LACTIC ACID BACTERIA INDUSTRIAL PLATFORM

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Cristiana Paşca Palmer, PhD
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, H2Y 1N9
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Re CBD Notification 2017-104 - Contribution to the first Assessment and Review of the Effectiveness of the Nagoya Protocol

Dear Dr. Palmer,

The Lactic Acid Bactria Industrial Platform has with great interest followed the preparation of the Nagoya protocol for benefit sharing of indigenous genetic material and the on-going work on implementing the provisions of the Nagoya Protocol in EU and national legislation.

The Lactic Acid Bacteria Industrial Platform (LABIP; www.labip.com ) is the industry platform for European Union-sponsored research programs on Lactic Acid Bacteria "LAB". LABIP is a European Economical Association, founded in 1994. The current 21 members of LABIP represent companies that produce or use LAB and have production or research facilities within the EU. One of the aims of LABIP is to coordinate communication about topics of industrial relevance between academia, industry and EU authorities. LABIP was organizer and sponsor of the expert workshop "Future access and improvement of industrial LAB cultures" held in Amsterdam NL in May 2017. At this expert workshop the conditions and practical implications with regard to the legal implementation of the provisions of the Nagoya Protocol were discussed.

Industrial fermentations based on micro-organisms such as the lactic acid bacteria (LAB) play an important role in several industries globally and represent an extremely important businesses. LAB provide a natural way to produce safe, sustainable, and environmentally friendly products for a variety of industries. LABs are used in the production of a large variety of fermented foods including cheese, yoghurt, sauerkraut, pickles, sausages, as well as in the production of animal feed (silage).

Industrial production of these products has been based on the use of commercially produced starter cultures for more than a century. Product innovation is a key requirement for these industries to survive and grow globally.

The intentions of the Convention on Biological Diversity "CBD" and the Nagoya Protocol are considered valid and are fully supported by LABIP. However, as will be described below, there are a number of uncertainties about the interpretation of this protocol. The challenge is to ensure benefit sharing without removing the incentive for industrial use of the microbial/bacterial genetic resources; otherwise, there will be no benefit to share. E.g. it is tempting to source strains from countries which do not exert their sovereign rights and consequently would not require benefit sharing. This is the exact opposite effect of the intentions of the CBD and the Nagoya Protocol but is feasible due to the wide geographical distribution of most bacteria.

LABIP finds that implementation of the Nagoya Protocol raises a number of questions:
1): A precise definition of 'utilization' is required to allow an unambiguous determination of when the conditions of the Nagoya Protocol are to be invoked. If these are invoked too early in a project, the regulatory burden may keep companies from exploring resources from (microbial biodiversity-rich) provider countries. This is especially relevant in screening campaigns of large numbers of strains.
2) The establishment of which country has sovereign rights over highly mobile genetic resources such as bacteria and bacteriophages is a concern, especially considering the tenet that 'Everything is everywhere, but, the environment selects' first formulated by the microbiologist Baas Becking in 1934.
3) There is the question of *in silico* descriptions of genetic materials which can be analyzed without access to the genetic resource itself but which form the basis of much of modern biotechnology. Defining 'sovereign rights' can be difficult, especially considering that gene sequences exist for (micro)organisms which became extinct far before any of the current national boundaries were established.

LABIP will in this context recommend to the Secretariat of the CBD that the Nagoya Protocol should encourage the use of microbial genetic resources from provider countries, not restrict it. This calls for a pragmatic approach where the efforts required to obtain PIC and MAT are proportional to the value of the immediate foreseen benefits. Otherwise there will be no benefit to share.

A number of specific recommendations were formulated by LABIP at the expert workshop for your considerations:
1) Industry, academia and regulatory bodies should work together to share 'best practice' solutions;
2) Precise definitions of terms like "utilization" and "research and development" are required so there is regulatory certainty about what is included and what is excluded from the Nagoya Protocol; in addition, precise definitions are an important prerequisite for moving towards harmonized Access and Benefit Sharing (ABS) legislation among provider countries across the globe.

3) Screening of a large number of microbial strains to find a few candidates with specific characteristics should be excluded from the scope of the Nagoya Protocol and of national ABS legislation, as the regulatory burden is disproportionately high; research and product development activities on the few selected candidates from a screening campaign should remain in scope, as there is a reasonable chance of commercial valorization;
4) Research using digital sequence information should remain outside the scope of the Nagoya Protocol and national ABS legislation, as it would be a daunting task to obtain PIC and MAT for all relevant sequences in a database such as GenBank. Public sequence databases were created with the express ambition of openly sharing, accessing and using such data, for users in developed and developing countries alike;
5) The human microbiome should be specifically excluded because it is not considered ethical for any government to have sovereign rights to such an important element of human physiology. This also avoids questions of ownership and 'nationality' of a microbe as people travel around the world and the microbe moves from the human body into the environment.

LABIP hope that the above comments and recommendations will be included in the future work on implementing a fully practical and operational Access and Benefit Sharing legislation as per the intentions in the Nagoya Protocol.

Best regards

On behalf of LABIP
Esben Laulund Chairman
Aat Ledeboer Secretary