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Department
for Environment
Food & Rural Affairs

Consultation on implementing the Nagoya Protocol in the UK

A summary of responses and the government reply

March 2015

Llywodraeth Cymru
Welsh Government

DOE
Department of
the Environment
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The Scottish
Government

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Introduction

This paper summarises the responses to Defra's public consultation on our proposals for implementing the Nagoya Protocol and associated EU Regulation on Access and Benefit Sharing (ABS) in the UK.

Conducting the consultation exercise

The consultation was launched on Monday 17 March 2014 and closed on 22 April 2014[1]. To raise awareness of the consultation Defra issued an email on the launch date to our internal list of around 70 ABS and Convention on Biological Diversity (CBD) stakeholders providing a link to the consultation document and asking recipients to pass the message on within their trade bodies or other groups.

A recently-concluded project funded by Defra to identify users of genetic resources had produced an index of relevant companies and researchers. The policy team used this index to send out targeted emails raising awareness of the consultation to almost 600 firms in various sectors and to universities.

The consultation received 27 responses from a diverse range of sources (a full list of respondents is available on page 15). On March 12 Defra held a stakeholder meeting in London and via teleconference which was attended by around 30 individuals, some were respondents to the consultation and some not.

Key findings

Responses were analysed and considered by Defra together with the views expressed at the stakeholder meeting and through other communications. On the basis of this analysis and following discussions within Government we have finalised the Statutory Instrument (SI) that will implement the EU Regulation and the Nagoya Protocol in the UK. This Statutory Instrument is the **Nagoya Protocol (User Compliance) Regulations 2015** that was laid in Parliament on 23 March 2015. The Statutory Instrument will be available on www.legislation.gov.uk

Many of the questions raised during the consultation related to issues that are not explicitly addressed in the Statutory Instrument, but will be dealt with through administrative measures including the provision of guidance and through awareness-raising. Further detail on the steps Defra and the National Measurement Office (NMO) will take to ensure users are given the support and clarity they need can be found below.

[1] https://consult.defra.gov.uk/biodiversity/implementing-the-nagoya-protocol-in-the-uk/consult_view

The main change to our proposals in the consultation document is the revised approach to the sanctions regime. The new sanctions regime ensures that **only civil sanctions are available in the first instance for non-compliance with obligations related to due diligence**. Criminal sanctions will only apply to a failure to comply with either a stop notice or compliance notice (both civil sanctions). This addresses any residual uncertainty, as the regulator would have to specify in the stop notice or compliance notice what action the user is required to take, so the obligation will have been clearly established and the user given an opportunity to comply. We do however see the case for **going straight to criminal sanctions for offences which would undermine the enforcement of the regime**, such as obstructing officers exercising powers of entry/powers of inspection or failure to retain information. This is a common feature of other regimes and when such offences are committed it is sometimes necessary to go straight to criminal sanctions as civil sanctions would not always be an adequate remedy.

Another key decision to come out of the Consultation is that the **level of Variable Monetary Penalties in the Statutory Instrument will be unlimited** and not capped at £250,000. Placing a cap on the level of these penalties undermines the approach to link the fine to any potential benefit gained through non-compliance (which could in extreme circumstances be more than £250,000).

Responses to the consultation have confirmed the other proposed approaches, for example there was extensive support for the National Measurement Office's appointment. These are described in more detail in the following pages. The consultation responses also provided useful areas for further work including the need for comprehensive guidance.

In addition, the UK is committed to conducting a **review** no later than five years after entry into force of the UK Regulations to address any concerns that arise over both the EU Regulation and the UK's implementation of it; in order to ensure the continued effectiveness of the new Regulation. If this report concludes that the offences or penalties under the Regulations should be amended, we will propose amendments to the Statutory Instrument accordingly whilst ensuring that the sanctions are effective, proportionate and dissuasive, as required by the EU Regulation. As the EU Regulation requires Member States to provide a report on its application by 11 June 2017, as a minimum a light touch review of the UK Regulations will be carried out before that date.

Summary of responses and government reply

Below is a summary of the main points made by respondents to the consultation, and the Government's response to those points.

