THE ABS CAPACITY DEVELOPMENT INITIATIVE

L'INITIATIVE DE RENFORCEMENT DES CAPACITES POUR L'APA

An Online Permit and Monitoring System Supporting National Implementation of the Nagoya Protocol on ABS

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About the multi donor ABS Capacity Development Initiative

The ABS Capacity Development Initiative aims to contribute to poverty reduction, food security, technology transfer, social development including equity and rights, and biodiversity conservation through implementing the Nagoya Protocol (NP) on ABS and the third objective of the Convention on Biological Diversity (CBD) in its entirety. Established in 2006, the ABS Capacity Development Initiative is implemented by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH and funded by the governments of Germany, Norway and Denmark, the Institut de la Francophonie pour le développement durable (AfD), and the European Union (EU).

Executive Summary

This concept paper sets out the concept and model for an online research permit and monitoring system to facilitate national implementation of the access, benefit sharing, monitoring and reporting provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the United Nations Convention on Biological Diversity.

The core of this proposal is that Parties to the Protocol, and governments who intend to ratify or accede to the Protocol, may wish to adopt:

"A single electronic permit system that makes it easy to apply for permits and for government authorities to review and approve applications, monitor compliance and report on the access, benefit-sharing, compliance and reporting provisions of the Nagoya Protocol."

1. The majority of Parties to the Protocol will already possess national permit systems for research involving biodiversity and genetic resources within their jurisdiction and, in the case of indigenous peoples and local communities, for research involving human subjects. Research permit systems are normally the first point of contact between researchers seeking to carry out research on biodiversity and traditional knowledge and government authorities. Research permit systems have an important role to play in:
2. Implementation of the permit providing evidence of prior informed consent and mutually agreed terms foreseen in Article 6.3(a) of the Nagoya Protocol on access to genetic resources.
3. Creating simplified measures on access for non-commercial research purposes under Article 8a with due regard to the need to address change of intent.
4. Realising fair and equitable benefit-sharing arising from research under Article 5 of the Protocol and its Annex. Benefits arising from research of all types involving genetic resources may include, inter alia: funding, international collaborations, training, scientific publications, reports, patents, material transfer agreements and licenses, market approvals, clinical trials and commercial products.
5. Enhancing transparency on the utilization of genetic resources and monitoring to support compliance under Article 17 and providing a platform for evidence based valuation of genetic resources and associated traditional knowledge.
6. National Reporting under Article 29 and Decision NP-1/3 of COP-MOP1 and support for the effective operation of the ABS Clearing House Mechanism.

National research permit systems have typically developed organically over time in response to specific needs for the regulation of research (e.g. in protected areas or involving threatened species). Within a country multiple authorities may hold responsibility for issuing permits (e.g. scientific bodies, environment, national parks, agriculture, marine etc.) and coordination between authorities and consistency in permit provisions may be limited. The administration of research permits will also vary from purely paper systems to electronic systems or mixtures of the two.

This paper addresses the question of how research permit systems might be adapted to facilitate effective implementation of the Nagoya Protocol. We propose that an online electronic permit and monitoring system will:

1. Make it easier for Parties to the Protocol to review and administer permit applications;
2. Make it easier for applicants to apply for and receive a permit and obtain legal certainty based on compliance with the terms and conditions of the Party providing access;

3. Enhance the capacity of Parties to determine if a permit application triggers domestic access and benefit sharing requirements and obligations under the Nagoya Protocol;
4. Enhance the capacity of Parties to monitor compliance with permits and associated mutually agreed terms and contribute to building confidence in ABS and the Nagoya Protocol;
5. Enhance the capacity of Parties to realise non-monetary and monetary benefits arising from both non-commercial research and commercial research and development involving genetic resources and associated traditional knowledge over the long term;
6. Enhance the capacity of Parties to determine the actual and potential value of genetic resources;
7. Make it easier for Parties to meet national and international reporting requirements under the Nagoya Protocol and related international environmental agreements.

The core of this proposal is the use of "cost-effective communication tools and systems" as envisaged in Article 17.2 of the Protocol to simultaneously streamline the administration of research permits under Article 6, and make it easy for non-commercial and commercial researchers to apply for permits and report on the outcomes of research.

Advances in information technology mean that it is now readily possible to combine electronic data from different sources. We propose that by exploiting these developments it will become possible to link permit systems with the monitoring of scientific publications, patent applications and product registrations to create an effective long term system for monitoring compliance. In the process Parties to the Protocol will be able to create an evidence base for the long term valuation of genetic resources and associated traditional knowledge.

The concept paper is divided into 5 sections.

- Section 1: presents the Background to the proposal;
- Section 2: presents a Model for the online permit and monitoring system;
- Section 3: presents a set of Core Principles informing the design, maintenance and sustainability of the system;
- Section 4: Discusses the use of unique identifiers within the online system;
- Section 5: Presents a draft workplan to assist Parties interested in implementing the system;
- The Annex: Presents the draft work plan as a set of headings for log frame development;
- Schematics: A set of process schematics demonstrating the functioning of the system.

We would emphasise that the aim of this proposal is not to impose a single model. Rather, our purpose is to present a practical model that is robust and flexible enough to respond to the different circumstances and needs of Parties to the Protocol. For this reason we present the model as a series of integrated components (or modules) that can be developed and adapted by Parties interested in implementing the model. We hope that this model will contribute to building shared capacity and collaboration between Parties interested in developing effective ways to meet the access, benefit-sharing, monitoring and reporting requirements of the Protocol. The model may also lead to contributions from research organisations, such as public collections, interested in research permits and effective monitoring of compliance.

This concept paper is intended to evolve over time and is publicly available through the project website and open access GitHub repository in a variety of formats. Subject to interest in development and implementation of the model additional materials will be added over time and contributions are welcomed.

Linking research and ABS permit systems

Introduction

In this concept paper we describe the use of the national research permit system as a platform for administering ABS permits, monitoring compliance and realising non-monetary and monetary benefits arising from collaborations with non-commercial and commercial researchers and research organisations under the Nagoya Protocol.[1] We describe a model for an online permit and monitoring system for the efficient administration of research permits that can be linked to monitoring of scientific literature, patents and commercial products.

The purpose of the model is to support the implementation of domestic access and benefit-sharing frameworks and implementation of the obligations under the Nagoya Protocol. We anticipate that the model will:

1. Support decision-making on whether proposed access to genetic resources and associated traditional knowledge falls within the scope of domestic ABS frameworks (Article 2 & Article 3 of the Nagoya Protocol);
2. Support decision-making on the nature of intended utilizations and the appropriate elements for Mutually Agreed Terms (Article 8(a));
3. Enable effective implementation of Article 6 on access to genetic resources;
4. Contribute to the realisation of fair and equitable benefit-sharing in connection with research under Article 5;
5. Enable monitoring of the utilization and commercialisation of genetic resources and associated traditional knowledge and associated products (Article 17);
6. Contribute to the development of the ABS Clearing House Mechanism;
7. Support national reporting under Article 29 of the Nagoya Protocol.

The proposal does not seek to promote a one size fits all approach but instead to provide a model that is flexible and can be readily adapted to the specific needs of individual Parties to the Nagoya Protocol. We envisage the creation of an informal open coalition of countries with a common interest in an electronic permit and monitoring system that can be adapted to meet their particular circumstances and needs.

The core of this proposal is that Parties to the Protocol, and governments who intend to ratify the Protocol, may wish to adopt:

> *"A single electronic permit system that makes it easy to apply for permits and for government authorities to review and approve applications, monitor compliance and report on the access, benefit-sharing, compliance and reporting provisions of the Nagoya Protocol."*[2]

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[1] The research in this paper was conducted with the support of *The Bahamas Environment, Science & Technology (BEST) Commission* of the Government of The Bahamas under the UNEP/GEF project "Strengthening Access and Benefit Sharing (ABS) in the Bahamas" as set out in Oldham, P (2015) Concepts for an Electronic Monitoring Tool. UNEP/GEF project "Strengthening Access and Benefit Sharing (ABS) in the Bahamas". The present paper was written with the additional support of the multi-donor *ABS Capacity Development Initiative* hosted by the *German Federal Ministry of Economic Cooperation and Development* and implemented by the *Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH*. The views expressed are solely those of the authors and should not be interpreted as reflecting the views of the Government of The Bahamas, BMZ, GIZ or the ABS Initiative.

[2] Oldham, P (2015) Concepts for an Electronic Monitoring Tool. UNEP/GEF project "Strengthening Access and Benefit Sharing (ABS) in the Bahamas"

The majority of countries will already possess research permit systems. The available evidence suggests that in many countries there may be multiple permit granting authorities who administer research permits within their respective mandates. An important feature of this proposal is that we do not suggest that the administration of all ABS related research permits should be transferred to a single permit granting authority. Instead, recognising the diversity of legislative mandates of permit granting authorities within a country, we propose that a single online permit system should be implemented to serve the needs of multiple permit authorities. This approach can be described as a single online permit system with multiple authorities.

The aim of this model is two fold:

1. To provide a single electronic hub or platform for the administration of research permits that meets the requirements of permit authorities and simplifies administration, monitoring, and reporting in the fulfillment of their respective mandates.
2. To simplify the research permit application and reporting process for non-commercial research under Article 8(a) of the Nagoya Protocol and for commercial research and development while enhancing the capacity of countries to realise non-monetary and monetary benefits under the terms of the Nagoya Protocol.
3. More specifically we anticipate that implementation of the model will:
4. Make it easier for Parties to the Protocol to review and administer permit applications;
5. Make it easier for applicants to apply for and receive a permit and obtain legal certainty based on compliance with the terms and conditions of the Party providing access;
6. Enhance the capacity of Parties to the Protocol to determine if a permit application triggers domestic access and benefit sharing requirements and obligations under the Nagoya Protocol;
7. Enhance the capacity of Parties to the Protocol to realise non-monetary and monetary benefits arising from non-commercial research, commercial research and development, and commercialisation involving genetic resources and associated traditional knowledge over the long term;
8. Enhance the capacity of Parties to the Protocol to determine the actual and potential value of their genetic resources through a long term electronic monitoring system;
9. Make it easier for Parties to meet national and international reporting requirements under the Nagoya Protocol and related international environmental agreements.

Background

Researchers seeking to collect biological specimens, to work in protected areas, or to work with indigenous peoples and local communities are routinely expected to apply for a permit to carry out research. This is particularly true for researchers from foreign countries but is also true for domestic researchers.

Research permits frequently set out terms and conditions on the types of collections that may be undertaken and the geographic areas where research and collections may be conducted. It is quite common for research involving biological collections to require permission from more than one permit granting authority. Field research directed to commercial research and development may be subject to additional requirements and require export licences.

In the case of research involving human subjects, such as indigenous peoples and local communities, researchers will generally be expected to secure research permits from the relevant authorities, and to comply with standards for ethical conduct. In countries with indigenous peoples, specific

provisions may apply for conducting research in indigenous communities.[3] Other conditions may apply to research with members of society who are may be classified as vulnerable (e.g. minorities, women, children, persons with disabilities). Professional researchers are accustomed to meeting requirements for research permits and recognise their importance for developing longer term research collaborations that both benefit their research careers and contribute to the knowledge base in the countries where they work.

In return for obtaining a permit, applicants will normally be expected to meet certain conditions. These conditions will vary from one country to another but for foreign researchers commonly include:

1. Requirements for collaboration with local research organisations as research partners.
2. The deposit of biological samples with national institutions (such as herbaria).
3. The provision or deposit of equipment used during the research with local partners.
4. Reports on activities and copies of publications.

Requirements for local research collaboration are important for the development of local research capacity in specialist areas and create the foundations for longer term research collaborations and interchanges between countries. Many countries, including the European Union, have developed special programmes to promote international research collaboration that emphasise benefits for partner countries and communities.

The outcomes of research collaborations enabled by permits include:

1. Research funding for researchers and equipment in partner countries.
2. Training, including schemes for researcher exchanges and degree or advanced level qualifications.
3. Scientific publications, reports, datasets, deposits of samples etc. that improve the knowledge base about biodiversity and genetic resources in a country.

These outcomes are typically categorised as non-monetary benefits but are in practice supported by definable financial investments by external research agencies and contributions from local partner agencies and organisations. As such, there is a direct relationship between research permits and forms of benefit-sharing.

However, the extent to which the terms and conditions in research permits are legally-binding upon researchers once they are outside of national jurisdictions is open to question. For this reason, the use of ABS contracts establishing Mutually Agreed Terms (MAT) on benefit-sharing at the time when access is granted in accordance with the Convention and the Nagoya Protocol are regarded as necessary. Article 6 of the Nagoya Protocol establishes that Parties requiring prior informed consent will:

> *"Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly (Article 6.3(e))"*

As this makes clear, under the Nagoya Protocol, there is a direct relationship between a research permit and the establishment of mutually agreed terms (MAT), with the MAT typically involving an ABS contract. In the paper we use the term research permit issued under the online system to mean a research permit and associated MAT or ABS contract.

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[3] Examples of such guidelines in the case of indigenous peoples include the Australian Institute of Aboriginal and Torres Strait Islander Studies, *Guidelines for Ethical Research In Australian Indigenous Studies 2012* and Chapter 9 of the Canadian Research Councils *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*

The permit providing evidence of prior informed consent and mutually agreed terms is linked to monitoring provisions under Article 17 of the Nagoya Protocol which, inter alia, specifies that:

> *"To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:*
>
> *2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.*
>
> *3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent."*

There is therefore a close relationship between a permit under the Nagoya Protocol as evidence of prior informed consent and the establishment of MAT and monitoring of compliance. However, it is also important to recognise that there are distinctions between types of research involving genetic resources and associated traditional knowledge that may trigger different procedures and MAT under the domestic ABS framework.

Types of Research

As discussed during negotiation of the Nagoya Protocol distinguishing between types of research involving genetic resources and associated traditional knowledge is difficult because the distinction between non-commercial and commercial research is mainly located at the level of the intent of researchers rather than in methods, techniques and materials. Focusing on clarifying the "why" of particular research and identifying specific situations is in our view likely to lead to effective approaches to administration. Here we identify five broad situations that are likely to emerge over time in implementing the Nagoya Protocol.

Non-commercial research

In practice, many (and possibly the majority) of cases of research involving biodiversity, genetic resources and indigenous peoples or local communities will be non-commercial. Article 8(a) of the Nagoya Protocol establishes that:

> *"In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:*
>
> *(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;"*

As this makes clear Parties will create conditions to encourage research contributing to conservation and sustainable use including simplified measures on access for non-commercial research.

The implication of this for the research permit system is that simplified measures could be developed to provide access using standard mutually agreed terms. Where an applicant agrees to the standard mutually agreed terms for non-commercial research (which might simply involve a tick to a check box signifying acceptance of such terms), and subject to acceptance of any other non-ABS requirements (e.g. environmental impact assessment), a permit could simply be granted.

Change of Intent

However, as set out in Article 8(a) the negotiators of the Nagoya Protocol also recognised that what may begin as non-commercial research may become commercial research. It is therefore important that the terms and conditions of permits and associated standard MAT identify change of intent as a trigger for a requirement to return to the provider country for new or renewed prior informed consent and applicable mutually agreed terms for commercial research.

Mixed Research

A third situation may arise where applicants apply for a permit to conduct both non-commercial research and commercial research, or, in other words, research of a mixed type. This situation is perhaps more likely to arise where consortiums of researchers from different public or private organisations are involved in applications for research permits. This situation may be more likely to arise where research locations are remote or involve extreme conditions (e.g. marine research at depth). In these circumstances it may be appropriate to attempt to clearly distinguish between prior informed consent and MAT for non-commercial aspects of the research and those involving commercial research and development (e.g. focusing on a specific species). Alternatively, it may be appropriate to require MAT applicable for commercial research in the interest of certainty on the part of the provider country. This potential situation signifies that a research permit system should make provision for the possibility of permit applications for both non-commercial and commercial research.

