Department for Environment Food & Rural Affairs

The Nagoya Protocol (Compliance) Regulations 2015

Post implementation review

14 October 2021

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Contents

Introduction

In accordance with Regulation 19 of The Nagoya Protocol (Compliance) Regulations 2015 (Statutory Instrument (SI) 2015/821) ('the Regulations'), the Secretary of State is required to carry out a post-implementation review (PIR) of the Regulations within 5 years of the Regulations coming into force.

The Department for Environment, Food and Rural Affairs (Defra) has carried out a review, and this document sets out the conclusions of the review. The review was required to:

- set out the objectives intended to be achieved by the Regulations
- assess the extent to which those objectives are achieved
- assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved in a less burdensome way

The Regulations:

- enforce Regulation (EU) number 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (hereafter referred to as 'the EU Regulation')
- implement, within the UK, those elements of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation ('Nagoya Protocol') that relate to traditional knowledge which are not covered by the EU Regulation
- establish offences and sets penalties for the administration and enforcement of the EU Regulation

Background

The Nagoya Protocol is an international treaty under the Convention on Biological Diversity (CBD).

The CBD has 3 main objectives, the:

1) conservation of biological diversity
2) the sustainable use of the components of biological diversity
3) fair and equitable sharing of the benefits arising out of the utilisation of genetic resources

The Nagoya Protocol was adopted in 2010 to implement the objective of the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

The EU Regulation was adopted in April 2014 and came into force for the EU and its member states alongside the Nagoya Protocol in October 2014.

The Commission Implementing Regulation (EU) 2015/1866 came into force in November 2015. This contains detailed provisions for implementing the EU Regulation (including due diligence declarations, best practice, and registered collections).

The Nagoya Protocol (Compliance) Regulations 2015 (SI) 2015/821), hereafter known as the Regulations, came into force in October 2015, enabling the UK to ratify the Nagoya Protocol on 22 February 2016.

The UK was the first EU member state to enact domestic legislation to enforce the EU Regulation, including the provision of penalties for breach of the Regulations.

Although the UK left the EU on 31 January 2020, the EU Regulation and the Implementing Regulation continue to apply to the UK. They have been made operable in the UK by the introduction on the 1 January 2021 of 2 new Statutory Instruments[1].

Policy objectives

The Regulations enforce EU Regulation by:

- setting out compliance measures
- implements within the UK those elements of the Nagoya Protocol that relate to traditional knowledge which are not covered by the EU Regulation
- establishes offences and sets penalties for the administration and enforcement of the EU Regulation

The desired outcome of the EU Regulation is that the owners or guardians of genetic resources, or of traditional knowledge associated with genetic resources, gain benefits from the utilisation of those resources.

The EU Regulation implements certain articles of the Nagoya Protocol governing compliance measures for users. It does so by requiring users to exercise due diligence to:

- access genetic resources in line with the requirements of the country where the access takes place
- seek and keep related information
- declare that they have been diligent when receiving funding through a grant to support research and development
- the final stage of development of a product that emerges from the research

[1] The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 (SI 2018/1393) and the Environment and Wildlife (Legislative Functions) (EU Exit) Regulations 2019 (SI 2019/473)

The EU Regulation requires member states to designate competent authorities to enforce its provisions, adopting a risk-based approach.

The Regulations enabled the UK to ratify the Nagoya Protocol and demonstrate its commitment to all 3 objectives of the CBD, including the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

The Regulations make provision for civil sanctions for obligations related to due diligence, including failing to keep the information required under the EU Regulation and for obstruction of an officer. Criminal offences are included for failure to comply with those civil sanctions.

PIR's approach

PIRs can vary in the level of scrutiny applied. A light touch approach is appropriate for low impact regulations, whereas a more detailed review approach is necessary where the impact is high.

The following aspects have been considered when deciding the extent of the review for the Regulations:

Impact assessment

An impact assessment was not produced for the Regulations as no significant impact on the costs of business or the voluntary sector could be foreseen because of them[2].

Regulatory Triage Assessment

A Regulatory Triage Assessment (RTA) was prepared to assess the impacts of the new measures on stakeholders.

The RTA showed that there are minimal costs associated with the measures and given the low costs, further efforts to monetise other impacts would be disproportionate. Based on the information provided in the RTA, the Regulatory Policy Committee confirmed that the proposal qualified for the fast track as a low-cost regulatory proposal[3].

Subsequently, it is considered that these Regulations are below the 'de minimis' £5 million threshold required for independent scrutiny.