Guidance

Practically all respondents stressed the importance of Defra and the NMO providing **clear and precise guidance** on the implications of the Regulation for users. Researchers in particular would need ready access to this guidance to ensure they were fulfilling their obligations in the course of ongoing research. The main request for guidance was on what would constitute **due diligence** in various circumstances. Respondents also stressed that they would like to be involved in the development of the concept of due diligence by the NMO.

Specific requests were made for guidance on the following topics:

- the definition of '**utilisation'**
- how the NMO will interpret **unclear** substantive provisions;
- collaboration with organisations operating in states that are **not signatories** to the Nagoya Protocol;
- how to negotiate the '**benefit sharing'** aspect of **Mutually Agreed Terms (MAT)**;
- the applicability of the Regulation to **traditional knowledge in public sources**;
- how to determine a '**country of origin**' or the owner of a genetic resource;
- applying for **new Prior Informed Consent (PIC) and Mutually Agreed Terms** when acquiring genetic resources *ex situ*;
- how to develop **best practices**;
- how to access information from the **Clearing House Mechanism**.

Several respondents proposed that guidance be produced for **specific sectors**, including: non-commercial researchers; managers of gene-banks and other collections; microbial researchers and ornamental aquatic traders.

It was suggested that this guidance should be **developed in partnership** with users and other stakeholders and in collaboration with **other competent national authorities** in other EU Member States. Respondents also suggested holding **face-to-face** seminars to explain the impact of the new provisions. Another helpful suggestion was for the guidance to include **worked-through examples** of how the Regulation would apply, and to develop these in partnership with stakeholders with a firm understanding of how genetic material is used.

There was wide support for the NMO to begin immediately the development of model contractual clauses, FAQs and codes of conduct, and awareness-raising. Some responses pointed out that within both the research community and certain sectors there **is a very low awareness** of the Nagoya Protocol and requested the NMO focus its awareness-

raising activities in these areas. One respondent noted that the NMO's ABS website should be **set up rapidly** to provide appropriate guidance and information during the early months after entry into force of the Protocol, when many institutions will be updating their best practices to ensure compliance.

A valuable suggestion was that NMO's awareness-raising activities should also cover the reasons why benefit sharing is important, for the economy and the environment, and how it could support Corporate Social Responsibility strategies in business.

Government response

We are committed to ensuring that all users have access to the **clear and precise guidance** they need to meet the Regulation's due diligence requirements and that guidance is developed at the appropriate level. Guidance on issues that directly concern the EU Regulation itself may be better developed at EU level to ensure consistency of approach and application across EU Member States.

Explanations of what constitutes due diligence for different sectors, for example, will be developed at EU level on the basis of consultation with users and important decisions about the definition of 'final stage utilisation' (Article 7.2) will be detailed in 'implementing acts' (secondary EU legislation negotiated between the Commission and the Member States) over the next few months, as specified in Article 7.6 of the EU Regulation. Defra will work closely with the other Member States and the European Commission and will seek views from the user community during the negotiations.

The NMO will develop any additional UK-specific guidance that may be needed in consultation with representatives of affected sectors and in collaboration with other parts of government with relevant expertise. Following their appointment **the NMO will also focus on raising awareness of users' obligations**, especially in those sectors where awareness is likely to be low at present.

Civil sanctions

Most respondents **welcomed our proposed system of civil sanctions**, particularly the incremental approach with informal communication and voluntary actions forming the first steps in any enforcement process. The range of possible civil sanctions was noted for its similarity to existing legislation, and the system for providing notices of intent was welcomed for the same reason. Many respondents approved of the fact that users will be able to deal **directly with the owner** of genetic resources when entering into an enforcement undertaking to correct non-compliance, as this will minimise the involvement of the regulator. Several stressed that a stop notice should only be issued by **court order**, and other questions were raised over whether sanctions would be **suspended during an appeal**, including an appeal against a notice of intent.

