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IMPLEMENTATION AND SUSTAINABILITY FOR THE 21ST CENTURY
MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

D3.5

Report on the effect of implementing the MIRRI Policy and Best Practice on ABS on trust and use of mBRC services by stakeholders

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Abstract:	This Deliverable presents the state of affairs of implementing the MIRRI best practices on Access and Benefit Sharing (ABS), to identify the main challenges in reaching compliance mBRCs to ABS legislation, and to report on the findings and conclusions regarding the level of trust and experiences of users of MIRRI services. To collect information stakeholders' interviews were conducted and the results discussed in a workshop dedicated to ABS. Main conclusions and plans for the future are presented.
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Abstract

This Deliverable presents the state of affairs of implementing the MIRRI best practices on Access and Benefit Sharing (ABS), to identify the main challenges for mBRCs in reaching compliance to ABS legislation, and to report on the findings and conclusions regarding the level of trust and experiences of users of MIRRI services. To collect information stakeholders' interviews were conducted and the results discussed in a workshop dedicated to ABS. Main conclusions and plans for the future are presented.

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1. Introduction

1. Introduction

The aim of this Deliverable is to summarize the state of affairs with regard to implementing the MIRRI best practices on Access and Benefit Sharing (ABS), to identify the main challenges in reaching compliance within microbial domain biological resource centres (mBRC), and to report on the findings and conclusions regarding the level of trust and experiences of users of MIRRI services. For this, MIRRI Stakeholder interviews were conducted by IS_MIRRI21 partners in WP3, and the main results discussed during an ABS Workshop held on the 22nd of June 2022 in Louvain la Neuve, Belgium, an event hosted by BCCM-MUCL and Belspo, and organised in cooperation with IS_MIRRI21 WP3 partners.

To assess the progress of implementing the MIRRI Policy on ABS and Best Practices, a workshop was planned to discuss the state of affairs, challenges and possible solutions. However, MIRRI also needed to know the stakeholders' opinion, and to what extent microbial culture collections have been able to gain trust and what they need to do in order to provide what the stakeholders need to use microbial genetic resources while complying with applicable national and international legislation and regulatory requirements. For this purpose, stakeholder interviews on ABS were conducted, and the results were also discussed in the ABS Workshop.

For these interviews, stakeholders were classified into two categories: (i) scientists who are users and/or depositors of strains in mBRCs and working in public or semi-public organisations (universities, other (national) research institutes, public health agencies) and private bodies (companies of any size), and (ii) representatives of (inter)national organisations (other research infrastructures (RI), scientific organisations and other non-governmental organisations). The interviewees were all based in European countries, chosen from client (users or depositors) pools of the involved partner mBRCs, but the questions were put in a broader sense about the performance and experiences with mBRCs in general. The interviews were conducted by KNAW-WI, MUT, IP and CECT, in the form of video calls of 30-45 minutes each and interviewing one or two employees per organization (primarily a scientist, and in some cases accompanied by a legal expert) in the period from November 2020 to January 2021. All interviews were recorded with permission from the interviewees. Results are presented in Annex I. These results were discussed by the partners during the ABS Workshop. Representatives of all IS_MIRRI21 partner mBRCs involved in ABS and invited external experts participated in this event and in the active discussions about possible solutions and ways forward. The most important ones are summarized below. During this event the tools MIRRI had developed during the preparatory Phase project of MIRRI were also briefly reviewed and discussed, in the light of the current ABS regulatory context.

The main conclusions and actions needed are summarized in this Deliverable.

2. MIRRI Compliance

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2.1. MIRRI achievements to date

MIRRI developed tools for ABS compliance during the Preparatory Phase project (2012-2016). The Nagoya Protocol and Regulation (EU) No 511/2014 (in short, EU regulation) entered into force in 2014, so halfway the runtime of this project. In the design of the RI, ABS related elements were included in the Statutes, the Partner charter and related Policies, of which one is dedicated to ABS: the MIRRI Policy on Biological Diversity and the Nagoya Protocol. Furthermore, the Legal/Regulatory Issues & Standards Expert Cluster was initiated as the first of several Expert Clusters for the infrastructure, and this cluster includes a section specific to ABS compliance. An important output of the preparatory Phase was the MIRRI Best Practice Manual on ABS, completed in April 2016.

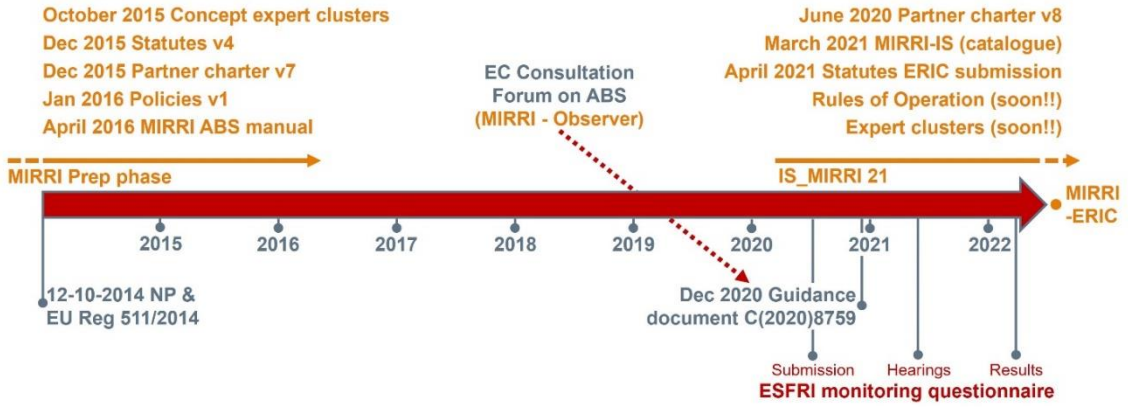

Figure 1 – Main MIRRI achievements and developed tools/elements in the field of ABS.