Commercial Research

The fourth situation involves cases of explicit commercial research and collection. Viewed from the perspective of the permit system it is likely to be desirable that commercial research is signalled at the application stage and triggers a procedure for the negotiation of MAT with the applicants within a reasonable period of time (Article 6.3(d)). While it may be desirable to develop a standard template for MAT for commercial research this is likely to serve as the starting point for a negotiation phase in arriving at mutually agreed terms and granting prior informed consent.

Research with Indigenous Peoples & Local Communities

As noted above, research involving human subjects, such as indigenous peoples and local communities, is typically the subject of requirements for permits both from relevant authorities (such as Ministries for Indigenous Affairs or their equivalent), subject to requirements for ethical conduct (including by agencies funding the research) and the prior informed consent of the participating communities and research participants.

Access to the genetic resources and associated traditional knowledge of indigenous peoples and local communities for research purposes will require their prior informed consent and mutually agreed terms on benefit-sharing in accordance with the relevant provisions of the Nagoya Protocol and the domestic ABS framework.

Article 6.2 of the Nagoya Protocol specifies that:

> *"In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources."*

Article 6.3(f) further specifies that Parties shall:

"Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources."

Article 5.2 of the Nagoya Protocol on benefit-sharing focuses on circumstances where indigenous peoples and local communities hold genetic resources:

"Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms."

Article 5.3 focuses on benefit-sharing in connection with the utilization of traditional knowledge associated with genetic resources:

"Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms."

The emphasis in the Protocol with respect to prior informed consent with respect to a permit and monitoring system is placed on ensuring, in the relevant circumstances, that prior informed consent is obtained and setting out criteria or processes for obtaining prior informed consent. In this respect, the emphasis is likely to be placed on the provision of information on how an applicant for a research permit might go about obtaining prior informed consent from relevant indigenous peoples and local communities.[4]

Avoidance of prior informed consent & mutually agreed terms

A final situation of relevance to an online permit and monitoring system is a situation where researchers or organisations seek to avoid requirements for prior informed consent and mutually agreed terms altogether. In this situation the permit system will normally be blind.

In this proposal we provide for a fall back position in the monitoring system that uses automated searches to capture publications, patent applications and other electronic materials making reference to a country and its biodiversity. While no system will be perfect, the growing availability of large scale digital data and digital methods will increasingly allow for the capture of cases of avoidance and, among member states of the European Union, failures to perform due diligence.[5]

The issue of avoidance of ABS regulations is however linked to enhancing the general capacity of Parties to know, in empirical terms, what is happening with genetic resources and associated traditional knowledge from within their jurisdictions.

Addressing the Capacity to Know through Monitoring

A fundamental precondition for the successful implementation of the Nagoya Protocol on the national and international level is the capacity of Parties to know that the terms and conditions set out in permits and associated mutually agreed terms (ABS contracts) are being complied with by

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[4] See for example the recently developed voluntary guidelines on prior informed consent from the Ninth meeting of the Working Group on Article 8j and related provisions sent for consideration by COP13 in document *UNEP/CBD/COP/13/3* at I9/1.

[5] *EU Regulation No.511/2014*.

recipients. As noted above, Parties will also need to know when efforts are made to avoid requirements for prior informed consent and mutually agreed terms.

Research permit data provides the basic building blocks for identifying research activity involving genetic resources and associated traditional knowledge originating from a country that appears in data sources including:

1. Research publications on biodiversity, genetic resources and the traditional knowledge of indigenous peoples and local communities.
2. Patent applications and grants (as an indicator of commercial research & development).
3. Applications for market approval and products arising from utilizations of genetic resources and associated traditional knowledge.

The key to the use of the permit system as a tool for monitoring is to use the information provided by applicants (name, organisation etc.) and specifics of the permit data as inputs to search and compile information from other electronic data sources such as:

- Taxonomic data (e.g. *The Global Biodiversity Information Facility*, *Encyclopedia of Life*, *Catalogue of Life*, *NCBI*, *The IUCN Red List* etc.).
- Electronic literature sources (such as *crossref* or *PubMed* or *Europe PMC* using APIs (Application Programming Interfaces) providing free access to literature data such as author and organisation names, titles and abstracts.[6]
- Patent data using services such as *WIPO Patentscope* or the *European Patent Office Open Patent Services*.
- Product information including product registration/marketing authorization data.
- The results of general web searches or searches of social media.

The combination of data from different electronic sources to address particular questions is a fundamental feature of the rise of informatics and analytics. Within the biodiversity informatics community, it is manifest in the creation of databases of basic taxonomic data that are linked to the scientific literature, images, video and georeferenced data in other databases. This trend is set to accelerate as more data sources become freely accessible using Application Programming Interfaces (APIs) and the funders of research promote open access to data as a condition of research funding for non-commercial research.

The model presented below would allow a Competent National Authority to perform regular automated searches in online databases. Based on information provided by applicants searches could be conducted for publications by a researcher, publications from a permit holding organisation, or searches linked to a specific species or genetic data linked to a permit. The growing use of electronic researcher IDs (such as *ORCID*, *Researchgate* or *ResearcherID* could reduce the need for researchers to report on publications and provide data in an an electronic format that can be shared with others and is more amenable to analysis. In a short space of time it would be possible for a Competent National Authority to compile an electronic archive on biodiversity and ABS related research in the country that could be publicly shared and help to demonstrate the benefits of research on biodiversity and genetic resources within the country.

While information provided by applicants provides the core data for monitoring the system would be able to perform automated searches of data sources for information on references to the country in publications in connection with a species. For example *this search* highlights publications containing a reference to Kenya and the word species recorded in the non-profit *crossref* database of over 81

[6] Application Programming Interfaces are web services that use URL queries to obtain data directly from the electronic database sitting behind a web server. They are very similar to normal web queries except that larger amounts of data and specific data fields can be retrieved and the data is provided in either XML or JSON format.

million journals, books and datasets. *This search* does the same for the Seychelles. In short, the growing availability of large scale open access databases provides important opportunities for cost effective monitoring. In short, the growing availability of large scale open access databases provides important opportunities for cost effective monitoring.

The use of electronic monitoring and analytics based on permit data and independent searches would allow Competent National Authorities to:

- Check compliance with MAT provisions related to information in publications
- Check compliance with MAT provisions related to information in patent applications
- Identify cases of utilization that appear not to be based on ABS permits and ABS contracts.

Valorisation of Genetic Resources and associated Traditional Knowledge

One important challenge confronting countries involved in the negotiation of the Nagoya Protocol was the lack of reliable data on the economic value of genetic resources and associated traditional knowledge. Furthermore, as is now widely recognised, biodiversity and the knowledge, innovations and practices of indigenous peoples and local communities cannot be reduced purely to economic value. Rather, a broader approach to valorisation, including ecosystem services, is required. A fundamental precondition for this type of analysis is data. The approach presented below would facilitate evidence based valorisation of genetic resources and associated traditional knowledge over the long term and using a range of approaches to the definition of value. It would thus contribute to the creation of a clearly defined evidence base for the evaluation of the effectiveness of domestic ABS measures.

Conclusion

In this section we have explored the background to the proposed model for an online permit and monitoring system provided below. We have argued that the effective implementation of the Nagoya Protocol will require recognition of the importance of linking permit data with recognition of the possibilities for cost effective monitoring opened up by the rise of large scale electronic data about biodiversity. This combination provides important opportunities to increase the confidence of provider countries in ABS and thus contribute to the successful implementation of the Nagoya Protocol. At the same time, permit systems and access and benefit-sharing require a vision that may span decades. For that reason in presenting the model system we encourage Parties to take a long term perspective.

Outline of the Model

This section provides an outline of the model for an online research permit and monitoring system in support of implementation of the *Nagoya Protocol on Access to Genetic Resources and Benefit Sharing*.

The core concept behind the model is:

> *"A single electronic permit system that makes it easy to apply for permits and for government authorities to review and approve applications, monitor compliance and report on the access, benefit-sharing, compliance and reporting provisions of the Nagoya Protocol"* [7]

The model consists of a set of 6 components that contain functional elements. The model is informed by the set of Core Principles provided in *Section 3*. To assist Parties interested in implementation of the model a Draft Work Plan for implementation of the model is provided in *Section 4*. A series of process diagrams illustrating the functions in the model are available *online* or for download and display in presentation mode in *powerpoint*, *Apple keynote* or *pdf*

This section begins with a brief discussion of the existing characteristics of research permit systems and then moves step by step through the components of the system. The schematics were originally designed as a guide for IT specialists seeking to develop the system. As discussed below, a legal component is identified as a cross-cutting issue throughout the model system.

Existing Permit Systems

Research permit systems typically involve the submission of formal applications for permission to conduct research within a country by researchers from outside the country or researchers based inside the country. Specific rules will often apply to particular types of research (such as the collection of biological materials or research involving human subjects) or to research in specific places (e.g. protected areas, marine environments etc.).

Research permit systems have typically evolved organically over time to meet a range of government needs. We have not been able to identify a literature on the general subject of research permit systems and no international overview of research permit systems appears to exist. However, existing experience suggests that research permit systems in many countries are likely to display some, or all, of the following features:

1. Multiple government ministries may hold responsibility for issuing permits based on their respective institutional and legislative competences (e.g. Environment, Agriculture, Marine, Indigenous Affairs etc.). In the case of research involving external researchers, foreign ministries may be involved in facilitating research permit applications (e.g. through embassies). Non-governmental organisations/semi-autonomous organisations may be delegated with responsibility for issuing permits (e.g. national scientific bodies, National Trusts).
2. Applicants seeking permission to carry out research may be required to obtain multiple permits from different government or designated authorities. There may not be coordination between permit granting authorities and there may be multiple routes to obtaining a permit with different terms and conditions. As such, there may be a lack of coordination on the national level and applicants may face difficulties in navigating the system. In some cases relationships between ministries/organisations may be competitive with respect to claims to

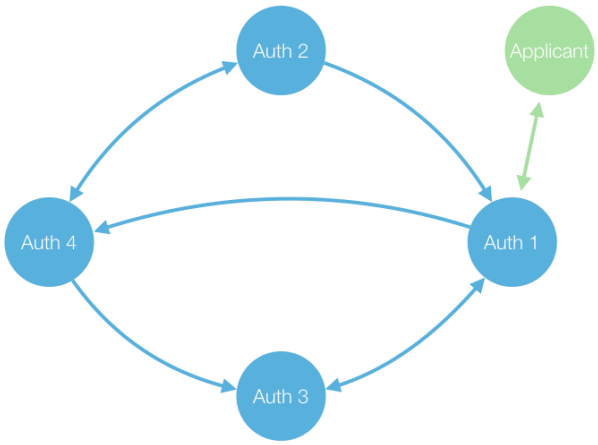
[7] Oldham, P (2015) Concepts for an Electronic Monitoring Tool. UNEP/GEF project "Strengthening Access and Benefit Sharing (ABS) in the Bahamas"

competence in granting permission for research of a particular type or in a specific geographic area.

3. Permits granted by different authorities may contain different (and potentially conflicting) provisions or may not be up to date with legislative developments (such as ratification and implementation of the Nagoya Protocol).
4. Personal relationships between researchers and officials may be an important factor in securing research permits where the system is complex. This introduces the possibility of "back door" access to research permits.
5. No one within, or outside, government may have a clear overview of the national permit system with each authority seeing only their respective part or parts directly relevant to them.
6. The maintenance of permit records may vary considerably within and between ministries/designated authorities. Records may be held in physical form in varying states of order and some records may be missing. Records may be transferred between ministries over time as responsibilities change.
7. Permit granting authorities are increasingly turning to electronic systems but may use different systems and data formats.
8. Permit granting authorities commonly require the submission of reports and publications arising from research conducted under a permit. However, follow up may be limited and it is unclear what use is made of written materials submitted by permit holders once received and filed.
9. Permit granting authorities may have no knowledge of the final destination or uses made of biological or genetic materials collected under a permit.

The characteristics of permit systems will inevitably vary between countries. We would not therefore expect that all national systems possess the features identified above.

One common feature of permit systems appears to be that applications circulate between permit granting authorities in either physical or electronic form. A purely hypothetical version of such a system is presented in Figure 1 below.

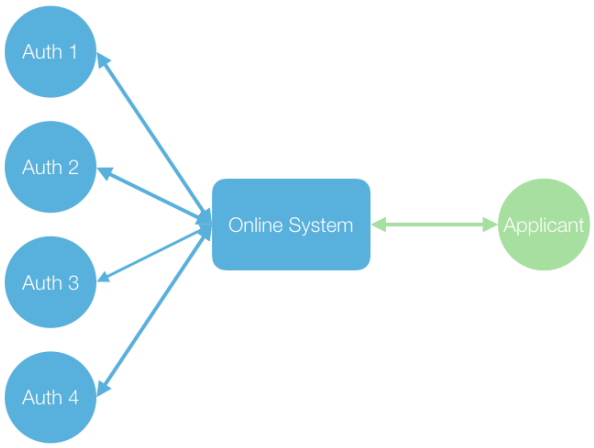


This schematic merely illustrates that once an application is received by a permit granting authority it may circulate in a variety of ways between other authorities involved in the process. How this plays out in practice will vary between countries and systems. We propose an alternative approach whereby applications are administered from a central online hub where permit applications are received, stored and administered.

A Hub Approach

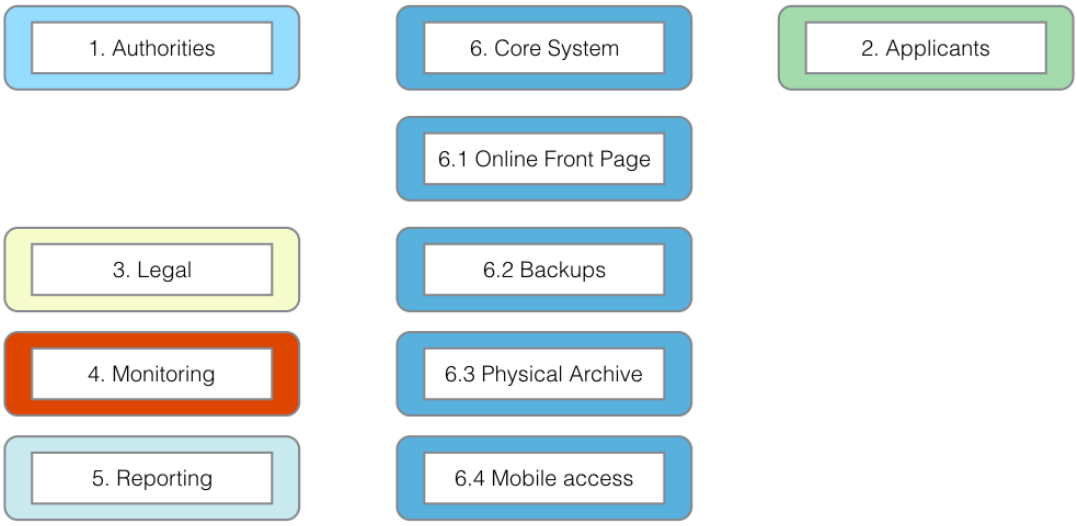
An alternative approach to the circulation of permit applications between authorities is a hub model whether the application stays in one place (an electronic system) and both the applicant and the

authorities log in to access the application. Under this approach the above schematic would be transformed into the following raw model in Figure 2.