Government response

We are pleased with users' reaction to the proposal to use civil sanctions and these are **included in the Statutory Instrument**. Defra reaffirms in this reply that the intention of the enforcement framework is to **assist users to understand their obligations and achieve compliance** with civil sanctions. Under our revised proposals following the consultation, civil sanctions will be available in respect of all offences and will be the **first recourse** in the case of failure to comply with obligations related to due diligence.

We also confirm that the ABS Statutory Instrument has been drafted to ensure that stop notices can only be issued on the basis of a **court order,** and that civil sanctions and all notices (other than stop notices) will be **suspended** during an appeal.

Criminal sanctions

Some respondents to the consultation felt that the criminal sanctions as proposed in the document **were not proportionate**. The reasons given for this included the fact that complaints of biopiracy are **rarely heard** in the UK; that criminal sanctions could dissuade users from working with genetic resources rather than risk prosecution; that most users of genetic resources do so on the behalf of larger **institutions** making individual penalties unfair; and that **civil sanctions** are dissuasive enough. A separate reason given for opposing criminal sanctions was that they carry a **higher burden of proof**, meaning that criminal prosecutions could be less likely to be successful than civil ones.

However, many respondents felt that **some form** of criminal sanction was necessary and appropriate to ensure the fair enforcement of the Protocol. One respondent suggested that criminal sanctions be limited to **cases of non-compliance with a civil sanction** imposed by the NMO. Given that some issues remain to be clarified through EU implementing acts and through guidance, some respondents thought that there should be **no prosecutions** where non-compliance results from **uncertainty**.

Government response

For the system of civil sanctions proposed to function effectively, it is essential that the NMO have the ability to call on criminal sanctions so that there are dissuasive sanctions in place to avoid cases of **serious non-compliance**.

The variety and combination of civil sanctions we are proposing gives the NMO the flexibility to address different behaviours of the various stakeholders in the most proportionate and effective manner. The focus of the NMO is to **deliver high levels of compliance**. This can often be achieved by cooperation with the regulated entity with a view to long term compliance in the future, improvement and best practice.

In a regime that includes a backstop of criminal sanctions, the regulator is bound by the requirements of the **framework legislation** and has to follow prescribed standards - even

where the likely outcome is civil sanctions. This is because the regulator knows that if the civil sanctions do not work, the entire investigation could be tested by a criminal court. Civil sanctions alone would not automatically have the same in-built safeguards.

Failing to include criminal sanctions also risks giving the impression that the UK does not take seriously the importance that **provider countries** have placed on fully implementing the Protocol. Several provider countries have indicated that they or their genetic resource holders will restrict access to genetic resources for users from Parties with what they consider to be sub-standard compliance measures. **Other developed countries** (for example France, Denmark and Australia) are known to be including criminal sanctions within their enforcement regimes, so if provider countries were to view the UK as falling short in this respect, it could impact directly on the ability of UK businesses and researchers to access genetic resources.

For these reasons Defra believe that **criminal sanctions should be retained** in the Statutory Instrument. However, we reiterate that for obligations related to due diligence **criminal sanctions would only apply to a failure to comply with either the stop notice or compliance notice**. This addresses any residual uncertainty, as the regulator would have to specify in the notice what action the user is required to take, so the obligation will have been **clearly established** and the **user given an opportunity to comply**. If the user disagrees with the civil or criminal sanctions these could be appealed to an independent tribunal.

We do however see the case for going straight to criminal sanctions for offences which would **undermine the enforcement of the regime**, such as obstructing officers exercising powers of entry/powers of inspection or failure to retain information. This is a common feature of other regimes and when such offences are committed it can be necessary to go straight to criminal sanctions. However, the NMO will have the flexibility to use a variable monetary penalty or a user could propose a third party undertaking instead of criminal sanctions where this is considered a more appropriate course of action.

On respondents' concerns about uncertainty, we stress the fact that the EU Regulation is built around a **requirement to exercise due diligence**. As explained above, for the obligations related to due diligence criminal sanctions **only apply** for stop or compliance notices, therefore users cannot directly be found in breach of their obligations for any failure to obtain access or negotiate Mutually Agreed Terms. It is also important to note that users will **not be prosecuted** for non-compliance with access legislation that is not published on the ABS Clearing House Mechanism.