The ABS Manual provides guidance for mBRCs to implement ABS institutional policies and assure compliance with the Nagoya Protocol and EU Regulation, thus going beyond the limits of the MIRRI community. It addresses the following aspects:

- ✓ Managing acquisition of biological material for accession into the public collection
- ✓ Transfer of material from the public collection to other mBRCs or third parties, and the delivery of other services
- ✓ Access and internal use of material, and benefit sharing by the mBRC
- ✓ Managing documentation and data
- ✓ Training and awareness-raising
- ✓ Managing secured collections

After the Preparatory Phase project ended, there were no resources available for some years and the main focus was directed towards preparing for the application of ERIC status for MIRRI. In this period, two experts from MIRRI partners were involved as members of the European Consultation Forum ("Microbial Biobanks group"), and gave active input to consultations for the design of the second EC Guidance document (C(2020)8759), which contained important additional guidance on ABS relevant issues for culture collections and was published at the end of 2020.

The first step submission for ERIC also opened the opportunity to apply for funding to further develop the infrastructure through the IS_MIRRI21 proposal, which was funded at the beginning of 2020. Later that year, MIRRI was positively evaluated by ESFRI and reached Landmark status on the Roadmap 2021. As part of the activities under IS_MIRR21, important steps forward have already been made and are planned for the remainder of the project runtime.

The fields providing ABS-relevant information were included in MIRRI Strains Catalogue. Several issues to transfer data from the mBRCs' databases to the MIRRI catalogue were discussed and agreed upon. Some ABS relevant information about strains may be missing, such as the country of origin or dates of collection or isolation. It was agreed that for the strains missing the information on the country of origin, the strains would only be admitted into the MIRRI catalogue when the earliest date available, be it the date of collection, isolation or deposit (always available), is before the 12th of October 2014, thus the date of entry into force of the Nagoya protocol.

2.2. Challenges for MIRRI mBRCs to comply

Some of the challenges mBRCs face in their daily practice were discussed during the IS_MIRRI21 ABS Workshop. Here, some details are provided and possible solutions discussed.

As clear from the MIRRI Best Practice Manual on ABS, checking information on the provenance of strains offered for deposit is key. In order to comply, mBRC need to check the following points:

- ✓ Right to preserve the strain, i.e., it has been legally accessed in the country of origin (by the collection or a depositor), for which proof in the form of documents is available (PIC, MAT), when legally required
- ✓ Right to conduct research on it (including information on what type of use is allowed)
- ✓ Right to supply it to the third parties.

These points apply to the practice of all public collections, regardless if they are a registered collection under Art. 5 of the EU Regulation or not.

An EU Member State-based mBRC can consider to apply for registration in the EU Register of Collection (Register of Collections.pdf (europa.eu)). As per EU Regulation Art. 4 (7), a user who obtains a genetic resource from a registered collection is considered to have fulfilled due diligence obligations (as regards the seeking of information) under the Regulation. It is up to the mBRC's organization to weigh the advantages and disadvantages of becoming registered, considering

e.g., administrative costs and liabilities. Currently, one MIRRI mBRC is registered (CIRM-CFBP, INRAE).

This registered collection explained, during the ABS Workshop, that it cannot be excluded that, for certain strains within the registered part of the collection, a user has to do additional work in order to comply. For example, if required by the national legislation of the provider country, a user may need to apply for PIC and MAT before the strain can be delivered by the collection. Regardless, the collection is legally entitled to preserve and distribute the strain (on the basis of its own agreement with the provider).

The application of PIC and MAT by a user may be free of charge or against payment. Procedures to be followed may well result in effectively blocking access for many researchers (see also below, challenges from national legislation), especially if a financial barrier has been created. So, although the EU Register of Collections was designed with the initial idea that it would be easier for users to comply, it does not work out that way in practice. Collections that are listed on the EU Register could benefit from increased trust with competent authorities of countries outside the EU. For example, Costa Rican authorities entered into an umbrella agreement with DSMZ, a collection on the EU Register (but not a partner of MIRRI).

A registered collection can be held liable in case the information that was available (and shared with the user) finally turns out to be incorrect. From the user's viewpoint, maximum legal certainty is only achieved when he/she has signed a document directly with the competent authority in the country of origin.

More challenges mBRCs face to comply are quite similar to those of the stakeholders, which are addressed in 2.3, below.