In this model, the permit application is lodged in the online system and the relevant authorities and applicants communicate around the electronic application inside the electronic hub. The hub approach allows for formalised intra-institutional communication and exchange of information between permit granting authorities and applicants around an application. Communications relating to an application can also be archived electronically in a retrievable file history or register.

The importance of this apparently simply shift in approach is that it allows for the construction of a formal model with definable components tailored to the requirements of the Nagoya Protocol that can also be adapted to meet other needs. This model and its core components are presented in Figure 3 below.



The core model is discussed in more detail below but consists of the following components.

1. An Authorities Portal
2. An Applicants Portal
3. Legal Issues (a cross-cutting issue)
4. Monitoring
5. Reporting
6. The Core System (the hub)

In considering the basic components of this model we would note that the legal component is a cross cutting issue. The reason for this is that the permit system and the functions required of it must be considered in the context of the overall environmental regulatory system. The overall system is generally seen as a cycle that starts with policy planning and the setting of standards and objectives, together with the establishment of legislation and regulations in order to give them legal effect. A number of countries are currently in the process of developing new or amending existing administrative, legislative and policy measures to meet the requirements set out in the Nagoya

Protocol. In this context, consideration of the legal implications associated with adopting an online permit system is quite key. As the online permit system requires cross agency/departmental coordination, legal mechanisms to give effect to this coordination have to be carefully assessed and designed. For these reasons we emphasise that the technical components of the system should not be seen in isolation from the legal component as a cross cutting issue.

Furthermore, a permit system as a technical system designed to fulfil specific objectives must in our view be informed by Core Principles that guide the design, maintenance and long term future of the system. The Core Principles are provided in *Section 3*.

An Online Permit and Monitoring System

We now turn to more detailed discussion of the proposed structure of the online system and its components. To facilitate discussion a series of process diagrams are available *online* or for download and display in presentation mode in *powerpoint*, *Apple keynote* or *pdf*. The process diagrams demonstrate the workings of the components and elements of the system. We will confine images in this discussion to the main images but suggest that the process diagrams are viewed to assist with interpretation.

The Core System consists of database and server software, programming code to execute the functions described below and hardware. For ease of explanation discussion of the core system (Component 6) will be considered last. Each component is informed by a concept setting out its purpose and a set of principles.

Component 1. The Authorities Portal

Figure 4 displays the core elements of the Authorities Portal displaying 7 functions. The numbering system below refers to the numbered elements in Figure 4.

Concept

A single electronic system or permit hub used by all permit granting authorities to review applications, communicate amongst themselves and with applicants, generate permits and engage in relevant monitoring and reporting.

Principles

a. Efficiency, timeliness and avoiding duplication of effort.

b. Support decision making in identifying the scope of requested access and intended utilization of genetic resources and associated traditional knowledge.

c. Fulfil the Article 6 Access obligations of the Nagoya Protocol.

d. Support implementation of Article 8 (a) of the Nagoya Protocol (special considerations for non-commercial research).

e. Support implementation of Article 17 of the Nagoya Protocol (monitoring utilization of genetic resources and, as appropriate, associated traditional knowledge of indigenous peoples and local communities).

f. Support the ABS Clearing House Mechanism.

g. Support Article 29 obligations (monitoring and reporting on national implementation of the Nagoya Protocol).

Functions

The functions of the permit granting authority portal can be divided into seven broad categories. Each of these contains a subset of activities with varying time frames. Note that the legal component is a cross-cutting issue embedded in many of these functions.

1.1. Enquiries

Receive enquiries and direct applicants to the applicants portal to review the applicants guide and checklist. Once committed to a single online system we anticipate that authorities would uniformly direct applicants to the applicant portal as the only point of access to the permit system or the integrity of the system will be undermined (see *Core Principles*). Note that applicants may seek to avoid using the system because of the obligations to provide full disclosure that it imposes.

1.2. Review

a) Receive applications through the applicants' portal.

b) Review completeness of documentation (checklist).

c) Notification to applicant on the status of the application (complete/incomplete).

d) If complete validate the unique identifier for use in the system (the identifier will be automatically generated, but requires a visual check).

1.2.1 Review type of request (non-commercial, commercial, both).

1.2.1.1 At this point the system will divide depending on whether the applicant is pursuing non-commercial or commercial research and development or both, if relevant in the context of the domestic ABS framework.

a) Define next steps accordingly:

   i) using standard Mutually Agreed Terms (MAT) or negotiation or a combination as required.

   ii) Record details in file system.

b) Issue a Notification to the applicant:

   i) Approve.

   ii) Request more information.

   iii) Reject.

1.2.1.2 Review application in light of environmental and other relevant legislation

a) Communicate with applications for clarification, as appropriate

b) Based on applicants response, either:

   i) Approve.

   ii) Request more information.

   iii) Reject.

c) Issue Notification to applicant.

1.2.2. Specify standard terms and conditions (using a menu of clauses) for inclusion in the permit.

1.2.3. Specify specific terms and conditions for inclusion in the permit (using a menu of clauses).

1.3. Negotiate

Typically for commercially related research the following broad steps can be identified. Note that each of these steps may require additional steps and that the list may be incomplete.

a) Purpose. What is the research for?

b) Actors. Who are the parties to the research? Who are the legal representatives in the negotiation? Who should be involved at relevant stages in the negotiation process on the part of the government?

c) Timeline. What is the timeline for commencement and conclusion of negotiations taking into account Article 6 of the Nagoya Protocol?

d) Establishment of mutually agreed terms (MAT) and agreement on benefit sharing modalities within an agreed time period.

e) Conditions of agreement.

Note that a negotiation phase may also be necessary for non-commercial research or circumstances where researchers plan to conduct both non-commercial and commercial research.

1.4 Approve/Reject

The authority will approve or reject the application. If approved the system will trigger:

a) A .pdf permit containing the relevant details and terms and conditions as defined by the authorities headed by a unique identifier (two letter country code, the year and numeric identifier e.g. BS20151234 for Bahamas 2015 1234), a QR Code, a barcode.

b) A “permit pass” to approved applicants for use on smart phones or tablets if requested by the authorities containing, the unique identifier, a QR code and basic information about the permit and permit holder along with the barcode.

c) Labels containing the unique identifier, QR code and barcode for labelling bags and jars of samples. It should be anticipated that the applicants will print multiple labels as samples are broken down and identified for record keeping.

d) HTML Embed Code. A html version of the above that can be embedded with electronic data.

e) If rejected the application will be linked to the proposed appeals process.

1.5. Appeals

This element provides:

a) Guidance on the appeals process

b) A timeline for appeals

c) Generates notifications for applicants on the progress with their appeal

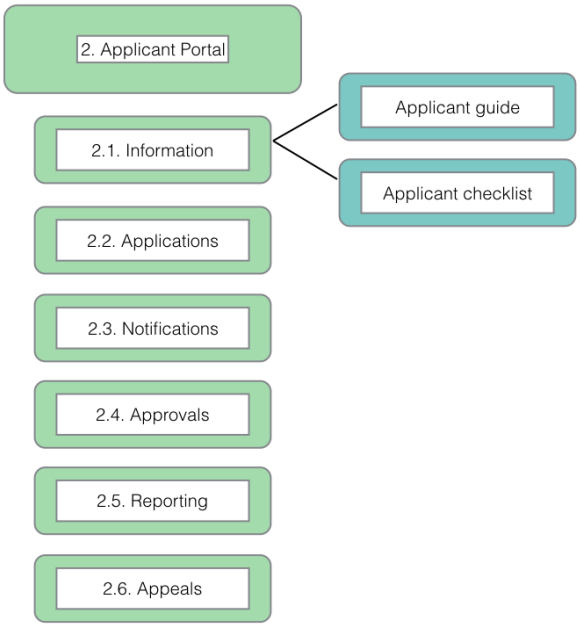
d) A clear written final decision.

The appeals process will assist Parties with demonstrating that rules and procedures on access to genetic resources are fair and non-arbitrary (Art. 6.3(b)).

The Monitoring and Reporting elements of the Authorities Portal are addressed under the respective main components of the system. This includes linkages with the ABS Clearing House Mechanism.

Component 2. The Applicants Portal

Figure 5 displays the main elements of the Applicants Portal. Numbering refers to elements of the Applicants Portal.



Concept

A single online space for applicants to submit applications and supporting information, receive notifications to monitor progress, receive permits and fulfil reporting requirements.

In a single applicant portal, applicants would be able to store information for future applications (such as legal status information) and to provide links to publications, conferences etc. arising from the permit that could, subject to confidentiality considerations, be made publicly available to highlight research and development on genetic resources and associated traditional knowledge.

Principles

a) Full disclosure of the purposes of research, the actors involved and funding.

b) Fulfil user reporting obligations.

c) Enable monitoring of utilisation.

d) Build lasting relationships.

e) Promote research of benefit to the permit granting country.

f) Triple redundancy for monitoring (unique country identifier, QR codes, barcodes, html embed codes).

Functions

The applicants portal would be divided into six elements with different functions:

2.1 Information (applicant guide and checklists).

2.2 Applications (applications in progress).

2.3 Notifications (communications).

2.4 Approvals (permits, permit passes, labels).

2.5 Reporting.

2.6 Appeals.

Please see the accompanying process slides *online*, in *powerpoint* or *pdf* for details.

2.1. Information

a) Provides a guide to the application process and documents required.

b) Provides a checklist for the completeness of applications.

2.2. Applications

Information to be provided by applicants (indicative list):

a) Legal information (researcher names, organisations, statutes, intellectual property policies etc.).

b) Funding information (copies of funding applications including reference/contract numbers, funding agency conditions of grant).

c) Type of research (non-commercial, commercial, both).

d) Objectives of research.

e) Proposed locations.

f) Expected outcomes.

g) Specific details of proposed collections.

h) Anticipated environmental impacts.

i) Measures to address potential environmental impacts.

j) Statement on compliance with national legislation on ABS.

k) Statement on meeting other requirements under relevant national laws.

2.3 Notifications

A single space for applicants to:

a) Receive and respond to requests for information from permit granting authorities.

b) Review notifications on the stage in the procedure of applications pursuant to Article 6 of the Nagoya Protocol.

2.4. Approvals

The approvals section of the applicants portal allows applicants to retrieve approved permits as:

a) A legal .pdf document (generated on the authority side) and any associated documentation.

b) To facilitate checking by local authorities (police, customs, park authorities) the site will generate a time-limited “permit pass” using QR/barcodes that can be stored on a mobile phone or tablet by the applicants and scanned by relevant authorities using QR recognition software.

c) To facilitate monitoring the system will also generate:

   i. Labels containing a unique identifier in QR/barcodes to be affixed to sample bags and individual sample records.

   ii. An electronic version of the unique identifier for tagging electronic data (e.g. HTML embed codes).

   iii. Instructions on the prescribed form for referencing in scientific publications and patent data using the unique identifier (e.g. BS20151234 or - “two letter country code - year - unique permit number”) and/or embed code links.

The granting of a permit for the specified purposes could be considered to constitute evidence that the applicant has received prior informed consent from the government of the country granting the permit and that MAT has been established for the purposes of the domestic ABS framework.

2.5. Reporting

This section of the applicant portal should make it easy for applicants to report on outputs and activities arising from utilisation. Reporting is envisaged to take the form of:

a) Links to research profiles (e.g. *ORCID profiles*, *Researchgate* etc.) and publications arising from the research (DOIs (document identifiers). Open access versions of publications, through services such as the *Directory of Open Access Journals* or preprints through services such as *bioRxiv*, are likely to be preferred and may be specified in MAT or funding requirements. The aim here is to reduce reporting by permitting automated retrieval of electronic information on publications.

b) Patent applications arising from the research (including electronic links).

c) Commercial products (market approvals).

d) Other (for discussion).

2.6. Appeals

This area of the applicants' portal would allow applicants to file and receive information on any appeals for rejected permit applications.

Component 3. Legal Component

The legal component is treated as a cross-cutting component across the online permit and monitoring system. For example, indicative areas for legal review and drafting are likely to include, inter alia:

a) The guide to applicants.

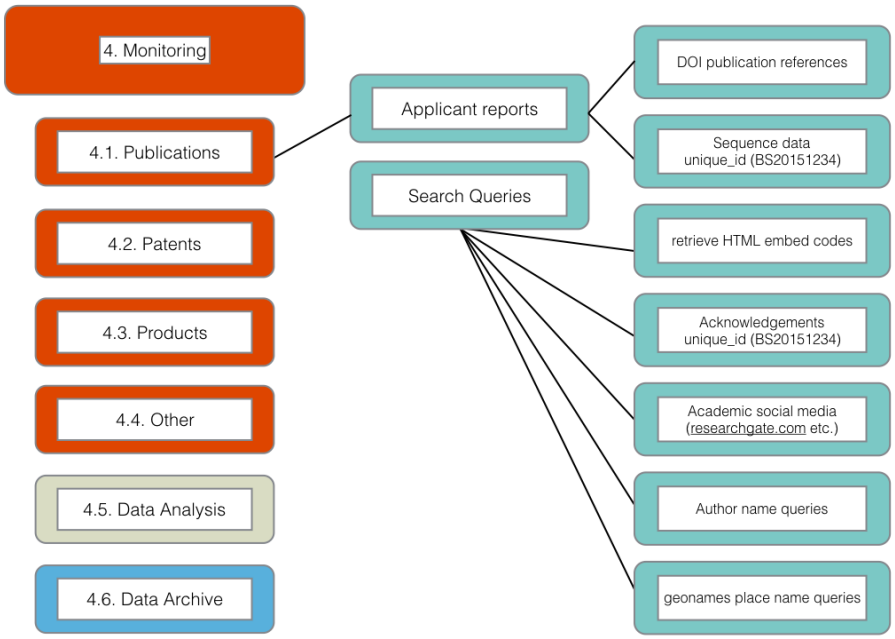
b) Terms and conditions for permits depending on the type of research.

c) Mutually Agreed Terms.

d) Definition of the criteria for rejection of applications and any appeals process.

Component 4. Monitoring

Figure 6 displays the elements of the Monitoring component and the specific details of the element for monitoring publications. For additional details on each element see the process diagrams in presentation mode *online*, in *powerpoint* or *pdf*.



Concept

A cost effective monitoring system for scientific publications, patents, and products arising from research and development involving genetic resources and/or traditional knowledge from the providing Party.

Principles

a) Monitoring and enhancing transparency on the utilization of genetic resources and, where relevant, associated traditional knowledge.

b) Use of cost effective communication tools and systems.

c) Provide an evidence base for the long term valuation of genetic resources and associated traditional knowledge.

Functions

One purpose of a monitoring system is to enable the providing Party to monitor utilisations of genetic resources and associated traditional knowledge originating from its jurisdiction as a basis for monitoring compliance by users with national access and benefit-sharing legislation and mutually agreed terms. A second purpose of a monitoring system is to allow Parties to identify cases where a user seeks to avoid or ignore regulatory requirements (e.g. for prior informed consent and MAT). A third purpose of a monitoring system is to enhance the capacity of Parties to know about research and development involving genetic resources and traditional knowledge as a basis for the valuation of genetic resources over the long term.

There are three main considerations in establishing a cost-effective monitoring system:

a) The availability of information provided by applicants as a key tool for monitoring (person names, institutions, locations, species, funding organisations etc.).

b) The need for independent information to validate and extend information provided by applicants with a view to capturing circumstances of potential non-compliance with national legislation and mutually agreed terms. Independent information is also required to identify cases of avoidance of regulatory requirements (absence of PIC and MAT).

c) Monitoring under Article 17 of the Nagoya Protocol and linkages to National Reporting under the Monitoring and Reporting (Article 29) provisions of the Nagoya Protocol.