[2] The Nagoya Protocol (Compliance) Regulations 2015, explanatory notes, last paragraph.

[3] Explanatory Memorandum to the Nagoya Protocol Compliance Regs 2015 number 82, Impact, paragraph 10.2

Stakeholder engagement

The UK Access and Benefit Sharing (ABS) Stakeholder Forums run by Defra provide an opportunity for stakeholders (specifically those subject to the Regulations) to engage with the National Focal Point (NFP) and enforcement agency to express their views and concerns about the implementation of the Regulations.

Enforcement

The Office for Product Safety and Standards (OPSS), a directorate of the Department for Business, Energy, and Industrial Strategy (BEIS), is the enforcement agency for the Regulations. It regularly engages with UK stakeholders about the implementation and enforcement of these Regulations. This engagement is conducted through webinars, face-to-face, email and through the OPSS's LinkedIn group.

Reviews

Reviews commissioned by the EU commission and the secretariat of the Nagoya Protocol (see the chapter on evidence sources for further detail).

By considering this information, including the outlined opportunities for engagement of stakeholders on the implementation of the Regulations, it was decided that a light-touch PIR was to be undertaken, without an evaluation of policy impacts through an impact assessment.

Evidence sources and data collection methods

This PIR was based on 3 information sources:

1) data and intelligence collected and provided by OPSS
2) stakeholder engagement through a targeted survey
3) reports on compliance submitted to the EU commission and Nagoya Protocol secretariat

The first source provided insights on the enforcement approach adopted by OPSS. While the second and third focused on how the Regulations are working in the views of stakeholders affected by them.

In terms of stakeholder engagement, the PIR was informed through ongoing dialogue with key stakeholders, including through the UK ABS Stakeholder Forum.

The forum brings together stakeholders from across the UK government, the private sector and academia, and allows for the sharing of views and comments relevant to ABS.

There are also other effective and established communication channels in place, including through social media networks.

The feedback from ongoing dialogue with stakeholders was supplemented with responses from an online survey, which included 4 questions based on the statutory review obligations set out in the review clause of the Regulations:

1) Has the policy successfully achieved its objectives?
2) Were there any unexpected consequences or costs from the Regulations?
3) Could we revise the Regulations to reduce cost to business?
4) How do the UK Regulations in this area compare with that in the EU?

The survey targeted known UK stakeholders as identified through the UK ABS Stakeholder Forum. These included businesses, trade associations and academic research institutions. Annex A provides a list of stakeholders approached via the survey.

Article 16 (2) of the EU Regulation requires the EU commission to submit a report to the European Parliament and the Council on its application to include an assessment of its effectiveness.

The first report was adopted on 24 January 2019 and covered the first 3 years of application of the EU Regulation (October 2014 to August 2017). This is reduced to 2 years of application for provisions concerning:

- due diligence (Article 4)
- monitoring of user compliance (Article 7)
- compliance checks (Article 9)

The UK government submitted a national report to the commission which is available on the European Commission's website. The national report has also contributed to this PIR by providing details of UK implementation of the Regulations.

The European Commission tasked Milieu Ltd to carry out a preliminary analysis of the implications of the compliance obligations for users of genetic resources under the EU Regulation.

The report dated May 2020, focused on the identification and analysis of the positive and negative consequences of compliance with the Regulations, for both public research institutions and industry, which includes, small and medium-sized enterprises (SMEs).

Seven SMEs from the UK, representing several sectors, contributed to the Analysis of implications of compliance with the EU report.

The UK also provided an Interim National Report, dated 30 October 2017, to the Nagoya Protocol Secretariat on the UK's progress against the Protocol's requirements.

This report references the Regulations adopted and implemented by the UK.

Enforcement approach

The Regulations, which enforce the EU Regulation, designate the Defra Secretary of State (SoS) as the competent authority for the EU Regulation. The Regulations establish offences and set penalties for the administration and enforcement of the EU Regulation.

OPSS has been designated as the enforcement body for the Regulations.

Recently, OPSS progressed from an awareness raising implementation phase, to greater focus on targeted enforcement activities.

OPSS take a risk-based approach to enforcement by making sure that their resources are targeted at the areas that pose the highest risk of non-compliance and where there is limited understanding about the risk presented by a particular sector.

This approach ensures resources are used effectively and that any subsequent enforcement actions are proportionate.

As part of this approach, they aim to encourage understanding and compliance of the Regulations by providing useful tools and guidance. The OPSS also applies the legislation equally to ensure businesses can compete on a level playing field.

Although transitioning to a more enforcement-led approach, there have been no enforcement sanctions issued to date.