2.3. User perspective on challenges to comply with national ABS legislations

2.3.1. General

From the stakeholder interviews it became clear that researchers experience the national ABS legislation in certain provider countries as particularly hampering the scientific research and development, and the international collaboration (see Annex I, questions ORG-A-6, IND-B-2 and ORG-B-4). Issues the stakeholders mentioned include language barriers in communication with national authorities, difficulties in understanding the ABS legislation of some countries, the slow responsiveness of authorities to queries, and the difficulties to get permission to access the resources in some countries. As a result, stakeholders avoid using genetic resources from countries where these problems occur, and turn to other countries with less restrictive access rules or free access to alternative resources.

2.3.2. DSI

Furthermore, stakeholders are very concerned about how in the future digital sequence information (DSI) associated with genetic resources will be handled within the framework of ABS. If the outcome of the current discussion among CBD Parties is that DSI is going to be considered in scope of the CBD (and Nagoya Protocol), then the stakeholders expect that the situation would considerably worsen, or that the international cooperation and development in microbiology could even effectively stop.

2.3.3. Restricted-access countries

For researchers in several countries, it has become increasingly difficult or impossible to deposit strains in public collections outside the provider country of the genetic resource. This is for instance the case for researchers in India and Brazil.

In case of Brazil, under the present Law 13.123, collections outside Brazil could accept strains for deposit in their collection if they sign a model Material Transfer Agreement (MTA) with the depositor in Brazil. This model is a type of umbrella agreement that remains valid for at least 10 years, and under which multiple shipments of strains for deposit could be executed. In addition, prior to every shipment, the depositor in Brazil must register the exported strains in SisGen, and the mBRC and the depositor must sign a second document, the so-called Shipping Invoice stipulating the further conditions. It should include the kinds of use allowed and state that the resource may be transferred to third parties under certain conditions (not allowing third party transfer makes no sense if it concerns a deposit in a public collection).

To supply these Brazilian resources, the mBRC will use an MTA that needs to include all terms and conditions of the above-mentioned model MTA, along with a new Shipping Invoice document, in other words a copy of the above one that the mBRC can modify and in which it will stipulate the kind of use allowed. In order to minimize the risk of non-compliance (beside several other reasons of good practice of Culture collections), the mBRC will not allow third party transfer under that new Shipping Invoice. If a customer orders such strains, they will thus enter into an agreement with the supplying mBRCs, by which they are bound to oblige to all terms and conditions of the Brazilian ABS legislation.

There has been limited experience to date with Brazilian strains deposited since the new law entered into force. One of the MIRRI partner mBRCs that has accepted quite a number of strains under these rules, reported that such strains are not ordered, even if it concerns type strains. The reason why they are not ordered has not been investigated, but according to this collection the conditions are perhaps too restrictive or risky from the viewpoint of most mBRC customers, viz., (i) the ordering researcher needs to partner with a collaborator in Brazil (who will have to take care of all necessary reporting to the Brazilian competent authority), and (ii) the supplying

collection would have to send copies of those MTA revealing the identity of the recipient/user to the competent authority in Brazil (once per year).

Representatives of the Brazilian research community (of which one representative participated in the IS_MIRRI21 ABS Workshop) and the Brazilian authorities are discussing options and are working to overcome these difficulties and lift this burden on science in their country.

To maximize legal security, users, especially those with an interest to commercialize, will more likely try to close a direct agreement with a provider of the materials of interest in countries of origin with complex and/or restrictive national legislation, rather than to order it from a collection outside of these countries.

3. Stakeholders' perspective – Trust in and experiences with microbial culture collections

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The main findings concerning stakeholders' experiences with mBRCs are summarized below: the level of trust in MIRRI the stakeholders demonstrate, to what extent the services offered by MIRRI respond to the needs of the stakeholders, and how MIRRI can improve these services or fill gaps. It also summarizes the main concerns and practical problem of compliance that were expressed by the stakeholders, which they would like to have MIRRI convey for them to the policy makers and competent authorities.

The interviewees' opinions reflect the experiences with at least one MIRRI partner mBRC, and in several cases also a wider range of mBRCs. The interviewees were not asked to reveal the identity of the mBRCs.

MIRRI is a young infrastructure, therefore not all interviewees were already familiar with it. Nonetheless, when asked, they considered their opinion and expectations as equally relevant to MIRRI partner mBRCs and other mBRCs. The interviews were completed shortly before the MIRRI catalogue of strains was launched (March 2021).

Some general observations [between brackets the ID of the question(s) as per Annex I]:

- Level of ABS implementation within the stakeholders' organizations is still limited: a little less than half of interviewees indicated that neither the policy, best practices, or MTA were implemented, nor a dedicated person for ABS was designated. Some were working on these issues [C2].
- Generally, there was a great interest in ABS training courses (ca. 80% of interviewees), and consultancy services (ca. 50%) even if paid, although several stakeholders warned that their university would probably not allow paying for such information, because there are several other alternative sources that are offered for free [E2, 3]. Also, the organisations already having legal support would not be interested.
- Stakeholders frequently use information resources from their own organization (including the staff of in-house mBRC, if available), or staff and websites of (external) mBRCs. The official resources of the ABS-Clearing House and the national websites on ABS (often run by the national focal point) were less consulted than it could be expected. They are less consulted, especially among stakeholders in private entities, because they are not so well-known to these stakeholders or considered less useful (information unavailable, or too difficult to understand or interpret, language barrier, etc.) [B1, 3].