In practice, a range of bibliometric/scientometric and analytical methods exist for mapping and monitoring research and patent activity. The growing availability of electronic data (on taxonomy, DNA sequences, publications, patents and products) allows for the mobilisation and application of these methods to access and benefit-sharing.

The monitoring component is particularly relevant to implementation of Article 17 of the Nagoya Protocol. As noted above, there is a direct relationship between the permit foreseen under Article 6.3(e) and monitoring under Article 17.2, notably with respect to the use of a permit as an International Certificate of Compliance. In such cases the International Certificate of Compliance will provide the following information, where such information is not confidential (Article 17.4):

a) Issuing authority

b) Date of issuance

c) The provider

d) Unique identifier of the certificate

e) The person or entity to who prior informed consent was granted

f) Subject matter of genetic resources covered by the certificate

g) Confirmation that mutually agreed terms were established

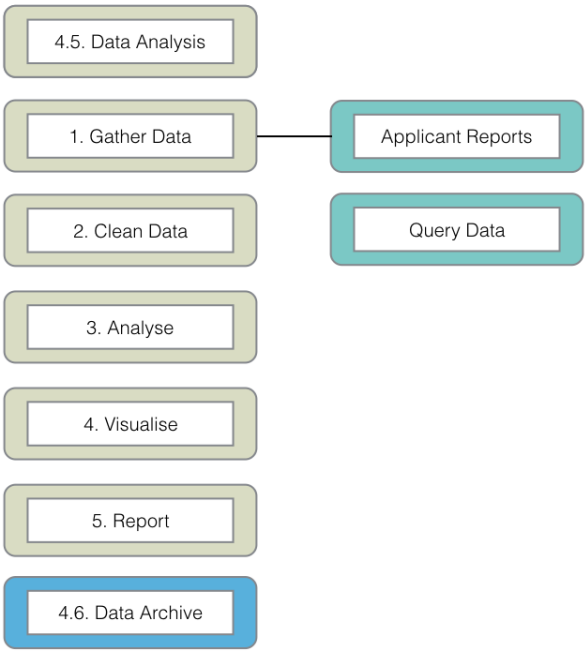
h) Confirmation that prior informed consent was obtained; and

i) Commercial and/or non-commercial use.

It is anticipated that this information, subject to confidentiality considerations, will be made available to the ABS Clearing House Mechanism. Specific consideration will need to be given to information collected under the monitoring element that is submitted to the ABS Clearing House Mechanism (see *Decision NP-1/2*).

The provisions of Article 17 are also linked with Article 29 (Monitoring and Reporting on implementation of the Protocol) with respect to a requirement for Parties to monitor implementation of their obligations under the Protocol. This should be borne in mind when considering a monitoring system and its relationship with reporting (below). Close attention should be paid to the interim national reporting guidelines agreed at the First Meeting of Parties to the Nagoya Protocol as provided in *Decision NP-1/3* and any subsequent COP-MOP decisions in this area.

Data Analysis is a sub-component of Monitoring and involves the processing and analysis of data collected under Monitoring. A schematic for a typical data analysis workflow is provided in Figure 7.



The data analysis step involves a set of methodological steps that may involve a range of software tools. Increasingly, sophisticated data analysis is becoming possible using programming languages such as as *R*, *Python*, and *MySQL* (for databases). Languages such as R are widely used in biological research and a range of free packages exist for accessing taxonomic and DNA databases and scientific literature databases (such as *PubMed* and *crossref)*. A growing emphasis on open access publications as a requirement of funding in European Union and other countries facilitates both monitoring and data analysis.

The data analysis sub-component is closely linked to reporting under Component 5.

Component 5: Reporting

Figure 8 displays the elements of the reporting component.

Concept: Facilitate national reporting under the Nagoya Protocol and other relevant environmental agreements.

Reporting takes place on two main levels:

a) Internal reporting (within ministries and to national Parliaments/Congresses).

b) International reporting requirements linked to treaty obligations.

It is anticipated that the reporting component of the online permit and monitoring system will contribute to supporting internal and international reporting. This will occur by identifying data

under the monitoring component that can be fed into reporting (e.g. statistics on number of permit applications, summary statistics on applicants, number of permits granted, MAT established, publications generated and so on) and is likely to be mainly of a statistical type.

We propose that at the design stage of monitoring consultations take place on existing reporting requirements and how data collated under the monitoring component might be collated into reporting templates.

National reporting is addressed under Article 29 of the Nagoya Protocol and is linked with issues relating to compliance by Parties with the obligations set out in the Nagoya Protocol. Particular attention is drawn to the 66 questions included in the interim national reporting format contained in decision NP 1/3 that will be due for submission 12 months prior to the 3rd meeting of the Parties to the Nagoya Protocol COP MOP NP3 that is expected to take place in 2018. Future decisions by COP-MOP on national reporting should also be taken into consideration.

Principles:

a) Facilitate national and international reporting.

b) Reduce the burden of information compilation on research on genetic resources and associated traditional knowledge.

Functions:

a) Support the compilation of data for national reports under the Nagoya Protocol.

b) Facilitate the provision of non-confidential information to the ABS Clearing House Mechanism.

c) Support reporting needs for closely related treaties, such as the Plant Treaty, to which a country is a Party, as appropriate.

d) Maintain an archive of information used in reports (as part of the main electronic data archive).

Component 6: The Core System

The Core System refers to the core database and server software, code for specific functions and the infrastructure required to create an integrated system.

Figure 9 displays the components in relation to the core system.

Viewed from this perspective the core system consists of the following elements

6.1. Online Front Page. The online front page for the system consisting of a simple home page and secure access to the applicants and authorities portals.

6.2 Backups.

The standard of good practice in computing is to maintain multiple and secure backups of electronic information. The use of encryption in addition to standard security measures will be desirable to protect confidential information.

6.3. Physical Archive.

Countries will typically maintain physical archives for legal purposes. Physical storage is particularly important in circumstances involving timelines of decades. The outputs of the system such as permit applications, permit grants, communications and other materials should be readily printable for storage in the physical archive.

6.4. Mobile Access.

This element of the system is intended to respond to the needs of customs officials, police and national park authorities involved in spot checks of permit documentation. The growing use of mobile phones and tablets by authorities responsible for checking permits provides important opportunities to facilitate their work. Under this element we envisage the use of technologies such as a time limited "permit pass" (similar to an airport boarding pass with a QR code) that can be scanned by customs and other authorities with access to the relevant parts of the core system.

System Requirements

The precise details of how the system is implemented are likely to depend on the needs and capacities of individual Parties. We propose that as far as possible, for reasons of cost, a wide user base, security and extendibility that standard versions of open source software should be used to implement the core system (e.g. a MySQL Database and Apache web server). The use of open source tools is widespread in information technology (e.g. Apache serve software powers most websites). As discussed in the Core Principles, the use of open source software tools enjoys the benefit of permitting Parties to share and learn from and adopt software modules developed by other countries seeking to implement the system. In short, the use of open software provides a platform for collaboration and capacity-building between countries participating in implementing the model. Finally, the use of open source tools in the core architecture mitigates against the risk that contractors will seek to capture the system over the long term.

Outline Structure

Figure 10 provides a simplified outline of the structure of the system. At the core of this system is server software (e.g. Apache) attached to a database (e.g. MySQL) and code and subsidiary systems to perform the functions described above.

Two areas of the system are likely to present technical challenges:

1. The notification system. It is envisaged that this will be an email based system with existing systems (such as ticketing systems and open source push notification systems meriting investigation).
2. Mobile access for permit checking authorities.

Monitoring (using queries and APIs) will require investment in the development and refinement of search queries across a range of data sources and capacity building in the use of analytics software for those responsible. Opportunities may exist for shared capacity between countries in some of these areas.

Resources

Figure 11 provides an outline of the resources needed to implement the system. Entries on the left are indicative and are likely to include a mix of free and commercial software tools (e.g. databases and analytics tools).

The model anticipates that, in the case of monitoring and analysis tools, a phased approach will be taken depending on existing internal capacities. This may involve the use of off the shelf commercial tools requiring only limited skills and knowledge in the first instance to develop internal capacity followed by the adoption of more sophisticated free software tools (e.g. RStudio) for monitoring and analytics accompanied by the use of open source packages for accessing scientific literature, taxonomic data and patent information.

The use of free tools such as the R language is suggested here because of the large number of resources focusing on biology such as Bioconductor and the links with statistics, mapping and

modelling. In particular attention is drawn to the suite of free packages being developed by rOpenSci. Widely used alternatives or complements to R include Python.

The long term advantage of the open source route is a large ecosystem of users and culture of collaboration to address common needs. However, open source tools depend on investments in training people to use them. It is sensible to anticipate a period of capacity building before the transition from off the shelf to open source tools is made. It is also sensible to anticipate that a mix of approaches and tools may prove to be the most cost effective. In short, it is important to concentrate on what will work best for a Party, or group of Parties, taking into account their circumstances, existing capacity and needs.

Core Principles

The development of a streamlined electronic system requires consideration of the principles that inform the development and maintenance of the system over a time frame involving decades. The following are a set of Core Principles that focus on the objective, how the objective is to be realised, and the features of the system.

Design Principles

These principles refer to the design and implementation of the online permit and monitoring system.

1. *A Single System* that serves the needs of permit granting authorities and applicants seeking to access genetic resources and/or traditional knowledge associated with genetic resources within a country's jurisdiction.

2. *A Central Hub*. In existing systems a permit application may be circulated by email or by post to various permit granting authorities. In this system the application, once submitted in electronic form, stays in place at a central server based hub. It is assumed that more than one authority may be involved in reviewing or authorising a permit. In this system notifications are dispatched to relevant authorities to inform them of the need for action on a particular application. Authorities log in to the system and take action accordingly, including communications with applicants that are transmitted through the notification system. Communications arising from an application are stored with the application as part of the electronic file register for the application.

3. *Easy to Use*. The system should be as simple as possible and not require specialist knowledge or software to access or use the system. The system is intended to be used by non-specialists using simple check boxes and entries in forms.

4. *Responsive*. The system should be sufficiently flexible to adapt to the needs of different authorities, including their reporting needs. The needs of police, customs and national park authorities should be addressed through responsive mobile formats (phones and tablets) including use of "permit passes" with QR codes (Quick Response codes) and bar codes similar to a mobile airline boarding pass. The "permit pass" would be carried by applicants and could be checked by relevant authorities on the ground using reader software on mobile phones with minimal effort. Consultation and practical testing with the relevant authorities is required to implement this principle.

5. *Secure*. The system should meet standard security requirements (e.g. https:) and comply with applicable data protection laws. Attention should be paid to the provisions of the Nagoya Protocol on confidentiality (Article 14.2, 17.3, 17.4). Particular attention should be paid to the storage of commercially sensitive information linked to a permit and ABS contract including secure offline storage of such information. Backups of the system should be maintained securely and encrypted in accordance with existing standards for the protection of digital information. A physical archive of the documents should be maintained in accordance with existing practice.

Attention may also be required to protect against back doors. A back-door is a secret route into an electronic system that bypasses normal authentication requirements. Back doors may be built in at the design stage (to provide a means of restoring access to the system resulting from lockout) or discovered by users seeking access to the system. Consideration should be given to limiting the potential for back doors in any code and monitoring to detect

back doors that may subsequently be discovered by users. For discussion on types of back doors see *Wysopal, C and Eng, C (2015) Static Detection of Application Backdoors.*

6. *Independent*. The system should be based on, and maintained, using widely available standard open source software tools and standard text formats to avoid dependency on a single supplier/contractor or data format. No third party should own all or part of the system. Note that public procurement rules are likely to be of relevance in implementing this principle.

7. *Long Term*. The research and development cycle involving biological and genetic resources or associated traditional knowledge may take place over a period of decades. It is therefore important to take a long term perspective on the functioning of the permit system and its integrity over time, including proper back-ups.

8. *Unique Identifiers*. Unique identifiers enable internal coherence within the system and monitoring outside the system. For a permit and monitoring system the starting point could be a unique identifier such as a standardised country code (e.g. BS for the Bahamas or UG for Uganda and ZA for South Africa), the date (2015) and unique number (1234) to produce unique identifiers such as BS20151234, UG20151234 or ZA20151234. This system functions very effectively for 90 million patent documents in multiple countries and is recommended.

9. *Triple Redundancy*. The permit system should build in the principle of triple redundancy in its tracking system rather than relying on a single point of reference. Triple redundancy is an engineering design principle that means that three distinct systems perform the same function. Because they are independent systems, if one system fails the two others will continue to work. If a second system fails then one other system, normally the simplest, will continue to work. Further details and examples of the implementation of this principle for ABS are provided in *Section 4* on unique identifiers.

10. *Integrating Technical and Legal Components*. The development of an online permit and monitoring system is a technical development that is directed towards the effective realisation of legal obligations on the part of Parties to the Protocol and establishing clear legal requirements on the part of applicants. Legal aspects of the system, notably with respect to the terms of permits and contracts as well as change of intent should be recognised at the design stage. In practice this means that the development of the technical aspects of the system and the legal aspects should be closely linked. Longer term legal advice should be built into the development cycle to respond to changing legal requirements.

11. *Minimal Human Intervention*. Primary responsibility for data input should rest with applicants in entering legally required information. Government action should be confined, as far as possible, to approval of electronic applications, communications related to approvals, and archiving of physical copies of records. The basis of this principle is that human intervention introduces typological errors (such as spelling mistakes) or errors of interpretation (such as interpretations of person or institutional names). These errors affect the integrity and utility of the system over the long term, particularly with respect to monitoring and reporting.

12. *Anticipate Legacy*. A development cycle approach to the permit system should be established that involves forward planning and transitioning from an existing system (that becomes the legacy system) to a new system over time. A formal development plan should be developed and periodically reviewed based on experience gained.

13. *Value Permit Staff*. The permit system is important to the ability of Parties to the Protocol to implement their obligations, generate benefit-sharing and the valuation of genetic resources and associated traditional knowledge. The time horizon for the realisation of benefits may span decades. While most countries have a permit system it is also important to value the staff who

process permit data. This role will become increasingly important in future years in terms of the capacity to bring benefits for conservation and sustainable use. Consideration should therefore be given to recognition of the importance of staff roles and maintaining continuity in the skills required to run and maintain the system.

Access and Benefit Sharing Related Principles

14. *Timeliness*. The Nagoya Protocol sets out minimum access standards. *Article 6.3(d)* requires that Parties to the Protocol:

"…provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and written within a reasonable period of time".

The single permit system should facilitate compliance with the terms of the Protocol by the governments operating this system. This could include creating an applicants portal providing clear information on the progress of applications in the procedure, the name and contact details of the relevant person at each stage of the procedure and extend to the generation of automatic emails notifying applicants when a stage in the procedure has been approved or providing written information on issues requiring resolution. Implementation of this principle could also include a clear, transparent and time limited appeals process.

15. *Transparency*. This principle has four aspects:

a) *Accuracy*. Applicants should be required to provide full and accurate information on each legal person applying for a permit and the legal entities (universities, companies etc.) with whom the government is entering into a relationship through the research permit and ABS contract. Failure to provide accurate information should be grounds for revocation of a permit and other appropriate sanctions. "Group" or "bulk"" permit applications by a lead investigator accompanied by unnamed others should not, in our view, exist as an option because it prevents monitoring of compliance.

b) *Clarity*. In accordance with Article 6 of the Nagoya Protocol government authorities will provide clarity on the steps in the procedure, and the status of applications.

c) *Responsibility*. To ensure clear lines of responsibility and prevent bottlenecks in the processing of applications the designation of a lead authority within the system is desirable. In cases where multiple permit granting authorities are involved in processing an application, applicants should be notified on the name of the authority holding the permit within the system at a given stage in the procedure. In cases of undue delay the designated lead authority should possess the authority to assist the authority involved to resolve the delay.

d) *Fair and Non-arbitrary*. Clear written reasons should be given for rejection of applications. A menu of standard reasons for rejection (e.g. incomplete information, inaccurate information, failure to comply with environmental impact assessment legislation etc.) could facilitate timely and transparent communications with applicants while meeting the terms of Article 6 of the Protocol. Applicants may be provided with the opportunity to appeal against rejected applications through a well defined and transparent procedure.