Variable monetary penalties

Many respondents had trouble identifying the **rationale for setting a cap** at £250,000 for the level of variable monetary penalty that could be issued to a user. Some thought that this should be higher due to the significant revenues of businesses involved in some sectors making use of genetic resources. Others noted that the average penalty was likely

to be lower and that the £250,000 cap could attract higher penalties than would be appropriate.

Most respondents agreed that the aim of penalties should be to **remove the financial incentive** of non-compliance, and that the monetary penalties should therefore be **proportionate** to likely financial benefits of non-compliance. Many agreed that an arbitrary cap would undermine this principle. Such an approach would also protect non-profit organisations like universities.

Government response

It is right that the aim of financial penalties should be to **remove the financial incentive of non-compliance**. The most effective way to achieve this is to link the level of fine to any financial benefits obtained by a user. Placing a cap on the level of these penalties would undermine this approach.

In light of this we have decided to **remove the cap** on the level of variable monetary penalties. The NMO will **write and publish a detailed methodology** based on the Regulatory Enforcement and Sanctions Act (2008) for working out the level of those penalties. This would be made public as has been done in the other policy areas where the NMO can impose variable monetary penalties. For an example of a penalty methodology employed by the NMO in a different policy area, please see Annex 1 and 2 of the NMO's guidance for the use of civil sanctions for enforcing the Eco-Design Regulations[2] (pages 26-30).

Status of sequenced genetic information

A large number of respondents asked whether the definition of *biological resources* or *biotechnology* in the Protocol extends beyond the physical genetic material to **sequenced information**.

One respondent made the case that the Nagoya Protocol only governs *access* to Genetic Resource, not ownership, and therefore that states can only ever control *physical* access to their Genetic Resource, therefore **exempting** sequence data. Others noted that 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**.

[2] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/286799/ERP_and_ELF_Combined_Civil_Sanctions_Guidance_5_March_2014.pdf

Government response

Those using published sequence data from material **accessed prior** to the entry into force of the Nagoya Protocol are **out of scope** of the Protocol, the EU Regulation and the UK's Statutory Instrument.

There has been **no agreement** at an international level that the definition of genetic resources in the Nagoya Protocol includes sequenced data. **The UK view is that the Protocol does not apply to sequenced data** and this is not addressed in the Statutory Instrument.

The use of published sequence data from material accessed after the entry into force of the Protocol could be included in a **provider country's ABS legislation**. This will not, however, be addressed by the UK enforcement regime as it does not form part of the Protocol.

Any application of the Protocol to sequenced genetic resources would be limited to where this is addressed in **Mutually Agreed Terms** (contracts) between providers and users. Issues related to contracts would be resolved in private law and are not the subject of the EU Regulation, or the UK Statutory Instrument.

The deliberate sequencing of a **genetic resource in-situ** in order to deliberately by-pass national ABS requirements is likely to be covered by provider countries rules governing access to genetic resources – so although the use of the sequenced data would not be covered by the UK Statutory Instrument, the obligation to abide by the relevant access requirements cover this situation.

Users may wish to consider seeking Prior Informed Consent and Mutually Agreed Terms for the use of data derived from sequenced genetic resources as **best practice** where this is set out in provider country's ABS legislation.

Regulation of traditional knowledge

Respondents were split on our proposals for regulating traditional knowledge where it exists outside of Mutually Agreed Terms. Some expressed concern that the proposals would be extremely **hard to enforce** in cases where traditional knowledge was accessed from **public sources** or from other *ex-situ* sources. One respondent noted the difficulty of pursuing compliance with the Regulation in relation to a **non-physical material**, and others questioned the viability of obtaining **Prior Informed Consent and Mutually Agreed Terms** for an element of traditional knowledge accessed at a different time from the genetic resource it is associated with. However, other respondents supported our proposals as a constructive way to meet the obligations placed on the UK by the Nagoya Protocol without resorting to an entirely **separate regulatory framework**.