3.1. Trust

The level of trust in the mBRCs that the stakeholders demonstrate is reflected in the following conclusions derived from the interviews:

- Almost all interviewees that had contact with mBRCs and asked questions about ABS related issues in general or with regard to specific strains, were positive about the responses they received (even though it is not legal advice) [D2, 3].
- The ABS information that mBRCs provide on their strains in catalogues was regarded as sufficient by most interviewees [D1].
- In the organisations, with their own collections, the responsible person for these collections is often the internal “ABS specialist”.

For a majority of users/depositors, the choice of a particular collection would be influenced by whether it is listed on the EU Registered Collections or not. Not all interviewees were familiar with the concept of registered collection, though [D-2].

Notwithstanding their generally positive evaluation of information provided by the mBRCs about the strains, there were several companies which indicated that they always did their own verification of completeness and correctness of the ABS-relevant information (usually directly with the provider country). When a country’s administration authorities are non-responsive, or the legislation is considered too complicated or unclear, their resources were simply not used at all.

The representatives of mBRCs at the ABS Workshop concluded that as providers of genetic resources they have to take responsibility in carefully checking the legality of access in the country of origin, and in providing all (or as complete as possible) ABS-relevant information together with the material. At the same time, the recipients/users will have to accept their responsibilities regarding due diligence and compliant use.

3.2. Services and support

Stakeholders are asking MIRRI to give more support through the following:

- Provide ABS information more “proactively”, for example as periodic mailing alerts or news items on ABS on the MIRRI website, e.g., about progress on important negotiations (DSI) or changes/entering into force of national legislations [see Annex I, question E1].
- MIRRI is expected to provide more (detailed) information on ABS requirements and the use of individual strains (note that the interviews were conducted before the MIRRI Strains Catalogue was launched) [E1].

MIRRI mBRCs can be expected to share within MIRRI the information they have on the national legislations and requirements for the use of the holdings. MIRRI should investigate what information can be shared with the stakeholder community, and how (limited access, free access).

International networks and organisations for collections, such as the World Federation of Culture Collections (WFCC) and the European Culture Collections' Organisation (ECCO), provide support to their members to help them comply with ABS. An infrastructure like BBMRI (through its ELSI committee) does the same, but stresses that it provides information *and not legal advice*. MIRRI will do the same mainly through the Public Forum running the Expert Clusters.

In its design of services, MIRRI has chosen to provide support directly to the users whenever possible (in addition to providing support to the partner mBRCs). However, for ABS relevant information on the strains made available through the MIRRI catalogue, MIRRI must rely on the partner mBRCs holding those strains. Moreover, MIRRI may expect that the mBRCs are going to share (new) information especially when it pertains to strains for which equivalents are held in other MIRRI partner collections. If a user addresses MIRRI with a very particular question and it is unable to answer it. MIRRI will direct the user to the individual mBRC that holds the strain in question.

The provision of information to users about ABS, the requirements for using the genetic resources and performing due diligence were discussed in the workshop. Even if mBRCs and MIRRI take all necessary measures, it cannot be guaranteed that some information will not in time, be proven incomplete or incorrect. Hence, there is always some risk for the individual mBRCs or MIRRI to provide such information. At this point, not all mBRCs or MIRRI have their own lawyers to support them, so it is important to emphasize that mBRCs and MIRRI do not provide legal advice, but only information (like BBMRI-ERIC).

MIRRI should provide clarity about its structure and ultimate responsibilities, and reduce its own liability. Even though MIRRI will operate as a distributed infrastructure of mBRCs, the individual provider (mBRC) is ultimately responsible for transferring the material to the user and for associated ABS-relevant information. Furthermore, ABS information exists at two levels: (i) ABS-relevant documents or other particular information associated with the strains that will be transferred to the users, and (ii) more general information about national legislation in provider countries. In case MIRRI would like to support users in checking due diligence, this requires the consultation with lawyers.

Other practical guidance for users: a best practice (or the EU Guidance document) alone cannot provide answers, but advice from the user's own national authority monitoring compliance will be needed to resolve certain issues. For example, how many times should a question be addressed to a competent authority or National Focal Point that remain without the answer, before the user's due diligence obligations are considered fulfilled by the user. MIRRI could assist users by

providing exemplary questions for contacting their national authorities. Understandably, users would like the (direct) provider of the resources and associated information to be responsible for the compliance, however, the users must do the research on the materials and take the responsibility for due diligence and compliance.

Stakeholders also made suggestions on how collections should be involved [D-5]:

- Act as an intermediary between users and national authorities.

In cases where MIRRI-ERIC participates in consortia/projects involving (major) sampling, it could act as the main negotiator in requesting permits. Secondly, at national levels, the MIRRI-ERIC National Nodes could coordinate such activities.

- Convey/communicate the needs of users of microbial genetic resources to various national authorities:
    - *Negotiate to reach umbrella-agreements for deposit, use and supply of strains, at least at the European level*. A good example is one where a European mBRC (non-MIRRI) that is a registered collection managed to sign an agreement with Costa Rica. This should be a focus for MIRRI-ERIC in the future.
    - *Simplify (and quicken) procedures to apply for PIC and MAT.* In MIRRI Member countries with complex access legislation, the MIRRI National Nodes can try to play a pivotal role to move towards easier access. Success will depend on how open the competent authorities are to suggestions to improve the rules and on whether the MIRRI National Nodes and other stakeholders (outside the microbial domain) can join forces and have the same priorities.
    - *For culture collections to get recognition as competent authority*.