Table 1: enforcement activities

Timeframe	Enforcement projects	Enforcement visits	Awareness raising (workshops and visits)	Audits
2018 to 2019	1	0	9	0
2019 to 2020	2	10	15	56

OPSS undertakes and develops several risk-based projects as part of their enforcement role. The projects are based on access to open-source data, market intelligence and risk profiles.

Projects target specific sectors to include food and beverage (including agricultural technology), pharmaceuticals, cosmetics, genetically modified organisms, and academia.

Projects are based on known domestic and potential international areas and sectors of risk.

A sub-set of entities operating within a specific sector are approached and requested to provide evidence of due diligence. Officers will use this information to ascertain compliance with the Regulations.

In financial year (FY) 2018 to 2019, OPSS initiated its first enforcement project, titled ‘remote audit’, which continued into FY 2019 to 2020.

The remote audit project involved development of self-assessment tools with the aim of assisting UK organisations to determine whether their work falls in scope of the Regulations.

This project involved 46 audits and represented the first step in OPSS shifting focus away from awareness raising and towards enforcing compliance.

As a result of this project OPSS were able to develop a free tool which is available on their website to assist entities to identify if their activity is in scope and produce appropriate due diligence.

A second enforcement project began in 2019, known as the ‘academia’ project. The academia project involved face to face visits and audits with 10 academic organisations, who displayed potential to conduct activity which would be in scope of the Regulations.

In 2020, OPSS began a new project focussing on entities in receipt of grant funding. Officers initially contacted 25 organisations with the potential to conduct in scope research and development activity.

A request to produce a list of projects involving genetic resources was followed up by a request for evidence of due diligence related to specific projects.

Three awareness raising webinars were held by OPSS in 2020 (23 June, 18 August and 14 October) with many academic institutions and organisations undertaking grant funded projects in attendance at each.

The OPSS team decided to temporarily pause enforcement activity on a pharmaceuticals project in 2020 as it was expected that this sector was likely to be heavily impacted by COVID-19.

Instead, OPSS held a webinar aimed at the pharmaceutical sector with the objective of ensuring all 14 institutions attending were aware of the exemptions in existence under the Regulations during a pandemic.

Compliance levels

Given that the Regulations are still relatively new and that much of the focus up to this point has been on raising awareness, there are no examples that demonstrate deliberate non-compliance.

Nonetheless, it is unusual to find such high rates of compliance (100% to date), and this may be due to a lack of independent or available data that can be used to identify in-scope activities.

Most cases so far have been found to be compliant due to being outside the scope of the Regulations rather than in scope and compliant.

A high number of grants have been issued with the potential to be within the scope of the Regulations (1,500). However, only a relatively low number of in-scope due diligence declarations and Internationally Recognised Certificates of Compliance (IRCC) have been received.

This low number may be due to the amount of time taken to plan research projects and to reach certain milestones.

For example, research projects in the pharmaceutical sector can take more than 10 years to go from the initial discovery stage through to placing a product on the market. This could also account for the low number of due diligence declarations submitted to date.

By adopting a risk-based approach to enforcement, OPSS can focus on regulated entities where they suspect that compliance levels are lower than the 'industry' standard.

This may make it difficult to draw conclusions about the levels of compliance as an increase in detections of non-compliance may just indicate that there is better detection rather than increased non-compliance. Or in some cases, the move from awareness raising towards compliance checks.

The above approach, the relationship with Defra and the engagement with stakeholders will enable the OPSS to provide more clarity on compliance levels. This approach may also merit a targeted response where required.

Cooperation

OPSS have occasionally received concerns from other interested parties that an offence under the Regulations may have been committed. Where evidence is provided, the OPSS will investigate accordingly.

Where appropriate, the UK will work in a cooperative manner with other countries, including Competent National Authorities (CNA) and National Focal Points (NFP) of provider countries, to investigate and address concerns of non-compliance.

OPSS routinely shares intelligence with other enforcement agencies to identify possible cases of non-compliance. It also engages internationally to support implementation of the Regulations in the UK by supporting requests for access to genetic resources in other countries.

The creation of a strong international network on ABS compliance matters is important for the successful implementation of the Nagoya Protocol.

Stakeholder engagement

Both OPSS and Defra regularly interact with stakeholders at the national and international level on matters relating to the Regulations.

Meetings of the UK ABS Stakeholder Forum are arranged on an ad hoc basis, often in advance of international meetings, to provide updates on issues such as the development of new guidance or enforcement approaches.

A good relationship has been established between this group, Defra and OPSS.

