABS monitoring process should only focus on R&D that is conducted on the genetic and/or biochemical composition of genetic resources and should not apply to other cases.

Most consumer products companies utilize GRs sourced from suppliers, and are not typically involved in bioprospecting. Suppliers have proprietary and complex supply chains. How they may or may not use DSI in their research may also be proprietary, and not transparent to companies that manufacture with their ingredients.

Derivatives and Digital Sequence Information (DSI)

Under the Nagoya Protocol, "derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Derivatives are therefore understood to be the extraction products of genetic resources or part thereof, or products produced and secreted by genetic resources, like proteins, lipids, enzymes, RNA or organic compounds like flavonoids, oils or resins. DSI is simply data that results from research on a GR. Sequencing a GR for the purpose of taxonomic classification is commonly shared on public databases, and utilized for other research purposes. DSI is not a derivative according to the definition of the NP; it can be accessed and utilized without accessing or utilizing the GR, much in the same way that a synthetic compound based on structural information from a scientific journal does not require access to a genetic resource or its derivative.

Compounds that do not occur naturally as a result of the genetic expression or metabolism of a GR, but which occur as a result of human intervention, are also not derivatives under the Protocol. This applies to "unnatural" natural products obtained through the metabolism of

organisms specifically designed (engineered) to produce certain, sometimes novel, ingredients. In order to avoid hindering innovation and new ingredient development, it is important to not place roadblocks to using DSI.

Take the fact that there are approximately 500 million whole genome sequences in GenBank alone. Researchers across a wide variety of sectors access this information daily when designing assays, confirming taxonomic identity, discovering genetic pathways, and creating hypotheses and new insights through the comparison of a multitude of sequences. This type of open sharing of scientific data is one of the key driving forces of science and innovation. However, none of this research utilizes the material or biochemical composition of the material.

Conclusion

Engineered microbes are now routinely used to synthesize a variety of cosmetic, food and pharmaceutical ingredients. Sourcing these ingredients from nature, rather than via fermentation, is not necessarily more consistent with the objectives of the CBD. In fact, in many cases, developing alternatives via fermentation may be a more advantageous conservation strategy.

In light of the points we have raised above, we believe that requiring Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) on the use of publicly available DSI would make the utilization of this information extremely difficult.

Once again, thank you for allowing us the opportunity to share these comments. We hope that our viewpoints will serve to inform your deliberations on this matter.

Sincerely,

Francine Lamoriello

Francine Lamoriello
Executive Vice President
Global Strategies