Regulatory Policy Committee

Implementing the Nagoya protocol on access and benefit sharing

Department for Environment, Food and Rural Affairs

RPC rating: confirmed as a non-qualifying regulatory provision

Description of proposal

The proposed measure will introduce an enforcement regime, and create the offences and associated penalties, required to implement the Nagoya protocol on the use of genetic resources and associated 'traditional knowledge'. The protocol requires genetic resources to be acquired appropriately (as defined) and ensures that due diligence is exercised in relation to access and benefit sharing at the point of commercialisation of a product derived from genetic resources. This is intended to ensure that areas from which genetic resources originated can benefit from commercial successes, especially where 'traditional knowledge' of the genetic resource helped identify potential applications.

Impacts of proposal

The majority of the costs to business result from compliance with the requirements of directly applicable EU regulations. The Department has estimated the costs of the overall changes and attempted to provide sufficient information to show that the costs associated directly with the domestic enforcement regime are likely to be small, or negligible, in relation to compliance costs.

The Department uses data from the Natural History Museum to estimate the costs of retaining the relevant evidence and making the appropriate declarations at £245 per 1,000 resources acquired. The Department estimates that 556,000 genetic resources are acquired annually by 'public sector organisations' (Natural History Museum – 350,000, botanic gardens including Kew – 130,000, universities and research institutes – 72,000). This produces an annual cost of around £136,000.

Compliance costs will fall on businesses conducting research using genetic resources, such as pharmaceutical and cosmetics companies. The Department uses the costs of compliance with the EU timber regime to estimate a total cost of around £0.3 million each year, across 24 pharmaceutical companies, 16 cosmetics companies and 159 other small firms (such as agribusiness and biotech).

The total cost of protocol implementation is expected to be between £0.3 and £0.5 million each year. These costs are almost exclusively a result of the EU regulation.

The proposal will be considered as a non-qualifying regulatory provision of EU origin for the purposes of the business impact target.

Quality of submission

The Department has provided sufficient information to support their assessment that the proposal does not go beyond the minimum EU requirements.

The assessment as submitted is, however, difficult to follow and fails to respond to the issues raised in a previous RPC opinion. Any published assessment should include a clearer explanation of the types of genetic resources covered and what organisations will need to do differently. For example, it is not clear what the Natural History Museum would need to do differently in relation to the 350,000 genetic resources acquired annually. As with the previous submission, which received a triage confirmation, it remains unclear why the EU timber system is considered a reasonable proxy for the due diligence requirements. It is not possible, therefore, for the RPC to provide a view on whether the estimated costs presented in the assessment are robust. However, the majority of the new requirements would appear to be associated with directly applicable EU regulations, rather than the domestic enforcement regime and the concerns with the scale of the costs of the EU regulations do not affect the assessment of the measure as a low cost non-qualifying regulatory provision under the business impact target.

Any published version of the assessment should also reflect that many of the bodies referred to as ‘public sector organisations’ appear to be caught within the definition of community and voluntary bodies under the Small Business, Enterprise and Employment Act 2015.

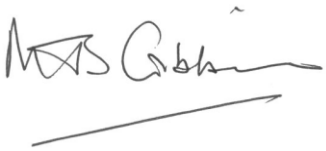
Departmental assessment

Classification	Non-qualifying regulatory provision (EU)
Equivalent annual net cost to business (EANCB)	N/A (fast track non-qualifying regulatory provision)

RPC assessment

Classification	Non-qualifying regulatory provision (EU)

Small and micro business assessment	Not required (fast track low-cost regulation)



Michael Gibbons CBE, Chairman