Defra and OPSS have also organised various training sessions and information sharing events, both in person and virtually. The in-person events have been held across the UK and both approaches have been well received.

The virtual setup has enabled Defra and the OPSS to continue to support UK stakeholders throughout the COVID-19 pandemic.

Various sectors have attended these events, including representatives from government departments, the private sector, and academia.

OPSS has delivered several awareness raising workshops to holders of various collections to support compliance in the sector.

OPSS has also started to approach the government entities responsible for issuing research grants, with the aim of sharing more data related to the research and compliance levels of those accessing government grants.

OPSS has published several press articles and blogs on the topic of ABS to raise awareness and understanding of the legislation amongst affected UK market sectors.

There are also effective and established communication channels in place to foster ongoing two-way dialogue on ABS, Nagoya Protocol, and compliance matters, be that at the domestic or international level.

OPSS officers manage a LinkedIn group for UK ABS stakeholders called ‘Nagoya Protocol on Access and Benefit Sharing: Compliance Forum’ and encourages all stakeholders that they engage with to join the group.

The purpose of the group is to facilitate general scope discussions, to encourage users of genetic resources to share questions and exchange views and experiences related to ABS.

The group will also help to distribute new UK ABS guidance, including processes for submitting due diligence declarations, registered collections, and best practice, which came into force on 1 January 2021, as well as provide an avenue for stakeholder feedback.

The group currently has 230 members.

Enforcement agency views on the Regulations

The OPSS has highlighted concerns over the sanctions available to them. For example, only Defra Secretary of State (SoS) has the authority to require a person to comply with a:

- compliance notice
- stop notice
- civil sanction

The SoS cannot delegate that authority to OPSS.

An OPSS inspector is authorised by the SoS to carry out inspections and there are provisions which enable the inspectors to carry out inspections such as, powers of entry and powers of inspection.

OPSS would welcome a review of the Regulations on this matter and are working with Defra to address their concerns.

Despite OPSS's engagement with stakeholders, there still appears to be a lack of awareness and understanding by stakeholders and entities of the Regulations, and therefore that provisions under the Regulations may be applicable to their activity. OPSS, through the engagement measures highlighted, are addressing this.

Stakeholder survey findings

This section summarises the feedback provided by those stakeholders who responded to the stakeholder survey. The views reported below are those of the stakeholders unless otherwise indicated.

Effectiveness of the Regulations

Question 1: has the policy successfully achieved its objectives?

The graph shows a mixed response from stakeholders on the effectiveness of the Regulations in achieving the original objectives.

9 stakeholders believed that the Regulations was counterproductive in achieving its objectives while 8 believed it to be successful in meeting its objectives.

One stakeholder, responding on behalf of a representative trade association, indicated that “the issue was not simply to do with the UK’s implementation of the Nagoya Protocol (regulation), the issue was strongly related to the time-consuming bureaucracy of the Protocol itself”.

A second stakeholder, also responding on behalf of a representative trade association, “did not feel that the Statutory Instrument to which the survey relates is particularly problematic”. However, he went on “‘the SI implements aspects of the EU Regulation and the Regulations (which are) deeply problematic”.

The stakeholder also commented on the Regulations “inhibiting effects on innovation and its detrimental impact on public health”.

Some of the concerns raised by stakeholders relate to the scope of the Regulations rather than to the effectiveness of the Regulations in achieving its objectives.

Additionally, in their feedback stakeholders have made it clear that there are genetic resources that they do not believe should be in scope of the Regulations.

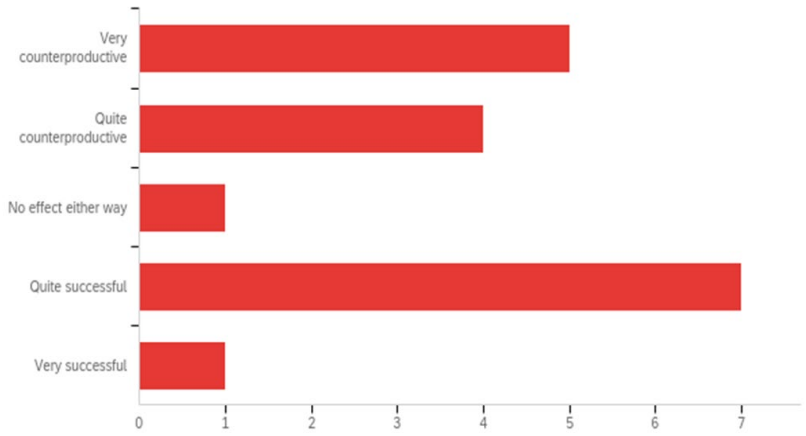

Figure 1: stakeholder responses to the query, has the policy successfully achieved its objectives?

