

DEFRA CONSULTATION ON IMPLEMENTING THE NAGOYA PROTOCOL IN THE UK

RESPONSE BY THE BIOTECHNOLOGY AND BIOLOGICAL SCIENCES RESEARCH COUNCIL (BBSRC)

April 2014

KEY POINTS

- BBSRC's primary concern is that implementation of the Nagoya Protocol and associated EU Regulation should not interfere with, or unreasonably restrict, access to biological / genetic material for research purposes.
- The plans for UK implementation as set out in the consultation document appear appropriate, and the 'due diligence', rather than prohibition, approach to compliance is welcomed.
- It is imperative to clarify the scope of all the groups that could potentially be 'at risk' of non-compliance under the EU Regulation linked to the Nagoya Protocol if they fail to register and exercise 'due diligence'; clarification is still needed on some of the terms used in the protocol, such as whether the definitions of '*Biological resources*' and '*Biotechnology*' extend beyond the physical genetic material to genetic sequence information.
- It is essential that clear information and guidance is available to UK research organisations and individual researchers. Defra and the NMO should work with research communities to raise awareness of researchers' obligations under the Nagoya Protocol, and in particular should seek to identify those communities that may be less familiar with the principles of Access and Benefits Sharing (ABS).
- In addition to the points above, BBSRC agrees with and supports the key points raised by other Research Councils.

INTRODUCTION

1. BBSRC welcomes the opportunity to respond to Defra's consultation on implementing the Nagoya Protocol in the UK.
2. BBSRC is the UK's main public-sector funder of academic research and training in the non-clinical life sciences. BBSRC funds world-class bioscience research in universities, institutes and centres, addressing major global challenges such as food security, infectious disease, sustainable energy/chemicals and maintaining health throughout life; much of this research is dependent on access to animal, plant or microbial genetic material. BBSRC also provides some funding for the development and / or maintenance of biological resources and culture collections for the use of the bioscience research community. Implementation of the protocol and associated EU Regulation will therefore have significant implications for the research, researchers and resources funded by BBSRC.
3. BBSRC's primary concern is that implementation of the Nagoya Protocol and associated EU Regulation should not interfere with, or unreasonably restrict, access to biological / genetic material for research purposes.
4. It is important that the UK continues to be part of the decision-making process for the further development of the Protocol, and that any further developments do not inadvertently create unnecessary barriers to research or to international research collaboration.

SPECIFIC COMMENTS IN RELATION TO CONSULTATION QUESTIONS

5. BBSRC is broadly content with the proposals for implementation, and is supportive of the adoption of a due diligence, rather than a prohibition, approach. The measures as set out in the consultation document appear appropriate in providing a monitoring and reporting system but with the necessary sanctions required to meet the serious issues of non-compliance.
6. The provision that allows for users obtaining a genetic resource from a collection with 'registered collection' status to be automatically considered to have exercised due diligence is particularly welcomed, as this will greatly assist institutions and recipients of genetic materials from such collections in meeting the requirements.
7. BBSRC notes that the continuing use of any material accessed before the Protocol comes into force for the EU is out of scope, and considers it important that this remains the case. The burden on the academic research community if the regulations were to be applied to previously accessed material would be significant, and would undoubtedly be detrimental to on-going research.
8. In raising awareness and providing guidance to the research and commercial communities it is now imperative to clarify the scope of all the groups that could potentially be 'at risk' of non-compliance under the EU Regulation linked to the Nagoya Protocol if they fail to register and exercise 'due diligence'. There is still a lack of clarity over some of the terms and definitions used in the protocol which continue to be a cause for concern when considering issues of IP decision making and possible commercialisation. The most notable being associated with the definitions of '*Biological resources*' which refers to 'genetic resources, organisms or parts thereof' and '*Biotechnology*' which refers to 'technological application that uses biological systems, living organisms, or derivatives thereof' as set out in article 2 of the Convention on Biological Diversity. If this extends beyond the physical genetic material to genetic sequence information, the scope of the Nagoya Protocol and compliance issues could extend to include synthetic biologists, which would have significant research and IP implications. Seeking independent legal advice on this issue as well as through the Governing Body would be a worthwhile exercise.
9. In response to Q9, BBSRC would urge the rapid development of the proposed web portal for provision of guidance and information, as well as significant awareness raising on the part of Defra and the NMO, in what is set to be a very active discussion phase where institutions will be looking to put in place revisions to their codes of best practise and Standard Operating Procedures on sourcing genetic resources to ensure that both the individuals and institutions are compliant with the Nagoya Protocol.
10. During implementation, and in developing guidance, Defra and NMO should be mindful that research communities will likely differ in their familiarity with the CBD and the issues of ABS surrounding the Nagoya Protocol. For example:
 - the proportion of the UK plant science community that works with crop genera falling under the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) should be well aware of the importance of keeping of Material Transfer Agreements (MTAs) and benefit sharing (although the compliance issues relating to the Nagoya Protocol will increase the need for due diligence and record keeping for those using genetic materials even when sourced via the ITPGRFA standard MTA).
 - Plant science communities dealing with materials not covered by the ITPGRFA may be less familiar with the issues surrounding the need for 'due diligence' and record keeping and the implications for future funding unless they are directly involved in sourcing material in third party countries.
 - The microbial science community - particularly that portion dealing with actinomycetes and antibiotic discovery – has high awareness that work needs to be conducted with amenable countries with appropriate permissions.

11. Defra and the NMO should also work with funders of research to ensure that the processes involved in confirming compliance are compatible with grant-awarding processes. BBSRC would be pleased to participate in any such discussions.

*BBSRC
April 2014*