16. *No Backdoor Access to Permits*. No legitimate means should exist to obtain a permit outside the electronic system. Users of the permit system may seek to avoid using the electronic system in order to avoid its obligations to disclose information and enter into mutually agreed terms. This is likely to be pursued through personal networking. There should be no back-door routes to obtaining permit data outside of the single system or the integrity of the overall system will be undermined at the expense of longer term benefit-sharing for conservation and sustainable use.

17. *Address Types of Permit and Anticipate Change of Intent*. Permits may be granted for different types of research, notably non-commercial or commercial research. The Nagoya Protocol in *Article 8(a)* also anticipates the possibility of a change of intent from non-commercial to commercial research and development. The single permit system should provide a basic set of options for applicants (e.g. is this non-commercial or commercial research?) that then triggers different pathways for the processing of the applications by authorities in accordance with the requirements for non-commercial and commercial applications. Issues relating to change of intent could be dealt with through a formal requirement set out in the permit and associated MAT to declare a change of intent and report such a change within the online system. A report of a change of intent (from non-commercial to commercial research and development) would then trigger a negotiation phase for informed consent and revised MAT appropriate for commercial research and development. This possibility should be anticipated at the design stage.

18. *Monitoring*. The system should support monitoring in two ways:

    a) By facilitating automated searches for scientific literature, patent data and online sources or product registries with respect to the provisions of Article 17 of the Nagoya Protocol.

    b) By providing applicants with a means to easily provide information on scientific publications, patent applications, products or other information relevant to the terms and conditions of the permit and associated MAT. Making it easier to provide information will at least partly overcome the limitations of reporting by researchers in existing systems.

19. *Tidy Data*. This technical principle relates to the conditions for using permit data as a tool for monitoring and reporting. Tidy data is the principle that a field in a data table should contain a single piece of information (e.g. a name) and no other information. A variable (normally a column) should only contain information of the same type (e.g. a country name, not a country name and an organisation name) (*Wickham 2014*). This principle is important in creating a cost-effective and efficient monitoring and reporting system because the majority of an analysts time is typically taken up with cleaning messy data prior to analysis. Anticipating the need for tidy data at the design stage will lead to cost savings at the implementation stage for monitoring and reporting.

20. *Reporting*. The system should contribute to the efforts of governments to meet internal national reporting requirements and to meet the obligations under *Article 29* of the Nagoya Protocol on Monitoring and Reporting (national reporting and compliance with the obligations set out in the Protocol). Particular attention may be paid to COP MOP *Decision NP-1/3* setting out guidelines and the format for interim national reports under *Article 29*.

The online permit system can facilitate information on subjects such as:

1. Numbers of permits granted by type.
2. Organisations/Companies involved.
3. Funding bodies involved.
4. Countries involved.
5. Publications/patent applications or products arising.
6. Provision of information to the ABS Clearing House Mechanism.

Unique Identifiers

Introduction

This section discusses the use of unique identifiers for permits and related documents and the application of the principle of triple redundancy.

Unique identifiers associated with permits and associated documents will allow for sets of documents linked to a specific application to be stored within a retrievable register or file history. As such, unique identifiers will enable internal coherence within the permit system.

Unique identifiers linked to a permit and corresponding MAT (an ABS contract) are also the key to monitoring the outcomes of research and the genetic resources. We propose a system consisting of the following unique identifiers:

- Country Codes, dates and unique numbers (e.g. BS20151234).
- Bar codes.
- QR Codes (Quick Response codes).
- Html embed codes.

In proposing the use of unique identifiers we also suggest the application of the principle of triple redundancy, notably in labelling. The principle of triple redundancy is a well established engineering principle that involves three different systems performing the same function. In the event that one system fails a second system takes over the same function. If the second system fails then the third system takes over. Given that the failure of all three systems is unlikely the function of a particular system within a wider system is maintained. It is important to note that triple redundancy does not guarantee that a system will not fail completely, rather it reduces the likelihood of failure.

The principle of triple redundancy is particularly relevant to an online permit and monitoring system in connection with the use of unique identifiers to maintain the link between a permit, mutually agreed terms and samples of biological material that are subsequently deposited with a collection, transferred to a collection in a third country and potentially utilized by third parties.

The problem that triple redundancy helps to address is in ensuring the maintenance of the connection between a permit and a document containing MAT (an ABS contract) and the materials that are collected and transferred. These materials may be either physical or electronic (e.g. DNA and amino acid sequence data). The scope of genetic resources is likely to be defined in domestic ABS legislation.

Country Code Identifiers

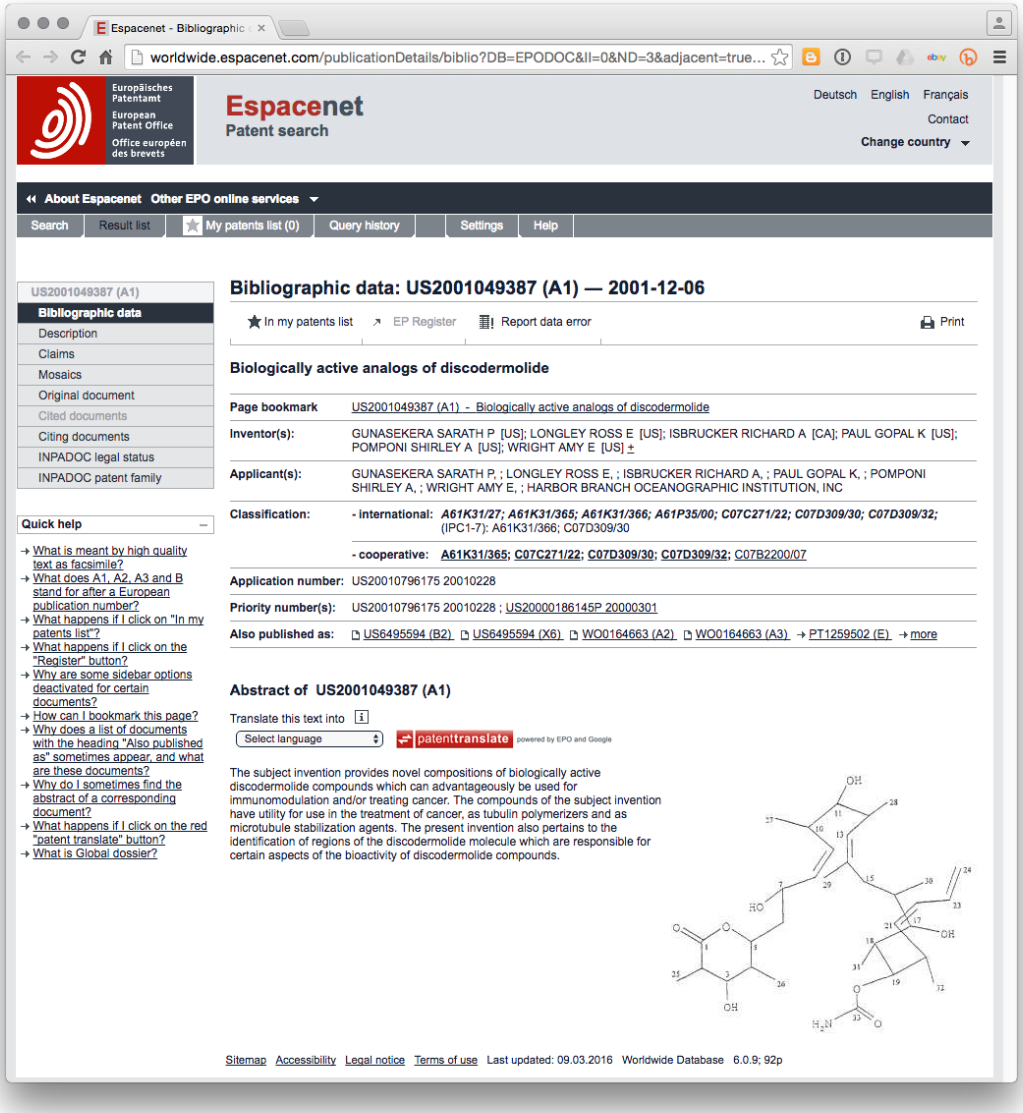
All countries possess a unique two letter country code defined in international standard ISO3166-1 alpha 2 (e.g. see *this Wikipedia entry* and the *ISO browsing platform* and select Country codes and search).

For example, the standard two letter country code for the Bahamas is BS, Kenya is KE, Uganda is UG and South Africa is ZA. If these country codes are combined with a date (YYYYMMDD) and a unique number (1234) a unique identifier will be generated. In this case we will simply use the year (YYYY) to generate the following identifiers.

- BS20151234
- KE20151234
- UG20151234

- ZA20151234

What is clear from this is that a single and distinctive unique identifier (country - year - number) has been created for each permit and corresponding MAT that is immediately distinguishable using the country code from similar numbers issued by other authorities. The combination of the country code, the date and a numeric identifier (country - YYYMMDD - number) is already used very successfully to keep track of approximately 90 million patent documents in countries around the world and is recommended. The example below is for a patent application from the United States that makes reference to collections from the Bahamas and can be viewed on the main worldwide patent database *espacenet* operated by the European Patent Office *here*.

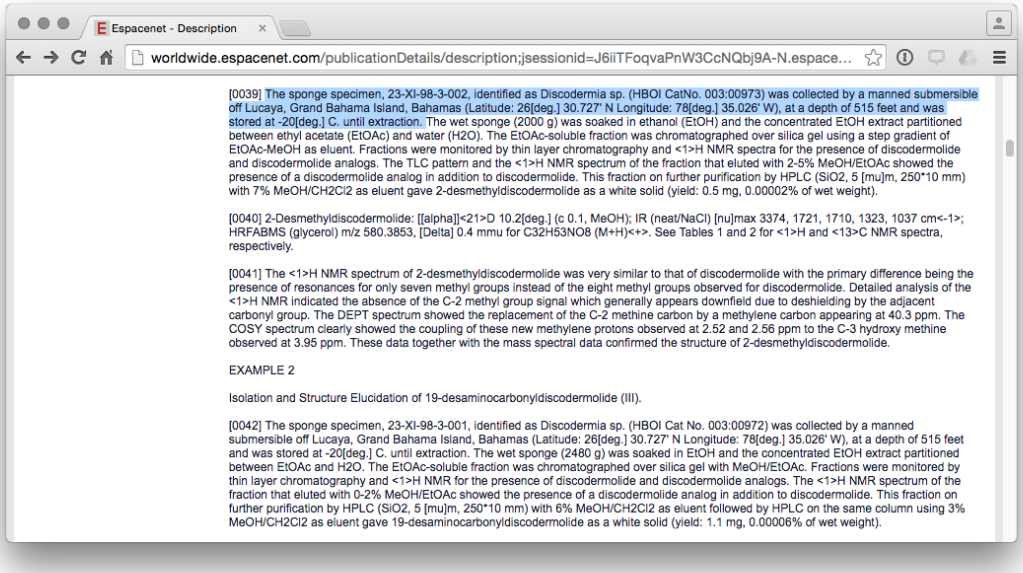


In this example we can see that the unique document identifier US2001049387A1 consists of the following [US] – the country code – [2001] the year of application – [049387] – the unique numeric identifier, and [A1] known as the “kind code” for the type of document (in this case a patent application).

The strength of this system is that the components combine into a unique identifier that is:

- distinctive, and;
- easy to retrieve.

The relevance of this type of numbering system becomes apparent when we consider the section of this patent application that makes reference to biological collections in a country. In this case the example is from the Bahamas (See the first paragraph highlighted or read directly *here*).

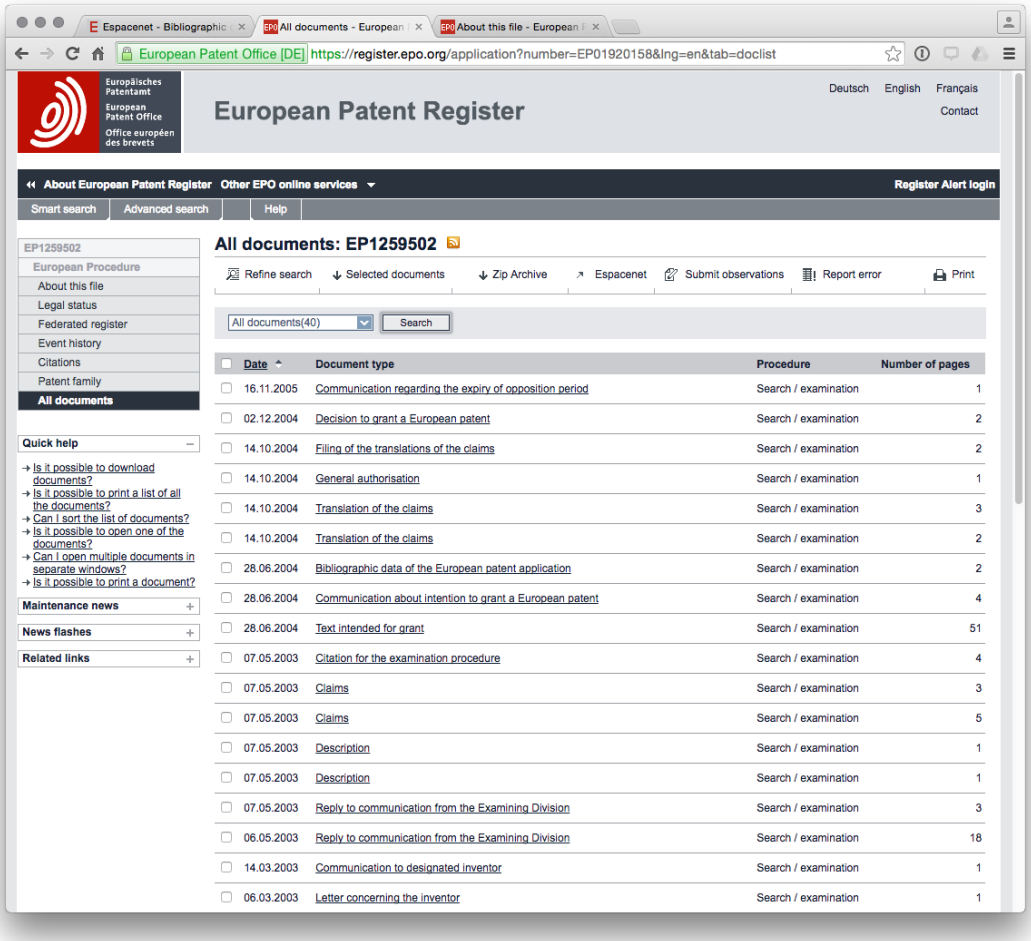


In this case, the applicants make reference to a sponge specimen 23-XI-98-3-002 and a HBOI CatNo. 003:00973. Under the proposal advanced in this document the ABS domestic legislation, permit and associated MAT could require recipients of a permit to disclose the permit number (e.g. BS20151234) in the description section of any patent application arising from the research.[8].

Unique Identifiers and Registers

An important feature of this system as deployed within patent databases is that the unique identifier is used to store all documents that relate to a particular application over time. In this case the United States application was also filed in Europe at the European Patent Office and this document can be identified in the *patent family* of the US document. European Patent Application *EP1259502A2* was filed prior to the introduction of the year into the identifier. However, for our purposes the document is important because in Europe it is possible to access all documents linked to that application, including formal communications between the patent office and applicants in the *European Patent Register*. The figure below displays the list of documents linked to this identifier and can be accessed *here*.