Implications and unexpected consequences

Question 2: were there any unexpected consequences or costs from the regulation?

61% of stakeholder responses (11 of 18 respondents) indicated that there were negative, unexpected consequences associated with the Regulations.

6 stakeholders responded there were no unexpected consequences whilst only 1 stakeholder believed there were positive outcomes.

As mentioned previously, some survey feedback does not indicate discontent with the Regulations per se. The concerns are with the EU Regulation and elements of the Nagoya Protocol, which the Regulations seek to implement.

Additional, anecdotal evidence and feedback from some stakeholders also indicate that there is a view that the totality of ABS legislation creates more bureaucracy which delays access to genetic resources.

From a public health perspective, it has been suggested by some stakeholders that such bureaucracy is delaying access to pathogens and therefore the creation of vaccines.

It is important to note that UK stakeholders have not directly questioned the underlying intent of the Nagoya Protocol, which is the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

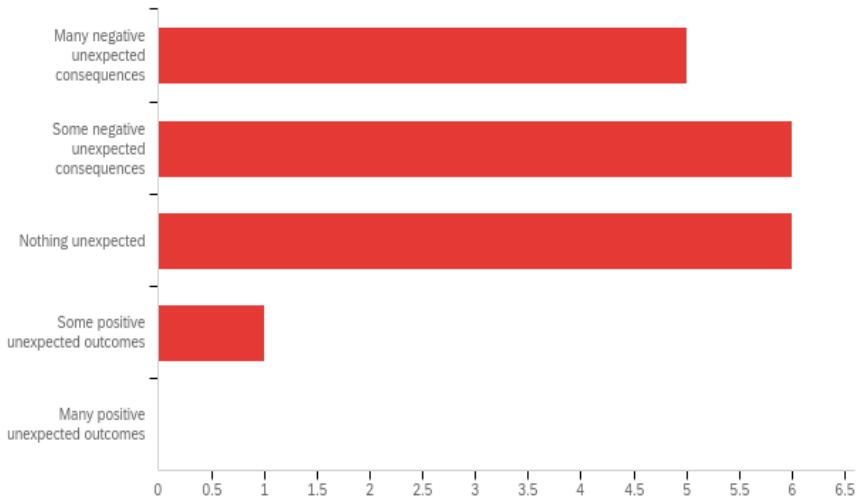

Figure 2: stakeholder responses to the question, were there any unexpected consequences or costs from the regulation?

Burden to users of genetic resources and revisions to the Regulations

Question 3: could we revise the regulation to reduce cost to business?

12 of the 18 stakeholders who responded, indicated that revisions to the Regulations are required, while the remaining 6 said that no revisions were required. There were no specific comments on the revisions to the Regulations that stakeholders would like to be made.

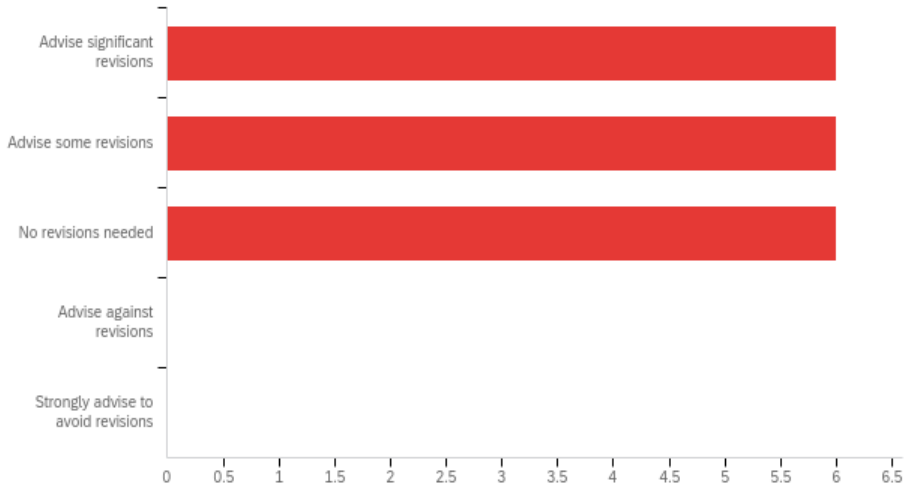

Figure 3: stakeholder responses to the question, could we revise the regulation to reduce the cost to business?

