Regulatory Policy Committee	Regulator	y Triage Confirmation	
Title of regulatory proposal	Implementing the Nagoya Protocol on		
	Access and Benefit Sharing (ABS)		
Lead Department/Agency	Department for Environment, Food and		
	Rural Affairs		
Origin	EU / Domestic		
<b>Expected date of implementation</b>	July 2014 (SNR 8)		
(and SNR number)	, ,	,	
Date submitted to RPC	24/1/2014		
Confirmation date and reference	07/02/2014	RPC14-FT-DEFRA-	
		2009(1)	
Departmental triage assessment	Low cost regulation		
Deposition and all matters and for this are notice.			

## Departmental rationale for triage rating

The Regulatory Triage Assessment (RTA) says that the directly applicable EU Regulation:

"will require EU users of genetic resources and, where covered in the same contract, users of traditional knowledge associated with genetic resources to exercise due diligence when accessing and utilising those resources, to declare this at set points, and to permit checks on their compliance (see supporting evidence section for further details) ... but Member States must perform a number of [additional] tasks such as establishing an enforcement regime, creating offences and setting penalties before the Regulation can take effect. The Nagoya Protocol also contains an obligation for signatories to regulate traditional knowledge associated with genetic resources but acquired through a separate contract ('separate' traditional knowledge). This obligation falls within Member State competence, and must be implemented through UK legislation ... [the proposed Regulation] will carry out both of these tasks."

Business and civil society organisations will be affected by the domestic regulation because it will require that "users of genetic resources and traditional knowledge:

- must exercise due diligence when accessing and utilising those resources.
- must also make a declaration at the point of commercialisation of a product derived from genetic resources (or traditional knowledge associated to genetic resources) that they have exercised due diligence.
- will be subject to compliance checks by an enforcement agency."

**RPC** confirmation

**CONFIRMED** 

Based on the information provided, this appears to be a deregulatory proposal	
Based on the information provided, this appears to be a low cost regulatory proposal	$\boxtimes$
Based on the information provided, this does not appear to be a deregulatory or low cost regulatory proposal	
Based on the information provided it is not possible to confirm the RTA	

## **RPC** comments

The RTA includes a description of the costs and impacts of implementing the Nagoya protocol, including elements associated with the directly applicable EU Regulation. The requirements of the domestic regulation will be a small part of the Nagoya protocol requirements. Following discussions with existing users of genetic resources and 'traditional knowledge' (skills and practices passed on from generation to generation within a community) the Department estimates the overall costs of implementing the protocol, including the directly applicable EU Regulation, to be £475,000 in the first year and £346,000 in each subsequent year. These costs are a result of undertaking and declaring due diligence, and being subject to compliance checks. As the elements relating to the domestic regulation are relatively small requirements, the gross costs can be expected to be less than £1 million per year.

The RTA separates the estimated costs between the public and private sectors. The impacts on some organisations, such as museums, would be more appropriately considered as impacts on civil society organisations rather than the public sector. As such, a higher proportion of the expected costs would fall on business/civil society organisations than is currently estimated in the RTA. Even so, gross costs are still likely to be below £1 million in any year.

Any subsequent impact assessment would benefit from providing a more detailed rationale explaining why the due diligence requirements can be considered analogous to those of the EU Timber Regulation for the purposes of estimating costs.

'One-in, Two-out' (OITO) assessment	Unable to
	confirm

The RTA states that the proposals is out of scope of one-in, two-out as it "is minimum implementation of an EU Regulation and international agreement. There is no 'gold plating' and the requirements are not being introduced early". However, there is not sufficient information presented within the RTA for the RPC to confirm this at this stage. The Department should provide further information, including whether the elements of the international agreement (the Nagoya protocol) that are not included in the EU Regulation

can be considered binding in nature, or whether the decision to implement those requirements should be considered as a domestic proposal. The requirements of the directly applicable EU Regulation will be considered out of scope of one-in, two-out, but any decision to implement other elements of the Nagoya protocol that are not binding in nature may be considered as a domestic regulatory proposal within the scope of one-in, two-out.

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Signed

Michael Gibbons, Chairman