4. How to proceed

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4.1. Improve MIRRI information resources

EU Member States and other countries in Europe have their own specific laws on ABS. To improve the information on national ABS legislation that MIRRI-ERIC will share with the users, the National Nodes should work with the mBRCs in their countries to collect all relevant information, try to resolve any existing uncertainties or queries with legal experts and if possible, the competent authorities. The National Nodes could then provide more comprehensive and clear information to MIRRI-ERIC and regularly update as needed.

Considering not only the risks involved for the mBRCs themselves, but also for MIRRI-ERIC, and as pointed out in ESFRI recommendations for the Roadmap 2021 evaluation, MIRRI-ERIC must insist that collections offering their strains through MIRRI will have to provide the necessary information. The MIRRI Best Practice Manual provides the minimally required information. In addition, while providing such information MIRRI should always stress that the users must also carefully check such information themselves.

For each strain in the MIRRI Strains Catalogue there is now more relevant ABS-related information available (beside the country of origin and date of collection), in the following two fields with fixed options:

Field "Restrictions on use"

1 - no known restrictions apply

2 - only for non-commercial purposes

3 - for commercial development special agreement is requested

Field "Nagoya protocol restrictions and compliance conditions"

1 - No known restrictions under the Nagoya protocol

2 - Documents providing proof of legal access and terms of use available at the collection

3 - Strain probably in scope, please contact the culture collection

Information regarding the national legislation of the provider country is crucial to the user. The challenge for the mBRCs and MIRRI-ERIC is to provide essential information in a concise form while assuring the correctness and minimizing the risk of misinterpretation. Some mBRCs have used free text fields in their strain databases for necessary flexibility, and when delivering such information for MIRRI strains catalogue, they face the challenge of having to transform it into the fixed field values of the above-mentioned fields. MIRRI-ERIC should therefore consider creating more flexibility.

Some interviewed stakeholders remarked that the mBRCs online strains catalogues should have more detailed information about what kind of use is allowed for particular strains. In the MIRRI strains catalogue (released after the stakeholder interviews), very concise information with regard to commercial use is included (thus with the above-mentioned limitations). More detailed information may differ per provider country or even per specific strain and would be more time-consuming and difficult to include in the catalogues. A solution may be for MIRRI mBRCs to provide online access to the ABS-related documents associated with the strains (PIC, MAT, as far as it is not confidential). But users look for easier ways to find the answers, instead of reading such documents. Moreover, if mBRCs would allow such documents to be viewed by all users, the content would need to be carefully checked and any information that is confidential made unavailable prior to release. When the numbers of PIC and MAT will increase in the future, the mBRCs might not be able to deal with the amount of work load.

As part of the MIRRI Expert Clusters, the subcluster on Legal and Regulatory issues also addresses the topic of ABS. At present, the users can make queries to MIRRI via acces@mirri.org, but soon the Public Forum will be available where users can post questions after registration.

Professional legal support from MIRRI-ERIC will not be offered, but in the future MIRRI could consider to implement such a legal service because it would be of great value and importance to the users. Creating such a service requires taking into account liability issues and appropriate management of user expectation - it is not always clear what the legally correct answers would be especially when not all information is available. It must be made very clear to the user that they will have to carry responsibility for their own activities and compliance. BBMRI-ERIC, a more mature RI providing (mainly) human resources, does not provide legal advice for these reasons.

MIRRI-ERIC will also develop booklets and public webinars on the important topic including ABS. These were also mentioned by several researchers during the Stakeholder interviews.

4.2. Updating tools for ABS compliance in MIRRI mBRCs

4.2.1. MIRRI's Policy on Biological Diversity and the Nagoya Protocol

The ESFRI evaluation report recommended to revise the policy and to make stronger commitments to support users in the framework of the Nagoya protocol. How to formulate the necessary changes to these documents requires careful consideration, and needs approval by the Assembly of Members.

For MIRRI to commit more strongly to supporting users in ABS compliance, it would need some kind of guarantee from its partner mBRCs that they will exercise due diligence. The

mBRCs are expected to adhere to the minimal requirements as formulated in the MIRRI Best Practice Manual. A best practice is of course less binding than a code of conduct. In case MIRRI-ERIC would need a stronger commitment from partner mBRCs to exercise due diligence (for instance through the Partner Charter), these mBRCs may argue that they require legal assistance for the checks. The obligation to do the due diligence checks is not legally binding for collections under the EU Regulation, as long as they limit their activities to "the maintenance and management of a collection for conservation purposes, including storage of resources or quality/phytopathology checks, and verification of material upon acceptance" (cf. EC Guidance document C(2020)8759). Collections do have such an obligation when they have been admitted to the EU register of Collections (but only with regard to resources that belong to the registered part of the collection).

4.2.2. MIRRI Best Practice Manual on ABS

The manual was created during the MIRRI Preparatory Phase project and was finished in April 2016 (https://www.mirri.org/wp-content/uploads/2021/02/ABSbestpracticemanual.pdf).

