NAGOYA PROTOCOL

Nagoya – should UK remain a member? If so, what needs to change?

Summary
The Nagoya Protocol to the Convention on Biological Diversity (CBD) is well-intentioned, but not well-balanced. It obstructs important research on genetic resources, so work on crucial topics such as human health and food security is complicated, delayed or does not happen. It needs to be interpreted and enforced in a way which gives proper weight to all three objectives of the the CBD, as well as to other important public policy objectives. The EU regulation that applies it fails to do this. Therefore, on Brexit, **it must not be transposed unchanged into UK law.**

History
The CBD[1] was negotiated and signed in 1993, in order to safeguard biodiversity. Nearly all countries are members, with the significant exception of USA. This gives important benefits to the USA (noted later).

It has three objectives (set out in Article 1):
- to conserve biodiversity
- to promote its sustainable use
- to share equitably the benefits resulting from such use.

It pursues these objectives by '*reaffirming*' (Preamble) that member states '*have sovereign rights over **their own biological resources***'. Article 15 recognises that '*access*' to genetic resources (GR) is controlled by '*national governments*' (CBD members: i.e., Parties). It relates to the provision of GR by national governments - Parties to the CBD - where those Parties are either '*countries of origin*' of that GR, or have received them under CBD agreements from other Parties. Parties are to facilitate access to GR – for '*environmentally sound uses*'. Access is subject to '*prior informed consent*' (PIC) from the 'provider country', and is to be on '*mutually agreed terms*' (MAT) which may include any conditions acceptable to both provider and recipient.

Two difficulties immediately arise. 1.What is 'access'? 2. Which GR is the provider country's 'own'?

Take the latter first. Is mere presence of a GR in a country sufficient to make that GR the country's 'own'? No doubt it is sufficient to give the country 'sovereign rights' over the GR, in the sense of the ability to control what happens to it while it remains in the country (including the power to control export). However, sovereignty (unlike ownership) ceases at national borders. Article 15 gives two classes of GR which the Party may control access to – GR for which it (Party A) is the 'country of origin' and GR which it has received from another country (Party B) under a CBD agreement. It seems implausible to regard the latter GR as the 'own' GR of Party A - so it is reasonable to assume that only GR for which Country A is the 'country of origin' is Party A's 'own'. 'Country of origin' is defined in the CBD (Article 2) as "*the country which possesses those genetic resources in in-situ conditions*" (e.g. growing wild). A Party is clearly entitled to control 'access' to a GR growing in its territory in the wild as long as it remains in that country.

But, now, what does 'access' mean? One simple interpretation is 'physical access'. If you have in your possession a sample of a GR, you have the physical access that enables you (within broad limits) to do what you like with it. If you do not already have a sample in your possession, you may need to negotiate with a 'provider country' to provide you with one, subject if required to PIC from that country and MAT.

Another interpretation is 'legal access'[2]. According to this, the owner of a GR sample has no inherent right to

1 Available at https://www.cbd.int/convention/text/
2 See discussion of 'Legal access' in http://webarchive.nationalarchives.gov.uk/20140603093549/http://www.ipo.gov.uk/ipreview-c4e-sub-roberts.pdf

do anything with it that has not been (specifically or by clear implication) approved by the 'provider country' that previously possessed it. This interpretation is favoured by most developing countries. Under it, any new research on a GR may first require the specific formal approval of the country providing it. And if in the course of such approved research a new line of inquiry opens up, a new negotiation for PIC and MAT is required. For more discussion contrasting 'physical' with 'legal' access, see https://www.publiceye.ch/fileadmin/files/documents/Biodiversitaet/The_two_worlds_of_Nagoya_11-16.pdf .

A third question is often raised. What happens where two or more countries have identical GR? Who controls that? The answer (probably – this is not necessarily agreed) is that each country controls that GR of which it is the country of origin. That other countries have rights in GR of similar or identical structure is not relevant. The right arises from derivation, not from identity alone – so it is analogous to copyright, rather than an absolute right in a particular structure, such as a patent might give. Of course, where several countries may be the source of widely distributed GR of the same or similar structure, finding out who controls rights in a particular sample may be impractically difficult.

Why Nagoya?