Implementation in other EU member states

Question 4: how does UK regulation in this area compare with that in the EU?

The consensus amongst those surveyed (12 of 18) is that the Regulations in the UK compares similarly or favourably with that of member states.

One stakeholder responded that the Regulations compares very poorly with that in the EU.

5 stakeholders indicated that the Regulations compared quite or very well to those in the EU.

Although some stakeholders disagree with certain elements of the EU Regulation (and Nagoya Protocol) and by extension, the Regulations, the actual implementation of the ABS legislation in the UK is a success.

This successful implementation was achieved and maintained through the establishment of regular dialogue not only with a domestic audience but also with EU member states.

The creation and adoption of an earlier EU guidance document on ABS, which included submissions from UK stakeholders, significantly added to the implementation of ABS legislation.

This was particularly important given many UK entities are users of genetic resources originating from EU member states, and vice versa.

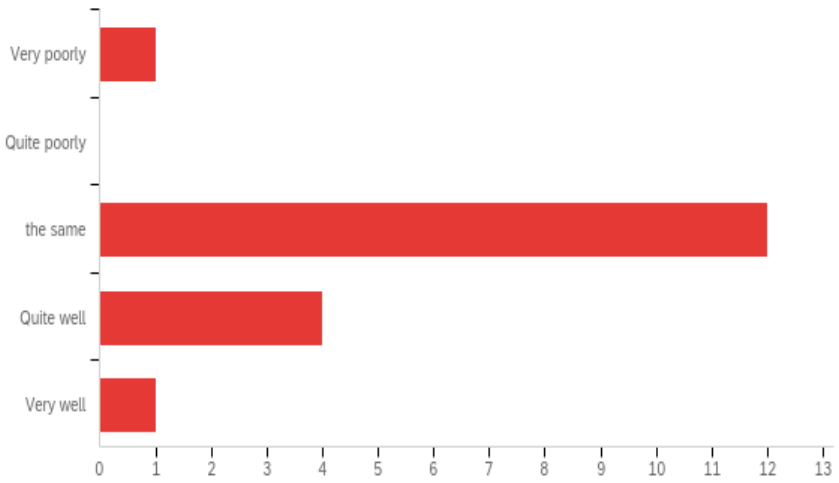

Figure 4: stakeholder responses to the question, how does the UK regulation in this area compare with that in the EU?

Summary of suggestions and responses

This is a summary of the comments or suggestions put forward by stakeholders in response to the survey, and Defra's responses to each of them.

Stakeholder comment

"While the concept of the Protocol is eminently laudable, it potentially creates time consuming bureaucracy that threatens timely action in urgent public health situations, where sharing of genetic data and microbial isolates for research and vaccine development is critical."

Defra's response

Under the Protocol there is a requirement for a bilateral relationship between the user (such as, the vaccine developer) and the provider (such as, the pathogen owner).

The stakeholder comment indicates a potential issue in time-critical access to, and utilisation of, genetic resources.

Defra understands the critical importance of timely action in response to public health situations, and this has been acutely demonstrated in responses to COVID-19.

Stakeholder suggestion

“Ensure that ABS obligations do not threaten timely action in urgent public health situations, where sharing of genetic data and microbial isolates for research and vaccine development is critical.”

Defra’s response

Article 8 (b) of the Protocol requires parties to pay due regard to cases of present or imminent emergencies that threaten human health. The Regulations recognise the Pandemic Influenza Preparedness Framework as a specialised international ABS instrument.

For other pathogens presenting a health emergency, the EU Regulation and therefore the Regulations afford UK users a delay in the submission of any due diligence declaration.

Stakeholder suggestion

“The SI implements aspects of retained EU Regulation 511/2014 which are deeply problematic. Address these problems, including its inhibiting effects on innovation and its detrimental impact on public health.”

Defra’s response

The EU Regulation and the Regulations recognise the critical importance of timely access to pathogens to protect public health, and the UK’s science and innovation sectors are world leading.

Defra’s revised UK guidance will seek to ensure that the implementation of the Protocol in the UK does not negatively impact innovation, whilst meeting our international obligations.

Defra will work with stakeholders to address these concerns within the revised guidance.

Stakeholder suggestion

“In light of the UK's exit from the EU, we believe that there is an opportunity and urgent need for the UK to address the deficiencies in the Regulations. As well as to legislate in a way that promotes the achievement of the ABS objective of the CBD, while also promoting innovation and public health.”

Defra's response

As a party to the Nagoya Protocol, the UK will continue to uphold and meet its international obligations.