The (proposed) way forward is as follows:

Firstly, the manual will be updated to fit the latest EC Guidance document C(2020)8759. The number of changes will be fairly limited and could be finished shortly after this Deliverable D3.5 is submitted. Main issues to be updated regard the following:

- The way DSI should be treated (pending the outcome of the COP decision on this important matter, see below)
- How to deal with services mBRCs provide which involve genetic resources being sent to the mBRC (e.g. for identification or characterization)
- Legitimate exchange
- Use for commercial purposes

Secondly, MIRRI-ERIC will seek recognition of its best practice at the European level (Commission Implementing Regulation (EU) 2015/1866). MIRRI and the EU evaluators would have to enter into a dialogue to build an optimal document which could be a lengthy process, but MIRRI's field of work is relatively limited compared to some other organisations who have requested recognition of their best practice. It deals only with microbial resources and offers fairly specific guidance.

4.2.2.1 Digital sequence information (DSI)

Several scientific organisations are in favor of establishing a multilateral benefit sharing system, mainly because a bilateral system would be impractical and unsuited for DSI, where thousands of sequences are used in a typical study. Moreover, for many providers (countries) as well as users of genetic resources, the bilateral system has essentially failed to meet the expectations for an effective benefit sharing mechanism under the Nagoya Protocol. A simple 1% levy from use of DSI to be deposited into a multilateral fund is one of the options that has been discussed in the various meetings organized by the CBD and other organisations.

Brazil had DSI in the scope of its national ABS law from the beginning, and there is a fund, from which money can be converted to conservation, capacity building, recognition of traditional providers etc. So far, not much money has been shared into this fund (only when there is a product, 1% of the net revenue).

During COP 15 in Montreal, the Parties decided that a multilateral mechanism, including a global fund, within the framework of the CBD (not the Nagoya Protocol) is the way forward for sharing benefits from the utilization of DSI. In the upcoming time, the Parties will continue to discuss and work out possible mechanisms in various fora, based on the principles that access to DSI should remain open, effective, efficient, feasible and practical. Where possible, MIRRI-ERIC will have to provide input to this process and continue to inform the decision-makers on the potential risks for further increasing the administrative burden for collection managers and researchers.

5. Conclusions and actions

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5.1. Trust of the stakeholders in MIRRI mBRCs and other public microbial collections.

Stakeholders interviewed by IS_MIRRI21 WP3 frequently turn to the mBRCs (affiliated with MIRRI or not) for general or strain-specific information on ABS, are generally satisfied with the answers they receive. Also, the stakeholders generally regard the information provided in the catalogues as sufficient. It should also be noted that stakeholders (in private organisations or other bodies) realize that they also have their own responsibility in checking certain ABS relevant information. The stakeholders' opinions reflect a good level of trust in mBRCs. The MIRRI strains catalogue has been online only since March 2021, which limited feedback on its content from the interviews. More feedback from stakeholders will be collected in the upcoming time.

5.2. EU Register of Collections.

Whether or not MIRRI mBRC will apply for a status as Registered Collection (under the EU Regulation) remains up to the individual mBRC or its legal organization. Advantages of becoming registered consist in the fact that the collection will build up competence on ABS as it goes through the process, and that it could help gain trust of the users and competent authorities of provider countries. Disadvantages including the administrative costs and liabilities need to be carefully weighed. The MIRRI stakeholders have indicated that the status of being registered does contribute to the level of trust they put in the collections. However, according to one of the collections, the current practice of ABS shows that there are still obligations to be fulfilled by the users who want to access strains from registered (part of) collections that originate from certain countries.

5.3. Accepting responsibility to comply by MIRRI-ERIC, the MIRRI mBRCs and users.

The MIRRI mBRCs take responsibility in carefully checking the legality of access in the country of origin for any strains accepted for deposit in the public collections. When supplying strains to third party users, they are providing all (or as complete as possible) ABS-relevant information together with the material. MIRRI has to carefully consider and provide clarity on the responsibilities at the infrastructure level and the individual partner mBRC (as providers of the genetic resources). At the same time, the recipients who order and use these strains will have to accept that they also have their own responsibilities to act with due diligence and comply with applicable ABS legislations.

5.4. MIRRI Information services on ABS and other support for stakeholders.

MIRRI will work to improve the provision of information on national ABS legislations and on the requirements that are associated with the use of genetic resources provided in the MIRRI catalogue. It will support the user community also by exchanging information and sharing experiences through the Expert Cluster and Public Forum, but not legal support. When providing ABS relevant information, MIRRI needs to take all necessary precautions and take all possible liability issues into account. Furthermore, it will develop booklets and (free) webinars on ABS, training courses and paid consultancy services.

Within Europe there are considerable differences in ABS legislations with respect to requirements for access to genetic resources. Stakeholders expect MIRRI to lobby at the national levels in order to convey the difficulties and needs of the user community to the national competent authorities. Through its National Nodes, MIRRI-ERIC will keep in touch with national ABS representatives to efficiently gather new information and make it available through its services.