[8] See Oldham and Burton (2010) Defusing Disclosure in Patent Applications, *UNEP/CBD/COP/10/INF/44* and Oldham, Hall and Forero (2013) *Biological Diversity in the Patent System. PLOS ONE*)



It is immediately clear that the use of this unique identifier system allows all documents related to that identifier to be linked together into an electronic register (file history) for each application. We propose a very similar system where a unique identifier is used to link all documents arising from a permit application both internally within the system and for samples, publications and patent applications arising from the research. Specifically, the use of the unique identifier in labels for samples and specimens would facilitate the monitoring of compliance by users.

This type of unique identifier is simple, easy to use and robust over time. For that reason it is recommended as the first component of a triple system.

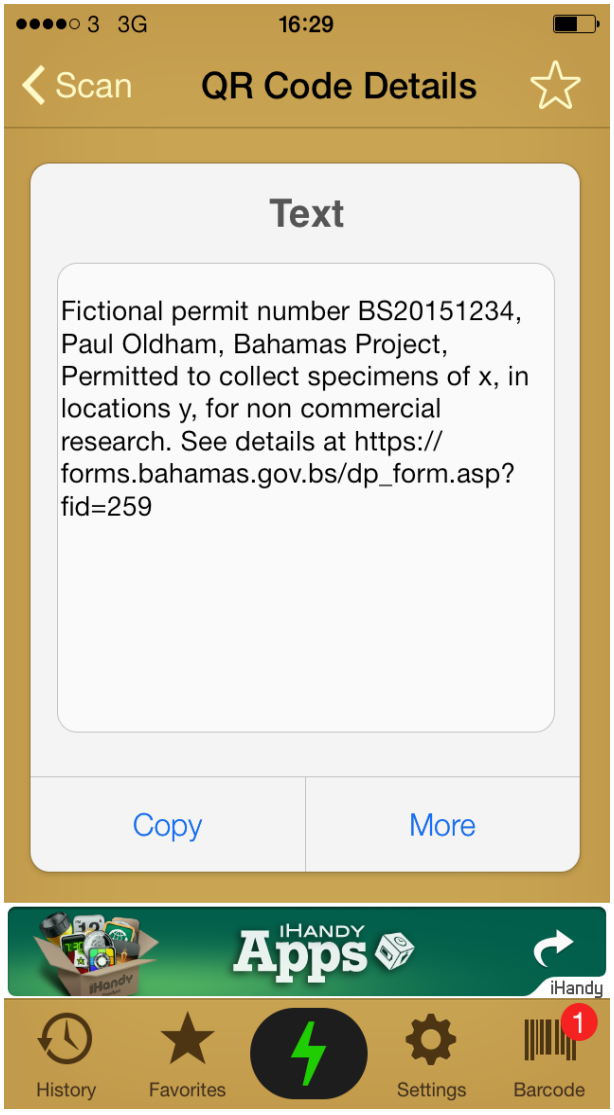
Simple Barcodes

A second system is the standard bar code which can be optically scanned to reveal basic information. The bar code system was developed in the 1960s and became ubiquitous for tracking and scanning products from the 1970s onwards. A range of bar code types are available along with free bar code generators. A simple example using a free tool is provided below. This bar code could be attached to documents and samples with basic information that could be encoded into the bar code. The advantage of a simple bar code is that it can be scanned by a machine.

Quick Response Codes (QR Codes)

The third system is QR (Quick Response) codes which provide a much greater level of embedded detail than bar codes and can be used to embed geographic and other information. An example is provided below.

The information in this QR code can be read using free software on a smart phone such as an iPhone, Android phone, or tablet, as can be seen in the image below (using QRReader on the iPhone). QR codes are normally open. However, encryption of data may potentially be desirable so that only authorised users (police, customs, port authorities) can scan the contents.



The combination of the three systems would meet the requirement for triple redundancy. The main issue is not likely to be the means to generate the identifiers and codes but with ensuring that both authorities and applicants consistently use the identifiers and codes in documentation (including sample documentation) linked to a permit and associated MAT.

Finally, the use of identifiers is likely to be desirable in cases where ABS domestic frameworks include DNA and amino acid sequence data arising from research under a permit and associated MAT. This requires further exploration but is briefly considered below.

DNA and Amino Acid Sequences

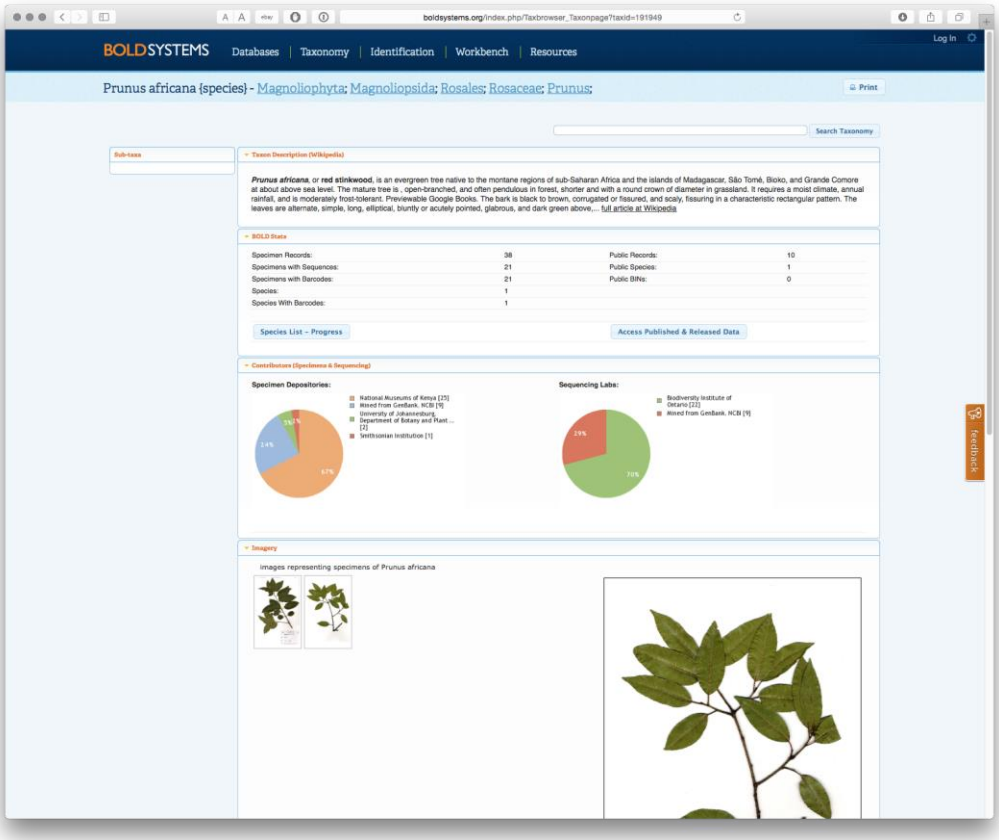
Additional options include a requirement to use the basic unique identifier (BS20151234) in the documentation entered into databases for DNA and amino acid sequence data or html embed codes (for web publications).

In the case of DNA data an example of the existing use of identifiers, and the ability to monitor DNA sequence and amino acid information is provided by the *Barcode of Life Database (BOLD)*.

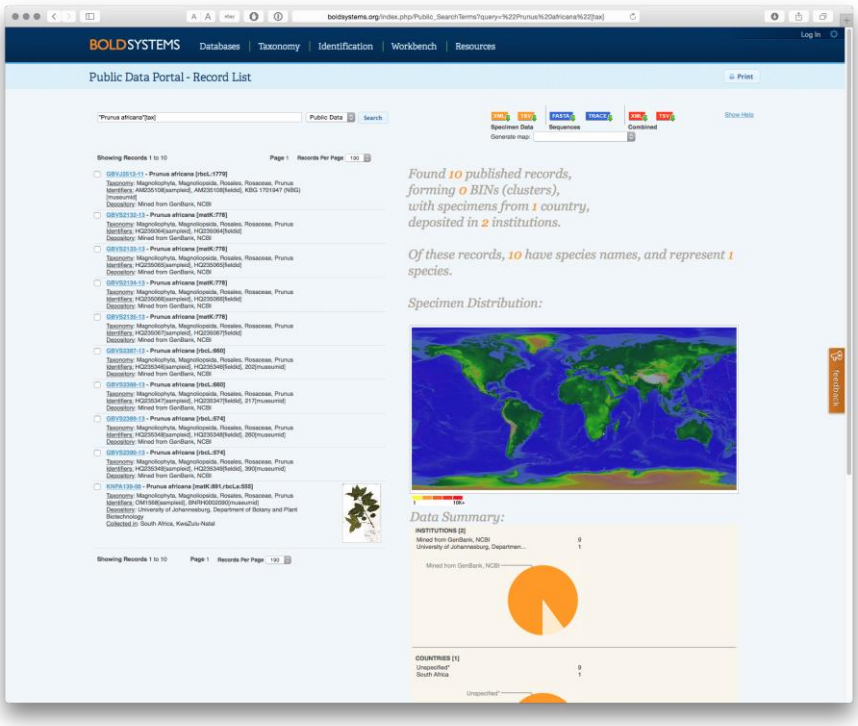
Information using species names or identifiers can be retrieved using the `taxize` package in R using *RStudio* which generates the following link for a search for a species name.

```r
library(taxize) # load the taxize package
get_boldid(searchterm = "Prunus africana") # search for the dna barcode id for a species

##
## Retrieving data for taxon 'Prunus africana'

## [1] "191949"
## attr(,"class")
## [1] "boldid"
## attr(,"match")
## [1] "found"
## attr(,"uri")
## [1] "http://boldsystems.org/index.php/Taxbrowser_Taxonpage?taxid=191949"
```

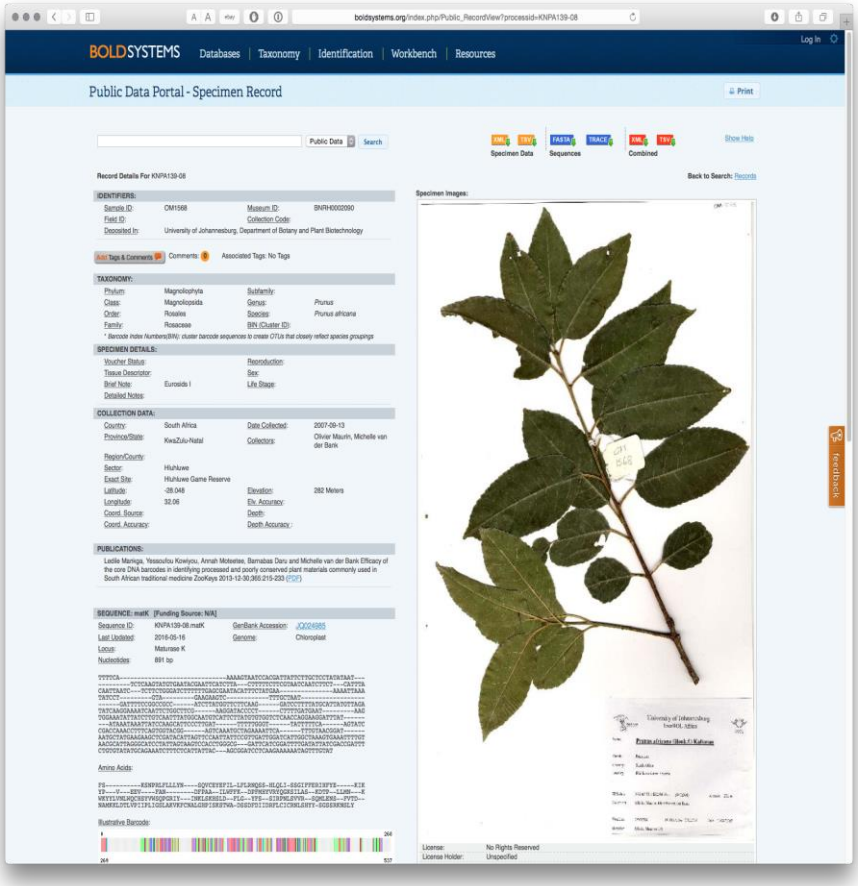
More information from the URL can then be accessed in R as a data table or through the BOLD website. On the BOLD website this produces a list of sequence related records. The image below is viewable *here*.



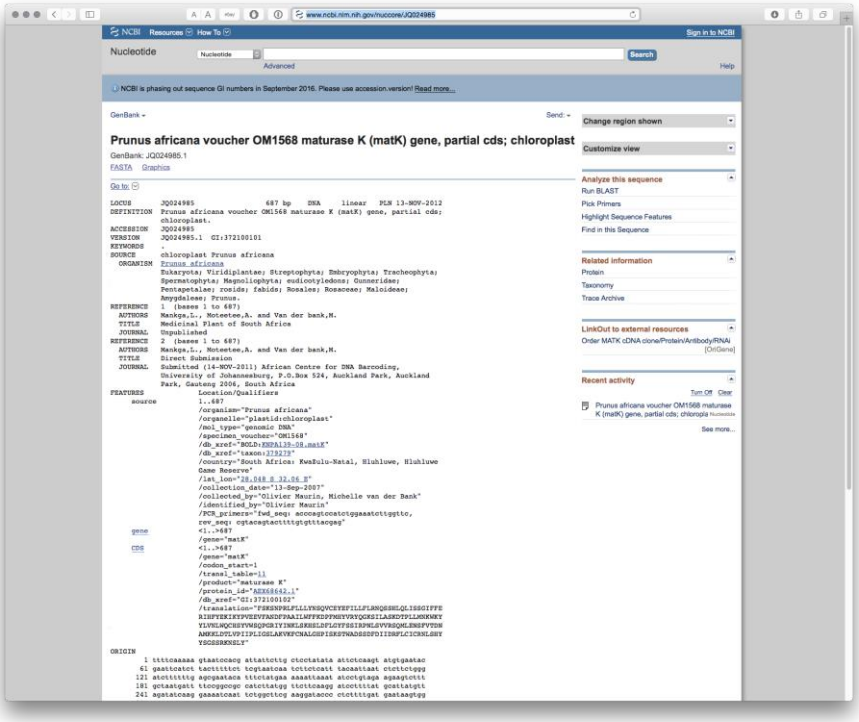
Selecting `Access Published & Released Data` produces the following list of *records*.



The final record in this list includes a specimen image and the *following information*.



A significant amount of information is contained in this record, including the record number, sample ID, Museum ID, where the specimen is located along with where the material was collected, by whom, along with the sequence listing. A link is also provided to the Sequence ID and *GenBank Accession number* as seen below.



As this demonstrates, it is increasingly possible to rapidly access sequence and associated record information for a particular species or list of species. Given the presence of multiple ID fields it appears reasonable to assume that the simple permit identifier (e.g. BS21051234) in sequence records arising from research could be included in the conditions of the permit and associated MAT. This could readily lead to the creation of an archive of electronic records for biodiversity in a country that contain known sequence data. Uses of such sequences could then become amenable to monitoring using the relevant IDs or sequence searching for identical or similar sequences using BLAST (Basic Local Alignment Search Tool) and associated tools.