As of 1 January 2021, powers have been repatriated to the UK, with the EU Regulations being made operable in the UK through the provision of 2 additional SI.

Defra will consider what amendments to the retained legislation could be appropriate in the future. Stakeholder consultation would be a critical part in any process considering changes and we would welcome discussions with stakeholders on what a future regime could look like.

Additionally, new UK guidance is being prepared. This new UK guidance offers an opportunity to address UK stakeholder concerns, and we will work closely with stakeholders to achieve that.

EU-funded review of the EU Regulation

Seven UK Small to Medium Enterprises (SMEs) contributed to an EU-funded review of the EU Regulation. Conclusions from that analysis indicate:

- The EU Regulation, when combined with the multitude of local laws under the Nagoya Protocol, is considered as creating a high administrative burden.
- Compliance (with ABS legislation) is disproportionally high and unattainable.
- Of concern is the scoping phase where most resources are dedicated to determining whether the provider country has implemented the legislation and what obligations and procedures need to be followed in a specific case.
- Adding to this administrative burden is the uncertain regulatory framework, where countries both outside and within the EU are approaching access and benefit sharing in a myriad of ways. This creates delays and additional costs for users for 2 key reasons:
    - The lack of relevant and updated information on the ABS Clearing House or national institutional websites. Users are typically reliant on the CNA or NFP to provide information on the provider country's ABS legislation. These contact points tend to be unresponsive or provide contradictory and sometimes conflicting interpretations of scope of their ABS laws.
    - Negotiating Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) entails protracted negotiations with local authorities, which can lead to long delays in obtaining permits and represent a hidden cost for research projects.
- There is a high level of confusion among stakeholders concerning the difference between the EU Regulation and national ABS legislation. Stakeholders often perceive them as 1 set of provisions, and do not identify which obligations stem from the EU Regulation and which are linked to the national legislative frameworks.

- The existence of ABS obligations (referring here to both national legislations on access and the compliance obligations under the EU Regulation) are also perceived as an obstacle for further research and development opportunities.

Conclusions

This review was required to:

- set out the objectives intended to be achieved by the Regulations
- assess the extent to which those objectives are achieved
- assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved in a less burdensome way

This review concluded the following objectives of the Regulations have been achieved:

- enforcement of Regulation (EU) number 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union ('the EU Regulation')
- implementation, within the UK, of those elements of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation ('Nagoya Protocol') that relate to traditional knowledge which are not covered by the EU Regulation.
- establishment of offences and penalties for the administration and enforcement of the EU Regulation

However, regarding the extent to which they have been achieved and whether they remain appropriate, several issues have been highlighted.

The survey highlighted that there are negative, unexpected consequences arising from the Regulations, with a majority indicating that a revision of the Regulations is required.

However, the additional survey feedback and evidence indicates that the issue may not lie with the Regulations themselves, but with the EU Regulation and to a lesser extent the Nagoya Protocol.

From a compliance perspective, the OPSS highlighted that the Regulations are relatively new and that much of their focus has been on raising awareness rather than on checking compliance.

However, where compliance activity has been undertaken, the OPSS have no examples of deliberate non-compliance and most cases investigated show compliance with the Regulations.

Concern amongst UK stakeholders was, in several cases, linked with the bilateral approach of the Nagoya Protocol and the requirement to seek PIC and MAT with the provider of the genetic resource.

This bilateral approach was considered to induce bureaucratic costs and delay in accessing genetic resources.

The additional due diligence declaration requirement of the EU Regulation which is implemented through the Regulations, is also considered by some stakeholders as an extra administrative obstacle. Some respondents also questioned the scope of the activities covered by these requirements.

Although some feedback falls outside the scope of this review, touching on areas relating to meeting international or bilateral obligations. We have taken note of the stakeholder and OPSS concerns, and we will continue to review them as it will help to develop the policy and guidance in this area.

The development of revised UK guidance is a key step in reducing the burden on businesses. This includes greater clarity on issues about the scope of the Regulations and the relationship between the Nagoya Protocol, the EU Regulation, and the Regulations.

Defra will work closely with stakeholders, through the ABS Stakeholder Forum and other channels, to develop this guidance in a collaborative manner.

Limitations of this review

Only a limited number of UK stakeholders responded to the on-line survey and the EU-funded survey.

The online survey was sent to over 40 UK stakeholders representing various sectors to include biopharmaceutical and academia. Only 18 provided responses but some were from representative trade bodies and therefore may represent the views of a wider group. The extent to which that applies is unknown.