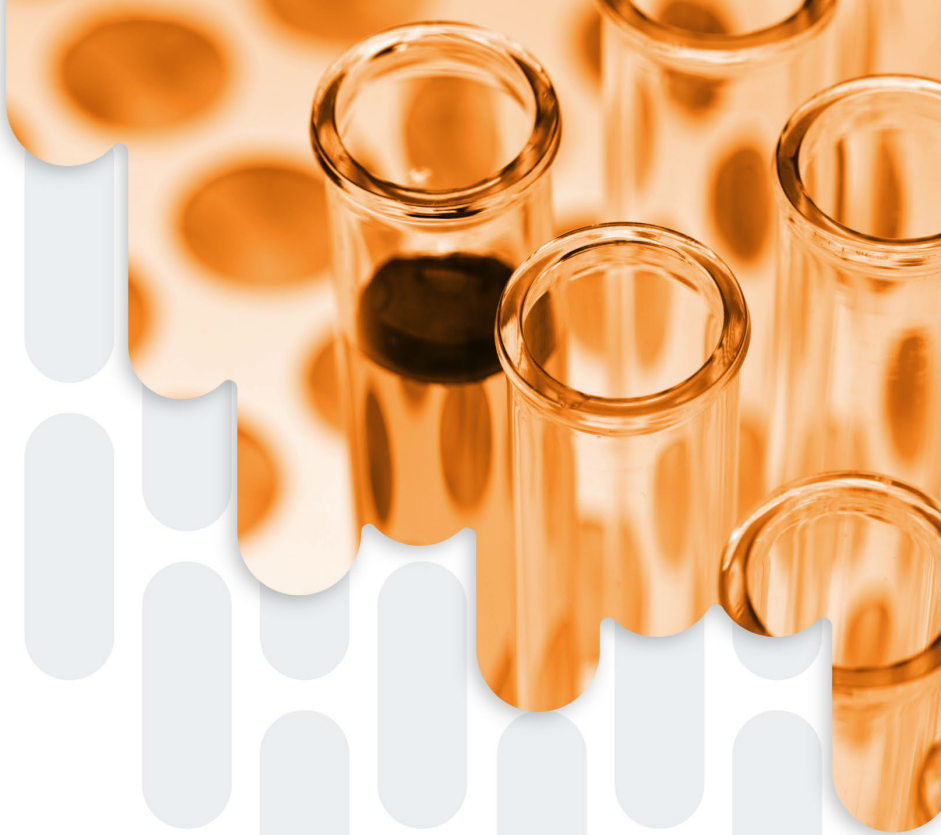
5.5. Legal documents for deposit and transfer.

No single model MTA or MDA has been implemented for the whole MIRRI infrastructure. Instead, the MIRRI Best Practice Manual on ABS provides the minimal requirements for MTA and MDA/accession form. These are not model clauses (although a few examples of possible clauses are given there), but offer the organisations the necessary flexibility to use transfer agreements fitting their national legal requirements and institutional framework while fulfilling said minimal requirements. Thus, the strains are always supplied by MIRRI under an MTA and strains deposited under an MDA/accession form. MIRRI recognizes that the level of harmonization should be adequate, helpful and attractive to the users. In the upcoming time, MIRRI-ERIC will gain further experience and collect stakeholders' feedback regarding the supply of cultures through the infrastructure. Transfer agreements and other aspects of the operational legal framework will be evaluated to see if further harmonization will be necessary and feasible.

6. Annex I Stakeholder Interviews

Details on the conducted interviews with stakeholders follow.

MIRRI IS21
IMPLEMENTATION AND SUSTAINABILITY FOR THE 21ST CENTURY
MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE



STAKEHOLDER INTERVIEWS

PRESENTATION OF RESULTS OF THE STAKEHOLDERS INTERVIEWS CONDUCTED UNDER IS_MIRRI21 (WP 3.2.2)

IS_MIRRI21 WORKSHOP ON ABS

22 JUNE 2022

The project “Implementation & Sustainability of Microbial Resource Research Infrastructure for 21st Century” (IS_MIRRI21) has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement nº 871129. This document reflects only the author’s view and the European Commission is not responsible for any use that may be made of the information it contains.

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-A-1	**Educational level & Function/position**	Curators, University Professors, PhD researchers and other highly educated staff. Managers, researchers and other high positions in companies.	(Deputy) Managers, researchers and project/compliance staff.
IND-A-2	**Awareness** Nagoya Protocol (NP) and the EU Regulation 511/2014	**Nearly all interviewees were aware of both!**	
IND-A-3/ORG-A-2	**Attendance at meetings or workshops on ABS**	**About half** attended such external meetings. Most others: - attended internal meeting on the subject - and/or rely on colleagues for information concerning ABS.	**All but 1** confirmed attendance of such meetings.
ORG-A-3	Has the organization organized **workshops/seminars** on ABS for the members?		**4 of 7** organized workshops/seminars on ABS for their members.
IND-A-4	**National legislation in home country**: **Awareness & understanding** Contact with the national authorities for ABS in home country, or through a stakeholders platform?	**19 of 26** interviewees **are aware** of the national legislation and **understand (most of) it**. Only 6 confirmed to be in contact with the national authorities on ABS themselves. Most did not have such contact, some relied on specialists involved through projects. The lack of contact seems more prominent in certain countries than in others .	
ORG-A-4	**Support for Members** to reach ABS compliance, if yes, how?		**5 of 7** confirmed to provide support by: - liaising them with experts (1) - providing on-line materials (3) - having dedicated officer/experts/WG to ABS issues (3) - providing ABS information in the catalogue of genetic resources (2)

