From: Jane Theaker [mailto:Jane.Theaker@LGCGroup.com]
Sent: July 5, 2017 4:41 AM
To: secretariat; United Kingdom of Great Britain and Northern Ireland - Ms. Holly Kelley-Weil; rmann@bioindustry.org
Cc: Julian Braybrook; Derek Craston
Subject: Nagoya Protocol-LGC comments

To whom it may concern,

Regarding the Nagoya Protocol,

LGC is very much in agreement with the principles outlined in the Nagoya Protocol. In summary, the Nagoya Protocol establishes a regulatory framework for how users of genetic resources and/or traditional knowledge associated with genetic resources can obtain access to such resources and knowledge and how the benefits arising therefrom should be shared. We see the protocol as supporting biodiversity and the resultant benefits to mankind not only now but for future generations.

We do have a comment regarding genetic information which is *already* available on public databases or already published, for the mutual benefit of mankind. We see availability of these publically available sequences to research and commercial scientists as being crucial for supporting scientific research. For example, these databases and publications are widely used in the development of new diagnostic tests against pests and diseases or, in the development of novel reagents used in molecular biology.

There is, therefore, a challenge in balancing the need to ensure biodiversity and the needs of society to benefit from new scientific advances. These needs are equally important and both are long term needs.

We consider that any publically available sequences, whatever their provenance or derivation which have been purposefully placed in the public domain for the benefit of all mankind, should remain free from regulation by the Nagoya protocol. It is well accepted that anything which is publically published falls outside of patent rules regarding novelty and inventive step and therefore would not in itself be patentable. Therefore, publically available sequences could not be commercially patentable.

In addition, there are practical difficulties in terms of the provenance of the data submitted to public databases. So, for example, data may be submitted which is artefactual of the sequencing and laboratory techniques used or may be derived from a cocktail of micro-organisms. The subsequent uses of these publically-available databases is also complex to police. So for example these databases may be used by research students to understand malaria better by studying mosquito genetics. Or these databases may be used by commercial AgBio companies wanting to breed drought tolerant plants. In which case, the commercial value which can be assigned to understanding the “wildtype” plant versus the “novel breed” plant may be hard to assign.

In summary, LGC support the principle that once a sequence is publically published, that information is available for the benefit of all mankind and this benefit is as important as ensuring biodiversity.

In addition, LGC consider that it would be useful to provide clear and precise guidance on:

- The implications of the Regulation for users, particularly researchers, to help ensure their fulfilment of obligations. For example, there has not been agreement at an international level on the definition of a Genetic Resource. Any potentially useful genetic material that contains functional units of heredity, including sequenced data, might be included here.

- what constitutes due diligence in various circumstances

- clarity on collaboration with organisations operating in states that are not signatories to the Nagoya Protocol. After all, it is only possible to control physical access to a Genetic Resource. The rapid sharing of sequence data is essential in the fight against infectious disease outbreaks, the monitoring of drug resistance and other matters of international public health importance. There may, justifiably, be a concern that the Protocol might introduce regulatory hurdles that could inhibit an ability to take part in national or international collaborative research efforts to address these issues.

- how to determine the country of origin or the owner of a genetic resource.

We would like to make the suggestion that this guidance be developed in partnership with users and other stakeholders, and even in collaboration with other EU Member States (assuming continued implementation of the Protocol beyond Brexit).

Jane Theaker

Jane Theaker | VP Science and Technology Development | Genomics |

LGC | Darwin House | Faraday Street | Birchwood Park | Risley |Cheshire | WA3 6FW | UK |

Tel: + 44(0)1925 248826 | Mob: +44(0)7408 813506

Jane.Theaker@lgcgroup.com | www.lgcgroup.com | www.biosearchtech.com | www.douglasscientific.com |

Now incorporating Douglas Scientific and Biosearch Technologies