When the CBD came into force, it was hoped that considerable benefits would flow to less-developed countries that were economically poor but rich in biodiversity. Disappointment that this was not happening led to the Nagoya Protocol, emphasising the 'equitable sharing' objective of the CBD. The Protocol was negotiated in 2010 and came into force on 12 October 2014 when 50 countries had ratified it. The EU is a member, and the UK has also ratified in its own right.

Nagoya controls research with GR. In principle, doing research (at least with a view to development) on a GR requires PIC and MAT from the 'provider country', in accordance with the CBD, if the 'provider country' asserts its rights (Many Nagoya members, including the UK, do not). Nagoya is weighted heavily towards countries who provide genetic resources. It does nothing directly to conserve biodiversity or to promote its sustainable use. It may well cut back the benefits to provider countries that it aims to increase.

EU Regulation 511/14

Nagoya is currently enforced throughout the EU by EU Regulation 511/14[3]. This is over-prescriptive in two respects. First, it fails to balance the third CBD objective of benefit-sharing with the other two. Secondly, it disregards all other important objects of public policy. These include research freedom in general; and in particular easing research on vital objectives such as human health and food security. Even so, it does not meet the full aspirations of developing countries to control GR research.

In principle, the Regulation takes the view that 'physical access' is what Nagoya controls. Thus, under the Regulation, samples of GR received by a researcher before the operative date (which is set at one year after Nagoya came into force, so 12 October 2015) are not controlled. However, 'research' on GR samples accessed after that date is strictly controlled. Before commencing 'research', the researcher must use 'due diligence' to satisfy himself that the GR has "been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements" of the 'provider country' and that (if required) there are benefit-sharing arrangements in place (Regulation Article 4.1). Note the use of the passive tense – it is not only the access of the enquiring researcher that is in question, but of all in the chain of ownership of the GR (back until 12 October 2015, apparently). Declarations of 'due diligence' are required at two points: when a researcher has received research funding (public or private) for work on the GR (Regulation Article 7.1) ; and "at the stage of final development of a product" resulting from the research (Art 7.2).

'Due diligence' requires either a formal certificate regarding the resource from the 'provider country' as filed with the Access and Benefit-sharing Clearing House(ABSCH)[4] of the Nagoya Protocol; or (if, as most often[5],

3 http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0511&from=EN

4 At https://absch.cbd.int/

5 On 31 May 2017, the ABSCH site listed only 52 such certificates – 47 of which were issued by India.

there is no such certificate) the researcher must 'seek, keep and pass on to other [researchers]' 'information and documents on' when and where the GR was accessed; a description of the GR; the direct source; presence or absence of conditions on benefit-sharing; etc.

These requirements are dauntingly complex. They are far too broadly framed. They should have been designed to control the activities of researchers seeking GR samples from **within** countries claiming rights in their resources. As it is, nearly **all** GR first accessed after 12 October 2015 requires 'due diligence' – even if it is native to, and accessed in, a country such as UK where no such rights are claimed. There are some narrow exceptions, but these are quite inadequate. For example, Art 4.8 of the Regulation provides that if the GR is implicated in a grave public health threat, research may be started before the requirements are met: but if formalities are not completed within three months, such (potentially essential and life-saving) research must stop! Three months is too short to agree PIC and MAT – often it is not enough even to find out who has authority to make such agreements[6]. In some cases countries have simply refused any access. The government of Indonesia invoked "viral sovereignty" in order to deny access to a new strain of avian influenza (H5N1) virus that was first detected in that country[7]. More general concerns have been expressed about monitoring and treating of infectious disease (for example by the Welcome Foundation, see footnote 6).

A Regulation so complicated and all-embracing must put researchers off. To be confident of operating legally, one will need frequent and expensive legal advice, and often expensive and protracted investigations of the history of specific GR samples – and in many cases undertaking difficult and lengthy negotiations with a 'provider country' to obtain necessary permissions. This will only be practical for the largest international organisations. Even they may not consider seeking such permissions worthwhile where they judge a particular GR unlikely to lead to a commercial product. For many SMEs and academics, the only practical option will be to avoid many areas of GR research.

The Regulation fails in two important respects. It discourages extending uses of GR, in direct opposition to two of the three objectives of the CBD. Making research more difficult frustrates the development of new uses for GR. And fewer new uses mean fewer benefits to share. It also seriously interferes with other legitimate objects of public policy. It inhibits important research, for example on public health and agriculture. It limits the freedom to do many kinds of research – which should not be curtailed without clear need. *"The inescapable conclusion is that the regulation will hamper research in the EU, while producing little concrete benefit for the countries of origin"*[8]

What should be done?