Government response

Articles 7 and 16 of the Nagoya Protocol require the UK to ensure that traditional knowledge associated with genetic resources utilised in the UK is accessed and utilised in accordance with the a**pplicable legislation or regulatory requirements** of the provider country. As the EU has regulated for traditional knowledge that is contained in the same contract as the genetic resources it is associated with, the **UK must bridge the gap** and either create a separate regulatory regime or expand the scope of the Regulation to cover traditional knowledge accessed independently of genetic resources.

Without taking either of these steps the UK would risk being found to have **breached our obligations** under the Protocol and would not be able to ratify. Given that most **respondents agreed** with our view that we can provide greater simplicity and reduce regulatory burdens by simply extending the Regulation, we will proceed with our proposal to do so.

Many of the concerns raised in the consultation would not be relevant to traditional knowledge within the scope of the UK Statutory Instrument (which only addresses traditional knowledge where this is set out in Mutually Agreed Terms). In such circumstances, the **conclusion of Mutually Agreed Terms** would address any uncertainties as to what constituted traditional knowledge in the context of the agreement in question and would be freely negotiated between the provider and the user.

Although only traditional knowledge described in Mutually Agreed Terms is directly covered by the Regulation and the SI, the **domestic requirements published on the ABS clearing house mechanism** will provide users with information on where and from whom to seek Prior Informed Consent and Mutually Agreed Terms. The ABS clearing house mechanism will also provide **guidance** on the ethics of consulting indigenous and local communities that will indicate best practice for accessing and using the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles associated with genetic resources.

Appointment of National Measurement Office and powers of entry

There was widespread agreement that the appointment of the NMO[3] was to be **welcomed** due to its solid reputation and collaborative approach. Several respondents urged the NMO to **engage constructively** with companies and organisations engaged with genetic resources and to work with them to overcome problems.

Most respondents who commented on the powers given to the NMO found the powers of entry and inspection suggested in the consultation document to be fair, and in line with

[3] From 1 April 2015 the National Measurement Office will be renamed the National Measurement and Regulation Office

what is expected from other areas. However, several suggestions were made, including that the power of inspection should include an **obligation not to 'use or disclose'** any information that they collect (otherwise than for the purposes of the Regulation); that forced entry to a property should only be allowed with a **court order**; and that those who accompany inspectors should not include competitors or others with a commercial interest.

Government response

The NMO and its inspectors are governed by the rules applying to all regulatory officials under the **Regulators Code**. These include adhering to obligations to use information collected in the course of inspections only for the purposes of enforcing the relevant regulation, and to ensure that only those inspectors that are necessary should be involved in inspections. Furthermore, the Statutory Instrument makes clear that forced entry to commercial properties will only be permitted with a **court order** and that inspections of non-commercial properties are **not permitted**.

Declarations

Several respondents had questions about the application of Article 7.1, the declaration of due diligence on receipt of funding to carry out research. These included whether the declaration would be **mandatory**; what **information** would have to accompany it; **who** would make the declaration, with most suggesting it be one person per organisation; **when** it should be made, with several recommending once a year; and what **types of 'research'** would trigger the declaration. Some respondents asked that the information that must be submitted with a research funding declaration should be the **minimum necessary** for compliance, to reduce the burden on businesses.

Others stressed that the declaration required by Article 7.2, to be made at the stage of final development of a product, should not be linked in any way to the **patent system**, and that all declarations made should be **confidential**.

Government response

Article 7.1 of the EU Regulation, places the obligation on Member States and the Commission to **'request'** that users make a declaration at the point of receiving funding. The **obligation is therefore on Member States** to make this request. In the UK, this request will be made by the **NMO**, through their website. Where public funding is made available by the State, those providing the funding should require the declaration. However, the extent of the declaration will be **limited** given the likely early stage of this request (before consent has been given and mutually agreed terms agreed).

Pathogens

Several concerns were raised about the feasibility of the rule that users must cease research on disease-causing pathogens after **three months**, contained in Article 4.8. Others expressed concern that the Protocol would introduce regulatory hurdles that could inhibit UK medical researchers' ability to take part in **international collaborative research efforts** to combat infectious diseases.