Annex A: stakeholders approached via survey

Table 2: this table represents the organisations by sector who responded to the survey

Name	Sector
Royal Botanic Gardens, Kew	Botanical research
Syngenta	Agriculture
National Museums Scotland	Conservation and research
AstraZeneca	Pharmaceutical
Welcome Sanger	Pharmaceutical
British and Irish Association of Zoos and Aquariums	Conservation and research
Royal Horticultural Society	Horticulture and research
Royal Society of Biology	Biology
Bioindustry Association	Trade association for life sciences
Biotechnology and Biological Sciences Research Council	Research and innovation
British Society of Plant Breeders	Plant breeding
Rothamsted Research	Not for profit agricultural research
Centre for Agriculture and Bioscience International	Not for profit agricultural research
Food and Environment Research Agency Science Ltd	Agri-food science

Name	Sector
Natural History Museum	Conservation and research
Seqirus	Public health research
Imperial College	Research
Agriculture Industries Confederation	Agriculture
Bristol University	Research
Nature Metrics	Biodiversity research and conservation
Keltie	Intellectual property law
Society for Applied Microbiology	Microbiology
Pew Charitable Trusts	Conservation NGO
Pirbright Institute	Animal research
GlaxoSmithKline	Pharmaceutical
Quadram Institute	Microbiology
Exeter University	Research
Roslin Institute	Animal biology research

Annex B: post implementation review

Table 3: responses to a pre-determined series of questions

Title: the Nagoya Protocol (Compliance) Regulations 2015	Post Implementation Review
PIR number: 2015/821	Date: 14 October 2021
Original IA/RPC number: not found	Type of regulation: Domestic
Lead department or agency: Defra	Type of review: Statutory
Other departments or agencies: Office for Product Safety and Standards (BEIS)	Date measure came into force: 12 October 2015
	Recommendation: Keep
Contact for enquiries: Katie.Beckett@defra.gov.uk	RPC opinion: Green

What were the policy objectives of the measure?

The policy objectives of the Regulations are to put in place the measures needed for the UK to implement the EU Regulation, and the elements of the Nagoya Protocol which are legally binding.

This is to ensure that where genetic resources (and traditional knowledge) are used in research and development. Any resulting benefits are shared fairly and equitably with the country of origin, where they require such benefit sharing.

What evidence has informed the PIR?

Evidence used to inform this PIR is collated from:

- Defra National Focal Point (NFP) on the Nagoya Protocol
- Office for Product Safety and Standards in their role as the UK enforcement agency
- 40 plus UK stakeholders from business, industry, research and development, universities and other government departments, who provided feedback through UK and EU surveys

and regular dialogue with OPSS and Defra. The UK survey targeted those stakeholders who are part of the UK ABS Stakeholder Forum and have a good understanding of the Regulations.

- Reports submitted to the EU commission and Nagoya Protocol secretariat.

To what extent have the policy objectives been achieved?

The Regulations enabled the implementation and enforcement of the EU Regulation in the UK, and the UK to uphold its international obligations as a Party to the Nagoya Protocol.

Although feedback received from stakeholders expressed some concerns, these concerns could be attributed to the scope of the EU Regulation rather than the implementation of the Regulations itself.

Sign-off for post implementation review by the Chief economist or Head of Analysis and Minister

I have read the PIR and, I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed

Date: 14 October 2021

Further information

In this section we detail any further evidence provided.

What were the original assumptions?

It was assumed that the Regulations appropriately and sufficiently implemented the EU Regulation. But that there is a need for greater clarity on scope of the EU Regulation to support compliance of UK users of genetic resources.

Were there any unintended consequences?

Stakeholder feedback indicates that the Regulations have, on occasion, resulted in research projects being halted or delayed.

This is due to the inability of the user to demonstrate that they have accessed genetic resources in line with provider country national access measures (such as, a demonstration of due diligence).

Has the evidence identified any opportunities for reducing the burden on business?

The revision of the guidance for UK stakeholders provides an opportunity to reduce the burden on users of genetic resources, by providing greater clarity and legal certainty. Particularly on the scope of the Regulations and the EU Regulation.

Defra will work closely with UK stakeholders to achieve the right balance of burden reduction, compliance and upholding international obligations.

For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business?

The UK's implementation is comparable to that of other EU member states during the review period (such as, prior to the end of the transition period on 31 December 2021).

The UK worked closely with other member states to ensure common approaches to enforcement, in part through the establishment of common EU-wide guidance.

The UK was also recognised for its good working relationship with UK stakeholders and the significant amount of awareness raising undertaken