Regulation 511/14, in its current form, **should not remain part of UK law**.

Should the UK also leave Nagoya?

A case could be made that the UK should leave Nagoya. It brings no clear benefit for UK citizens. While nearly 100 other countries are members, there are several significant countries who have not yet joined. Australia and Brazil have signed but not so far ratified; Canada has not signed; USA has not signed Nagoya or ratified the CBD. The consequences for the USA of not being bound by the CBD or Nagoya are that companies working in the USA are free to develop new products without the constraints of either. They are then free to sell these products around the world without restriction - even into countries bound by the CBD

6 According to the Wellcome Trust [September 2014, quoted in *Nature,* http://www.nature.com/news/biopiracy-ban-stirs-red-tape-fears-1.16028], "The protocol has the potential to hamper disease monitoring. Red tape could make it harder to quickly share samples across borders, which in turn could cripple efforts to monitor drug resistance in malaria, for example, or outbreaks of *Escherichia coli*."

7 See https://academic.oup.com/heapol/article/25/6/476/583821/Haggling-over-viruses-the-downside-risks-of ; also http://www.tandfonline.com/doi/abs/10.1080/09512748.2014.909523

8 Smyth D, https://www.chemistryworld.com/opinion/we-need-to-talk-about-nagoya/7408.article

and Nagoya, where carrying out the original research would have been illegal without PIC and MAT.

Another possible drawback of Nagoya has recently emerged. Provider countries are pressing to extend the obligations of Nagoya to cover not only research on samples but also use of published information derived from such samples (in particular, DNA sequences published in databases). This demand, if agreed, would alter the whole basis of the CBD. No longer would CBD control use only of physical samples, but also of derived published information – *in perpetuity*!

It is often alleged that developing country members of Nagoya, rich in GR, will be unwilling to make their GR available to non-member countries, so that leaving the Protocol would disadvantage UK researchers. However, it seems likely that most such countries overvalue the financial benefits obtainable from their resources, as well as underestimating the difficulty and cost of realising these. If so, any losses to the UK could be small. Where valuable resources were identified, it would still be possible for special agreements to be negotiated that would benefit all parties.

However, on balance, it does not seem advisable to leave Nagoya. Politically it would be difficult. If done now, it might complicate Brexit negotiations. Developing countries set great store by Nagoya. It is seen, perhaps wrongly, by other countries, and by much of the British public, as an agreement important for the environment. Also, to get full benefit from leaving Nagoya, it would probably be necessary also to leave the CBD, which would be even more difficult politically.

What the UK should seek to do – as a long term aim - is to establish a sensible and practicable framework for interpreting and applying Nagoya. This should recognise the rights of 'provider countries' to control 'their' genetic resources (that is to say, samples of resources for which they are the 'country of origin') *while those samples are within their boundaries*. 'Sovereignty' applies within national boundaries, not worldwide. Once such GR was outside these boundaries, the rights of 'provider countries' would be limited to enforcing contractual terms against parties with whom they had made access agreements. Breach of such terms – or exporting GR in defiance of local laws - might also be offences against the laws of 'provider countries'. The duties of other countries should be limited to requiring nationals not knowingly 'utilising' GR which had been exported from a 'provider country' illegally or passed to them in breach of an access agreement. But in general there should be no duty of 'due diligence' to determine if GR had been 'legally accessed', in the absence of some reason to suppose it hadn't. This should be combined with appropriate exceptions in cases of need, e.g. for research to combat pathogens.

To introduce a new law in UK conforming with such notions would require new legislation, drafted with some care. It could not be an immediate or short term aim. But relaxing the grip of Regulation 511/14 on UK research is too urgent to wait. On Brexit, the Regulation could be transposed into UK law in the Great Repeal Bill, but with specific exceptions. Thus, Article 4.8 (imposing special requirements on pathogen research) could be omitted, and preferably also Article 7.1, so that any obligation to show 'due diligence' would be deferred until a product was ready for launch. This could be combined with instructing the enforcing agency (NMRO[9]) to concentrate on ensuring that any GR sample collecting in Nagoya 'provider countries' was conducted in accordance with local laws.

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9 https://www.gov.uk/government/organisations/national-measurement-and-regulation-office