Government response

In line with the **introductory paragraphs** to the Nagoya Protocol and EU Regulation that explicitly acknowledge the need to consider both present and imminent public health emergencies. Therefore the NMO will carefully consider the **public interest test** before pursuing such cases. In case of a public health emergency, it is difficult to imagine circumstances where it would be in the public interest to take action in cases of legitimate use. The NMO could also accept an undertaking to allow the collection of evidence and a postponement of any action in agreement with the business to a more appropriate time.

Best practices

Many respondents welcomed the value that the NMO would place on participation in a best practice scheme when developing its **risk-based plan** for checking compliance However, some respondents inquired whether following a recognised best practice would **automatically** count as due diligence, in the same way as acquiring Genetic Resource from a registered collection. Another respondent noted that best practices agreed at European level would be a useful tool.

Government response

Following a **recognised Best Practice scheme** is one of the activities that users can undertake that will affect how the NMO as Competent National Authority applies their **risk-based approach** to conducting checks on compliance. The precise procedures by which associations of users or other interested parties will apply to the Commission for, and be granted, recognition of their best practice schemes will be detailed in 'implementing acts' (secondary EU legislation negotiated between the Commission and the Member States) over the following months, as specified in EU Regulation Article 8.7. Defra will ensure UK users are kept informed during this process.

Registered Collections and genetic resources acquired from them

Some respondents asked whether a **Registered Collection** would be held accountable if it provided genetic resources to a user who subsequently utilised the genetic resources in

a way not permitted under the mutually agreed terms between that Collection and the provider country.

Government response

The NMO would **not penalise** a registered collection for the actions of one of its customers, and customers will be **liable for their own activities**. The NMO will conduct **risk-based** compliance checks on users of genetic resources even if the user acquired those resources from a registered collection. Such a user will simply have to show that they are not using the resources beyond what was permitted by the registered collection in accordance with the terms agreed between the collection and the provider country.

The precise procedures by which Member States and the Commission will enter collections into the Register will be detailed in 'implementing acts' which the Commission has undertaken since late 2014. Defra will ensure that UK users continue to be able to provide their views during this ongoing process.

Retroactivity

There was widespread agreement that the **non-retroactive** application of the Nagoya Protocol was the right way to implement it. Some respondents were unsure whether **new uses** of previously accessed genetic resources would be in scope of the Regulation.

Government response

Defra can confirm that **new uses** of previously accessed genetic resources will **not be in scope** of the Regulation.

Responses outside the scope of the consultation

A number of responses raised issues outside of the scope of the consultation, concerning the existing EU Regulation on the Nagoya Protocol or the Nagoya Protocol itself, rather than the proposed UK Regulation. Whilst not directly relevant to the consultation, they have been noted and are of relevance to Defra's and the NMO's future work in this area.

Next steps

On 12 October 2014 the Nagoya Protocol came into force in the European Union through EU Regulation 511/2014. The main requirements of the EU Regulation (articles 4, 7 and 9) will come into force 12 months after this (12 October 2015) to allow time for the necessary implementation by the EU Member States, meaning that no declarations or checks on compliance will take place until October 2015.

The UK Statutory Instrument was drafted in light of this consultation response and Defra laid **'The Nagoya Protocol (Compliance) Regulations 2015'** in Parliament on 23 March 2015. The allocation of functions to the Secretary of State for the EU Regulation come into force on 9 July 2015. The remaining provisions (including civil and criminal sanctions) come into force alongside the EU Regulation on 12 October 2015. The Statutory Instrument will be available on www.legislation.gov.uk

Work has begun at the EU level on preparing the 'implementing acts' which will set out in greater detail the working arrangements for implementing Article 5 on the register of collections, Article 7 on making declarations of due diligence, and Article 8 on best practices. Defra will continue to keep UK users informed throughout this process.