Conclusion

In this section we have discussed the use of unique identifiers and the application of the principle of triple redundancy as part of the design of the online permit and monitoring system. Unique identifiers using standardised country codes, dates and sequences of numbers allow for the construction of an internal permit system that establishes and maintains links between a permit application and associated documents (MAT) and communications. This system already works well for millions of patent documents. The principle of triple redundancy was then applied to the generation of labels containing identifiers that could be used to maintain links between the original permit and samples, publications, patent applications, and sequence data originating from the grant of a permit under an ABS framework. The use of free tools (such as `taxize` in R) allows this information to be readily retrieved from a range of different data sources. While requiring further elaboration, the use of unique identifiers combined with the principle of triple redundancy provides a route to cost effective monitoring and is recommended.

Draft Workplan for an Online Permit and Monitoring System to support the Nagoya Protocol

Introduction

This section provides a draft workplan for governments interested in implementing the model for the online permit and monitoring system outlined in the previous sections. The draft workplan is intended to assist countries and authorities interested in implementing the model by identifying tasks for components and elements of the model for resource planning and costing. The draft workplan is intended as a guide and should be adapted in accordance with existing internal capacities and needs. The draft workplan is presented as a set of headings for project planning in the downloadable *Annex*.

The workplan is presented in terms of activities to be carried out in individual countries interested in implementing the system. However, there is a strong case for a network approach between governments seeking to develop and implement the model to meet their needs.

Network advantages would include:

1. Sharing computer code developed to address specific aspects of the system including specific modules.
2. Sharing lessons learned, guides and protocols.
3. Sharing methods for particular approaches to monitoring, analytics and statistics.
4. Avoiding duplication of effort.
5. Shared capacity building in implementation.

The draft workplan is divided into two sections:

1. Preparatory Components (labelled A-C).
2. Main Components, elements and tasks (numbered by Components in the model).

The legal component (Component 3) is a cross-cutting issue and an indication of relevant tasks is provided within relevant tasks. The list of legal related tasks is indicative and may require further elaboration.

Preparatory Activities

A: Map Existing Research Permit Systems

Objective: Identify and map the existing national research permit system relevant to access and benefit-sharing.

In countries where there is more than one permit authority, it is essential to gain an understanding of the research permit process as a basis for understanding the responsibilities of different permit granting authorities and for consultations on potential ways forward in either improving existing systems or establishing new systems. These activities could logically focus on:

i. Identifying existing permit granting authorities in the country.

ii. The legislative mandates of permit authorities.

iii. Application forms and the terms and conditions set out in permits.

iv. Permit storage conditions.

v. Experience to date in administering permits.

This scoping exercise will allow the national permit system to be mapped and for consultations between permit granting authorities on appropriate ways forward.

Task 1. Identify the authorities in the country with responsibility for granting ABS related research permits and the details of their mandates with respect to permits.

Task 2. Identify the persons responsible for administering permits in the country as a basis for consultations.

Task 3. Consult with permit authorities on experience to date including what has worked for them and problem areas. Discuss options for accessing permit data held by the authority for use in Component B and associated confidentiality issues.

Task 4. Obtain copies and information on:

a) Standard permit application forms.

b) Copies of the terms and conditions within permits (and any associated agreements).

c) Information on the storage of permit data (electronic, physical, both). This should including the name of any software and formats used for electronic data.

d) Identify who has access to permit data and for what purposes.

Task 5. Generate process diagrams for permits within a country.

Task 6. Workshop to discuss existing experiences and the desirability (or otherwise) of a single electronic system serving permit granting authorities.

Expected Outcome:

1. Clarity on permit granting authorities in the country, their mandates, permit forms and terms and conditions, data administration and storage including the generation of a national permit process diagram.
2. Agreement on appropriate ways forward in adapting the permit system to serve the needs of permit granting authorities and applicants in response to the entry into force of the Nagoya Protocol.

B: Baseline data on scientific and patent literature.

Objective: Establish baseline data on scientific research publications and patent activity relevant to access and benefit-sharing.

The prerequisite for this activity is access to permit data in either physical or (preferably) electronic form. Ideally complete data will be made available to maximise the utility of the outputs. However, if necessary sample data may be used.

Task 1. Obtain copies of permit data (preferably in electronic form) including use of confidentiality agreements and agreement on data storage (see Component A, Task 3).

Task 2. Clean and then tidy permit data into formats that can used to carry out searches of scientific literature and patent databases.

Task 3. Obtain data on the scientific literature for a specific country focusing on biodiversity, genetic resources and associated traditional knowledge (indigenous peoples and local communities) as the basis for analysis and refinement.

Task 4. Develop search patterns for patent literature using patent databases and identify appropriate tools and match criteria to distinguish between positive and negative results.

Task 5. Identify, and, as appropriate, develop programmatic tools to facilitate automated literature and patent searches in future that minimise requirements for human intervention. Examples include the programmatic use of crossref or the EPO Open Patent Services or WIPO Patentscope databases and the rOpenSci and biosciences packages in languages such as R or Python.

Expected Outcome:

1. A clear baseline and overview of existing publication and patent activity that can be linked to existing research permits.

This outcome will typically involve permits issued prior to the entry into force of the Nagoya Protocol and is intended to create an evidence base and electronic repository of historic data on publications and patent data. Historic data will also serve as a means to identify key researchers working in a country as a basis for engagement activities to discuss ways of improving the permit and reporting system following the entry into force of the Nagoya Protocol. Note that this outcome fundamentally depends on the availability of permit data for use in searches.

C: Development and Implementation Plan

Objective: Establish a costed development and implementation plan for an online permit and monitoring system .

Task 1. Identify organisations or partners in the country with the technical and programming capacity to develop an electronic permit system consisting of:

- Component 1: An Authorities Portal
- Component 2: An Applicants Portal
- Component 3: Legal Component (cross-cutting)
- Component 4: Monitoring
- Component 5: Reporting
- Component 6: The Core System

Task 2: Develop a working model and engage in field testing.

Develop an experimental working model to test different approaches, identify key tools and for demonstration purposes using dummy data. Note that the purpose of this activity is learning by doing to inform planning and accurate identification of resource requirements not the development of the final system. This task involves a set of sub-tasks.

Task 2.1. Develop one or more working models of the system including identifying solutions using different tools that may be best suited to the diversity of circumstances and existing capacities within a country.

Task 2.2. Consult with staff from authorities involved in checking permit data on the ground (National Parks, Customs, police and others) and identify existing approaches and tools, what already works, problems encountered, and potential solutions.

Task 2.3. Identify how checks by local level authorities can be most effectively linked to an online permit and monitoring system.

Task 2.4. Arrange field tests of solutions such as barcodes, QR code readers, html embed codes etc. with relevant authorities and adapt solutions focusing on meeting actual needs.

Task 2.5. In consultation with relevant national/international collections identify appropriate options for the inclusion of permit identifiers in sample labels and sequence data. A network approach among participating countries is likely to be effective in identifying common solutions. Public

collections in Europe interested in registered collection status under *EU Regulation No.511/2014*, a category likely to include most major collections in the EU, could be potential partners in testing this approach.

Task 3. Based on experience in Task 1 & 2, including assessment of existing capacities and strengths, identify appropriate software and hardware requirements for the Core System (Component 6).

Task 4. Develop a costed development plan over a period of 3 years and projected costs for future years.

Task 5. Document experience gained and lessons learned.

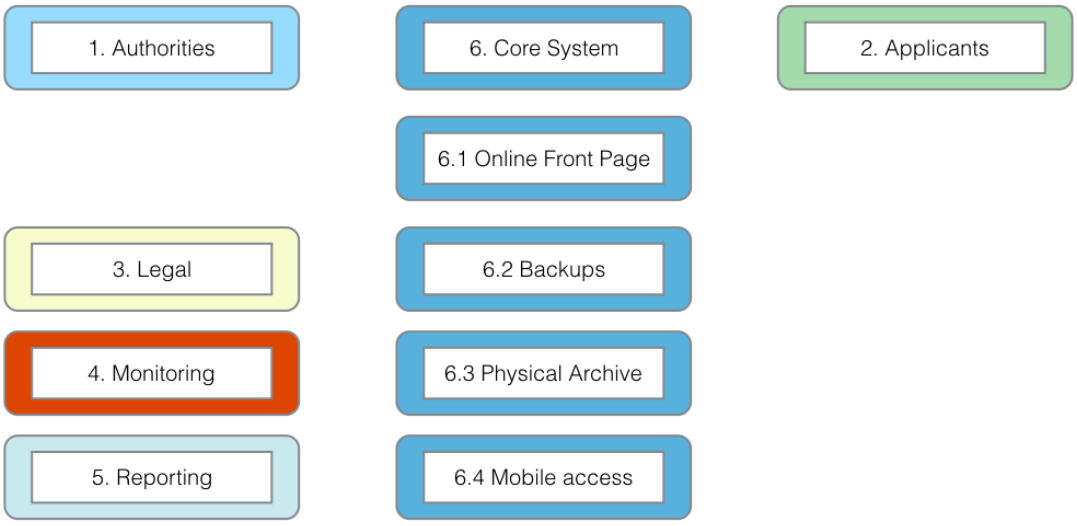
Task 6. Where the project forms part of a network of participating countries and organisations, deposit working code and documentation in an open access repository (e.g. GitHub) for potential use and further development by partners.

Expected Outcome:

1. A clear costed development plan for the online system with partners and stakeholders identified over a three year period.
2. An experimental working model accompanied by documented code, experiences and lessons learned.
3. Identification of software and hardware for the core system based on assessment of existing internal capacity and strengths (e.g. MySQL, Apache, ASP.NET, Node.js etc.).

System Implementation

The components of the overall system are provided below. The workplan focuses on the identification of tasks associated with the functional elements of each component.



Component 1: Authorities Portal

Objective: Establish an authorities portal for the administration of permit applications.

Element 1.1. Enquiries [Legal component]

Task 1. Establish standard responses to enquiries as inputs into the online permit system.

Element 1.2. Review [Legal component]

Task 1. Develop Guide for Applicants.

Task 2. Develop Applicants Checklist.

Task 3. Develop checklist for completeness by authorities (authority side should match to applicant side).

Task 4. Develop standard notifications to applicants on receipt and completeness.

Task 5. Develop individual authority checklist (or lists as appropriate to authority).

Task 6. Establish criteria for validating if non-commercial or commercial research (or both).

Task 7. Define next steps for non-commercial research including standardised MAT for non-commercial research under Article 8(a) of the Nagoya Protocol and addressing closely related issues (e.g. compliance with environmental legislation, local partners, national deposit of samples etc.).[Legal component]

Element 1.3. Negotiation [Legal component]

Task 1. Define next steps for commercial research

a) Establish criteria for negotiations. [Legal component]
b) Identify standard list of participants in negotiations. [Legal component]
c) Establish time frame for negotiations. [Legal component]
d) Establish environmental legislation and procedure criteria. [Legal component]
e) Establish criteria for benefit-sharing. Note legal component.
f) Establish criteria on Intellectual Property Rights. Note legal component.
g) Establish criteria for acceptance or rejection of commercial applications. [Legal component]
h) Define written notifications. [Legal component]

Task 2. Develop a template for standard MAT for commercial research taking into account that this may be a starting point for negotiations.

Task 3. Establish checklist of environmental terms and conditions based on applicable laws and policies. [Legal component]

Element 1.4. Approve/Reject [Legal component]

Task 1. Define standard terms and conditions (menu of clauses) for use in generating permits.

Task 2. Define areas where specific terms and conditions are likely to be needed (menu of clauses).

Task 3. Define templates for MAT/ABS contracts linked to the permit.

Task 4. Implement the harmonised document identifier system (e.g. BS20151234) to ensure links between the permit and MAT/ABS contracts are maintained across time and space.

Task 5. Implement the system to generate .pdf permits, QR codes, barcodes, HTML embed codes and labels (see applicant side tasks for testing).

Element 1.5. Appeals [Legal component]

Task 1. Establish a clear and transparent appeals process.

Task 2. Develop guidance on the appeals process for authorities and applicants.

Task 3. Develop a timeline for appeals.

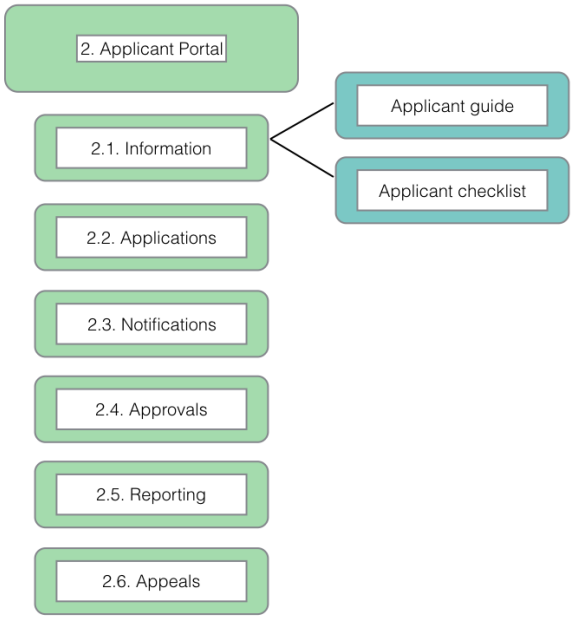
Task 4. Generate standard notifications for appeals to be sent to applicants on the stage in the procedure.

Task 5. Define the form of a clear final decision.

Expected Outcome: An easy to use authorities portal with a clear and transparent procedure and decision-making process that serves the needs of multiple permit granting authorities over the long term.

Component 2. Applicants Portal

Objective: Create a single online space for applicants to submit applications with supporting information/guidelines, to receive notifications and monitor the progress of applications, to receive permits and fulfil reporting requirements.



Element 2.1. Information.

Task 1. Develop a guide for applicants.

Task 2. Develop a checklist of required information for applicants.

Task 3. Test utility with selected applicants (survey/practical tests).

Task 4. Provide information on appeals process (see authority side).

Element 2.2. Applications

Task 1. Create applicant home page system.

Task 2. Establish secure username and password system.

Task 3. Define data fields for applications in consultation with relevant permit granting authorities. Use checkboxes wherever possible (e.g. Marine, terrestrial, national park etc.).

Task 4. Test and refine to final version.

Element 2.3. Notifications

Task 1. Establish a system for transmitting requests from the authority side to the applicant side with appropriate data fields (title, date, originator etc.).

Task 2. Define a standard list of information request types (authority side) while allowing authorities to provide specific details (headings for the request and content or body of the request).

Task 3. Establish a system for applicants to respond to requests and channel (email) the response to the originator with a notification.

Task 4. Establish a system linking unique identifiers (e.g. BS20151234) with notifications to create an integrated file register (file history) for applications within the data archive.

Task 5. Establish a system that:

a) Lists the stages in the application procedure.

b) Provides the name and contact details (within the system) for the person responsible for that stage of the procedure.

c) Updates the record upon completion to show the next stage in the procedure and persons responsible.

d) Generates the permit and associated material (passes, labels, embed codes) and inform the applicant of availability by email. Accessed through the approvals section.

Element 2.4. Approvals

Task 1. Create a system to generate a permit as a .pdf (links to authority generated master permit).

Task 2. Create a system to generate a time limited permit pass and QR code generation for mobile phones and tablets.

Task 3. Create a system to generate labels for sample bags, jars and individual samples.

Task 4. Create a system for HTML embed codes (for electronic data etc.).

Task 5. Provide instructions on the use of unique identifiers (e.g. BS20151234) in publications, patents, products, sequence and electronic data.

Task 6. Test approaches, including "permit passes" with a selection of applicants and adjust based on lessons learned.

Element 2.5. Reporting

Task 1. Establish reporting section of the applicant site.