List of respondents

Bayer CropScience

Biotechnology and Biological Sciences Research Council (BBSRC)

British Society of Plant Breeders

Chartered Institute of Patent Attorneys

European Molecular Biology Laboratory - European Bioinformatics Institute (EMBL-EBI)

European Seed Association

Glaxo SmithKline

John Innes Centre

Licensing Executives Society

Medical Research Council

Natural Environment Research Council

Natural History Museum

NCIMB

Open University

Ornamental Aquatic Trade Association

PhytoTrade

RBG Edinburgh

RBG Kew

Royal Horticultural Society

Synthace Ltd

Synthetic Biology Leadership Council

UK BioIndustry Association

University of Exeter

Warwick Genetic Resources Unit, University of Warwick

Wellcome Trust

+ two responses from individuals

Glossary and explanation of key terms

Convention on Biological Diversity (CBD)

One of the three ‘Rio Conventions’ that was negotiated at the Earth Summit in Rio de Janeiro in 1992, the CBD an international treaty that aims to preserve the earth’s biological diversity, promote the sustainable use of its components, and encourage the fair sharing of benefits that arise from such use.

Access and Benefit Sharing (ABS)

A term used to refer to the general policy of widening access to the components of biodiversity so that its resources can be used sustainably. Sustainably using the components of biodiversity is the second aim of the CBD; the fair and equitable sharing of benefits that arise from such use is its third aim.

Genetic Resources (GR)

Any potentially useful genetic material that contains ‘functional units of heredity’. Utilisation of genetic resources is the attempt to extract any useful traits. An example of a genetic resource is the Harpagophytum plant (‘Devil’s Claw’) found in Africa.

Traditional Knowledge (TK)

Knowledge held by indigenous and local communities about a particular resource that may help potential users to identify what that resource’s applications might be. Transfer of traditional knowledge is protected by the Nagoya Protocol to the same extent as genetic resources. An example would be the knowledge that extracts of the Devil’s Claw plant can be used for anti-inflammatory medicinal purposes, such as relief from arthritis.

‘Separate’ Traditional Knowledge

If references to traditional knowledge are included in the same contract as the genetic resources to which that knowledge is associated, then the EU Regulation applies to that usage. However, if the traditional knowledge is in a separate contract from those genetic resources (for instance, if access to the Traditional Knowledge was negotiated subsequently) then for competence reasons the EU Regulation cannot apply. For this reason such cases must be regulated separately by the UK, through this Statutory Instrument.

Prior Informed Consent (PIC)

Prior Informed Consent: the Nagoya Protocol makes access to genetic resources or traditional knowledge contingent on the user seeking the consent of the lawful owner of those resources, after having informed them of the intended use the resources will be put

too. Information on how to acquire Prior Informed Consent in each country will be made available on the ABS Clearing House.

Mutually Agreed Terms (MAT)

Mutually Agreed Terms: before resources are transferred to a user that user must agree terms in a private contract that set out how any benefits that arise from research on the resources will be shared.

Benefit Sharing

Mutually Agreed Terms may include provisions that cover not only monetary benefits but also non-monetary ones such as published research findings or taxonomic information.

In situ

The position of genetic resources ‘in the wild’, in their provider country. Collecting genetic resources *in situ* is one way of acquiring them, in contrast to purchasing them from *ex situ* collections (either in the provider country or in another country) to which they have been taken after previously being accessed.

Enforcement Undertaking

An enforcement undertaking is a voluntary agreement to undertake specific actions that would make amends for non-compliance and its effects within a specified timeframe.

Compliance Notice

A compliance notice is a written notice issued which requires a business to take specific actions to bring its operations into compliance with the law and/or return to compliance within a specified period.

Variable Monetary Penalty (VMP)

A Variable Monetary Penalty is a monetary penalty which could be imposed for moderate to serious offences where prosecution is not in the public interest.

Stop Notice

A stop notice is a written notice which requires certain actions to cease, for instance, to remove from the market a product that has been developed in contravention of the requirements of the Nagoya Protocol.

Third-Party Undertaking

A third-party undertaking is an undertaking in which the economic operator receiving the notice may offer an undertaking (including payment of a sum of money) to benefit any third party affected by the offence or non-compliance.

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