Task 2. Decide on mandatory and voluntary reporting options. [Legal component]

Task 3. Define required uses of unique identifiers (BS20151234, QR codes, barcode, html embed codes) in reporting (see element 2.4, task 5). [Legal component]

Task 4. Establish data fields for reporting, including, inter alia:

a) Links to home pages and/or academic record sites such as ORCID, and social media sites such as researchgate.com or academia.edu etc. (ideally imported from information provided on application under Element 2.2).

b) Uploads of publications and reports (pre-print or published).

c) doi (document identifier links to publications for automated retrieval).

d) Accession numbers for sequence data or deposits of genetic material.

e) Locations where collected samples are stored.

f) Transfers of materials to third parties and the terms and conditions of transfer.

g) Patent applications and grants.

h) Products for which market approval is sought or approved.

i) Other information on activities arising from the permit and associated MAT.

Task 5. Test system with selected applicants

Task 6. Adjust system based on user feedback. [Legal component]

Element 2.6. Appeals (see Element 1.5)

Task 1. Provide information on the grounds for appeal. [Legal component]

Task 2. Provide information on the timeline for appeals. [Legal component]

Task 3. Provide documents for submitting appeals. [Legal component]

Task 4. Provide information on the person(s) responsible for handling appeals. [Legal component]

Task 5. Provide information on the criteria for accepting or rejecting an appeal. [Legal component]

Task 6. Provide notifications to applicant within the system including the final written decision. [Legal component]

Expected Outcome: An easy to use applicants portal that provides legal certainty for applicants and provides data for monitoring and reporting.

Component 3: Legal

Objective: Ensure that the online permit and monitoring system complies with and supports relevant domestic laws and obligations under the Nagoya Protocol.

Task 1. Compile existing legislation relevant to permits and the terms and conditions in existing permits.

Task 2. Clarify and establish a clear legal relationship between permits and MAT (ABS contracts) for the purposes of legal certainty.

Task 3. Identify areas of the online permit and monitoring system requiring legal input.

Task 4. Engage in legal drafting for relevant elements of the permit and monitoring system.

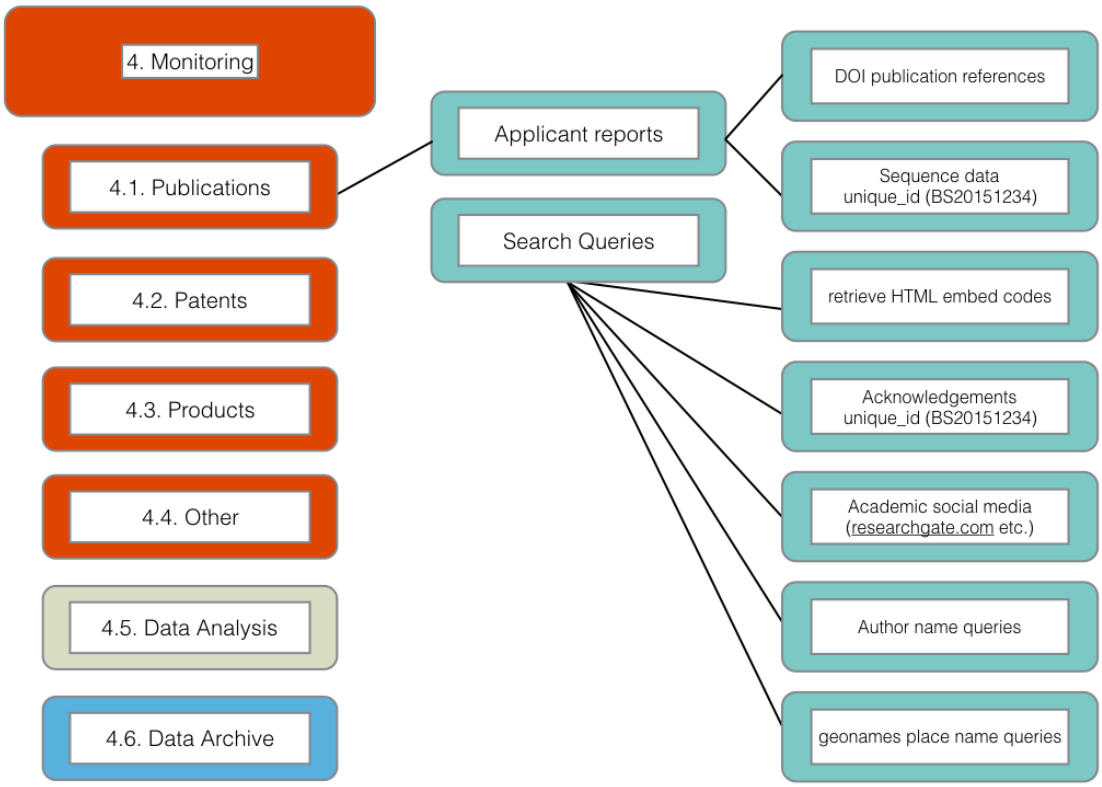
Task 5. Collaborate with technical staff in incorporating legal elements into the system.

Task 6. Identify future requirements for legal review as part of the system's development plan.

Expected Outcome: The online permit and monitoring system complies with and supports relevant domestic laws and implementation of obligations under the Nagoya Protocol.

Component 4: Monitoring

Objective: Establish an effective electronic monitoring system for compliance with the terms of research permits and mutually agreed terms under the Nagoya Protocol.



Task 1. Generate outputs from the core permit system (database) for use in the construction of search queries of scientific literature, patent literature, dna databases, product information and general web searches.

Task 2. Identify programmatic open source tools to automate search and retrieval of data from relevant sources (scientific literature, patents, product information and general web searches) (e.g. R, Python).

Task 3. Identify relevant commercial databases and analytics software to facilitate monitoring.

Task 4. Develop a plan for a phased transition from commercial to open sources tools (or appropriate mix of tools).

Task 5. Provide training for key staff focusing on developing and sustaining local capacity and provide formal training opportunities to encourage the acquisition of programming and analytics skills.

Task 6. Implement monitoring following the basic workflow defined in Element 4.5 on Data Analysis in the model (Gather, Clean, Analyse, Visualise and Report).

Task 7. Establish a system for ensuring that the outcomes of monitoring are documented and stored in the data archive for future use.

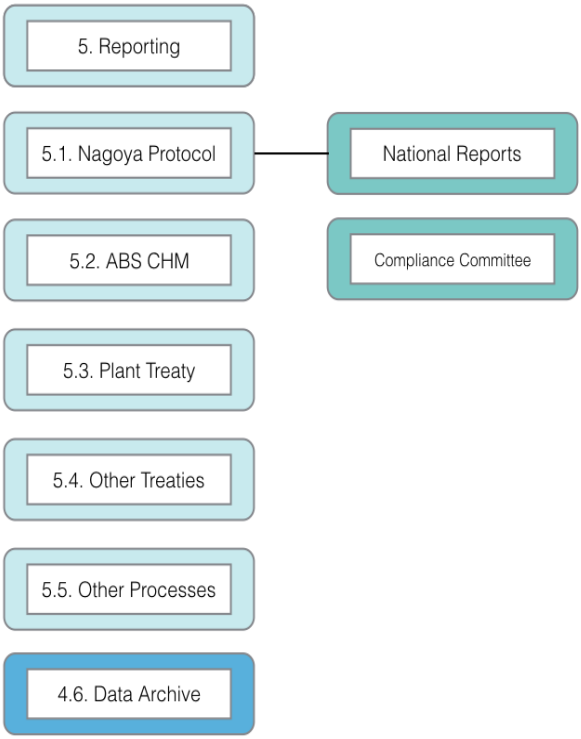
Task 8. Improve internal capacity through participation in a network of staff and specialists engaged in monitoring from participating countries.

Task 9. Develop, or contribute to, an open access Manual on ABS monitoring for use by staff and in training future trainers.

Expected Outcome: A cost-effective electronic monitoring system adapted to the requirements of the participating country that is sustainable over the long term.

Component 5: Reporting

Objective: Facilitate national and international reporting under the Nagoya Protocol and other relevant agreements linked to the permit system.



Task 1. Identify national and international reporting requirements under the Nagoya Protocol and, as appropriate, related international environmental agreements.

Task 2. Identify components of permit and related datasets that can contribute to meeting reporting requirements.

Task 3. Establish templates to automate data generation to meet reporting requirements in the formats required.

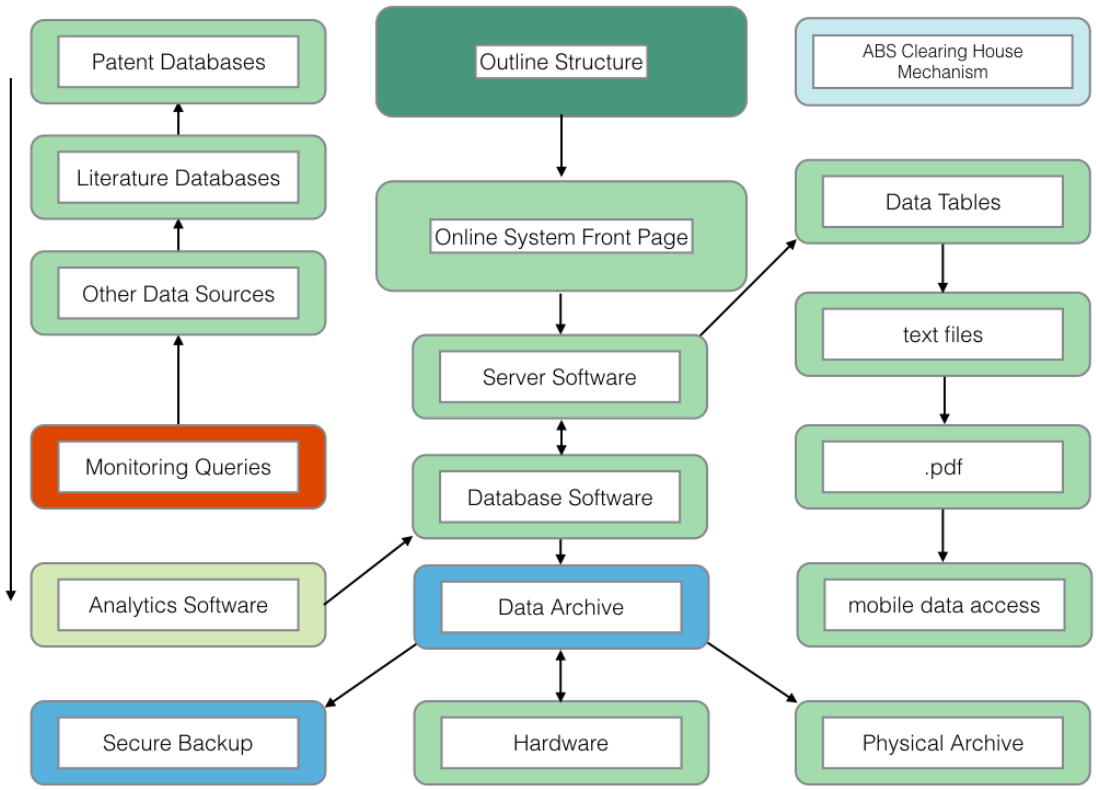
Task 4. Identify non-confidential information and develop a procedure to output appropriate data to the ABS Clearing House Mechanism.

Task 5. Integrate reporting templates and outputs with the core system data archive for future use.

Expected Outcome: A system that provides information from the permit system in a form suitable for inclusion in national reports and provides relevant inputs to support the ABS Clearing House Mechanism.

Component 6: Core System

Objective: Establish an efficient, secure, robust, cost effective and sustainable Core System to perform the functions described in Components 1-5 and additional functions described for the Core System on archiving and the security of permit data.



Element 1. Preparatory

Task 1. Identify internal and external programming capacity for development and maintenance of the online system. (see Component C, task 1).

Task 2. As part of an open source network approach, identify existing system elements (code) shared by network participants and consider potential adoption or adaptation of existing code.

Task 3. Based on the outcomes of Component C and Tasks 1 and 2 (above) identify the appropriate software and programming languages for system development within the national context.

Task 4. Acquire relevant hardware, server and database software.

Element 2. Server Software

Task 1. Build online front page system and unique home page system for authorities and applicants.

Task 2. Install secure password system for home page access.

Task 3. Install, adapt or build the notification system between applicants and authorities and link the system to the database and data archive.

Task 4. Based on lessons learned from Component C, implement the connection between the online system and authorities responsible for checking permits within national jurisdictions (e.g. park authorities, police, customs authorities). (See also Element 3, task 4).

Element 3. Database software

Task 1. Develop scripts for key functions with components and elements.

Task 2. Establish file register (file history) system using unique identifiers (e.g. BS20151234).

Task 3. Develop scripts to link to the Data Archive, Secure Backup and Physical Archive.

Task 4. Identify and address additional software/coding needs for the generation of permits with particular attention to the technical aspects of:

a) QR Code based permit passes

b) Labels for specimen bags, specimens and related records

Element 4. Data Archive

Task 1. Establish a Data archive including secure backups.

Task 2. Identify and implement appropriate ways of outputting data to the physical archive while maintaining links with the unique identifier system.

Task 3. Cloud storage. Assess the stability of existing infrastructure to determine the desirability of use of a cloud based server, cloud based storage and backups. Discuss the confidentiality and security implications of cloud based data storage outside national jurisdiction and take appropriate decisions on adoption. [Legal element]

Task 4. Secure offline storage. Identify appropriate options for secure offline storage of confidential information.

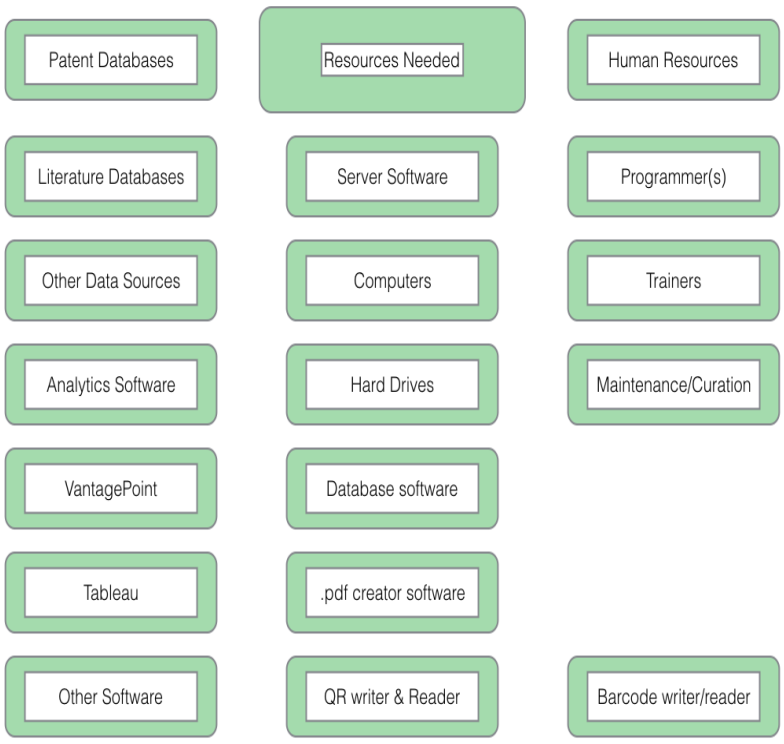
Element 5. Development Cycle Planning

Task 1. Establish a procedure for updating the development plan for the online system (Component C, task 4).

Expected Outcome:

A sustainable core system that operationalises and integrates the functions of the online permit and monitoring system.

Resources List



The figure provides an indicative list of resources to assist with planning. Note that analytics tools such as VantagePoint and Tableau are available in a range of paid and (in the case of Tableau), free versions. Paid software is included as part of a phased approach from paid to open source software over time. This is also true for databases of the scientific literature and patent databases where commercial tools such as Thomson Innovation offer convenience in data access but significant cost while open source options require significant investments in knowledge of their use (e.g. R or Python resources).

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