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
ORG-A-6 (related also to IND-C-3)	**Main challenges** for members with regard to compliance with ABS measures?		▪ Lack of awareness in the research community. ▪ Difficulty to understand and interpret ABS laws and learn how to comply with the different national and regional (EU) regulations. ▪ Language barriers. ▪ Difficulty to receive permission in some countries, even for non-commercial purposes. ▪ Lengthy processes. ▪ Differentiate PIC/MAT in the ABS framework from other type of permits. ▪ Lack of legal support.
IND-B-1	**Most used information resources** i..e., general information on ABS requirements for access and conditions for use (PIC and MAT)	Department of my institute/organization (internal): 7 BRC staff or their website: 7 ABS Clearing House : 7 National website on ABS/ABS NFP (or national authorities): 5 Not sure, unnamed resource: 3 Private consultant: 1	Members' own resources/contact persons were mostly mentioned (5) ABSCH (1) German Nagoya protocol hub (1) About half of the interviewees did not have information on this.
ORG-B-3	**Interaction (experiences)** with: CBD ABS National Focal Points Other national authorities		**3 of 7 interact** and mention the long time to receive response and/or permits; ▪ Some NFP more responsive and effective (2) ▪ Communication getting better but still not very helpful (1) ▪ Bureaucratic and unclear (1)

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-B-2 ORG-B-4	**Experience and performance** of - ABS National Focal Point in own country - in other countries - regarding provision of info and support	**ABS-NFP are responsive/reactive: 10** **Adequately provide answers to questions: 5** **Inadequate: 1** **Needs improvement: 1** **Not used yet: 12** (not needed, or thinks no NFP exists, or gets info elsewhere)	**4 of 7 did not know** ▪ Cases of helpful responses were mentioned ▪ communication improving ▪ Communication better orally than by written communication.
IND-B-3	**Have you requested access or negotiated benefit sharing?** Experience in terms of: - identifying the contact point - understanding legislation - time delay since first contact until receiving due diligence documentation.	**No: 14** **Yes: 6** PIC was obtained in at least 2 cases, one after ca. 1 year, 1 sooner; 1 case where collecting activity proved out of scope (so no PIC needed), was well-handled by the competent national authority. **Unclear: 1**	
IND-C-1	**Specially designated person** to collect and convey information within the organization, provide guidance and/or overlook compliance with ABS?	**No: 15** **No, but planned: 1** **Yes: 9** (f.e., BRC staff)	
IND-C-2	**Implementation in your organization** ABS policy Best practice Material transfer agreements (MTA)	**No: 11** **Yes: 11** Some interviewees did not directly answer the question concerning policy yes/no, but knew of documents (MTA) in place and used obligatory, and such cases considered as “Yes”	

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-C-3 ORG-C-1	**Impact on activities** by NP and ABS legislation	**(Serious) impact: 10** • Choice of sources for projects (but does not stop projects) (1) • Collaboration with scientists in provider countries more complex or frustrated (2) • Difficult to get permission to deposit in foreign (non-provider country) CC (1) • Delays in writing or executing projects (2) • less time for research due to administrative burden (3). **No impact: 3** ▪ Indirect impact: 1 - May limit what can be done with isolated strains, or when their origin is unknown. **Not aware, other: 2**	**Impact: 6** ▪ Change places of sampling to avoid ABS legislation (3) ▪ Higher investment in resources, training and tools (1) ▪ Impossibility to obtain validation of prokaryotic names from strains accessed in restrictive countries (1) ▪ Risk to be withdrawn from project catalogue if the partners do not follow the ABS laws (1). **No impact: 2**
IND-C-4/ ORG-C-2	**Public deposit of strains** Has the entry into force of the NP (12/10/2014) **changed the frequency /amounts** of strains you have deposited in public collections? If so, why?	**No : 18** ▪ more careful (1), or have changed the source of isolation (1). **Yes: 4, decrease in all cases** ▪ Could not deposit by lack of required docs (PIC, MAT) (1) ▪ Avoiding certain areas to collect (1) ▪ Only temporary, as initially rules were unclear but was resolved later on (1) ▪ Administrative burden too high (1) **No experience (no deposits needed): 3**	**No answer/do not know: 5** **Do not think so: 2**
IND-C-5/ ORG-C-3	**Ordering of strains** Has the entry into force of the NP (12/10/2014) **changed the frequency /amounts** of strains you order from public collections? If so, why?	**No: 21** ▪ ABS does influence choice for certain cultures, ABS-restricted strains are avoided, “I only order what I know I may use”. **Yes: 3** ▪ Strains from some countries are specifically mentioned as being unavailable for use (one case where attempt to obtain PIC unsuccessful). **No experience: 1**	**No answer/do not know: 5** **Do not think so: 2**

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-C-6/ ORG-C-4	**DSI** Effect on if digital sequence information (DSI) were to be put in scope of the NP	**Negative effect: 19** ▪ More difficult/time consuming to share data (8) ▪ Worry how to continue using data from public repositories and still comply (2) ▪ More complexity expected ▪ More resources needed to analyze and comply ▪ Limit sharing of information, slowing down research (4) **Positive effect: 3** ▪ A good challenge (1) ▪ Data more curated and checked (1) ▪ Greater protection of the rights of countries of origin (1, a company) **Cannot foresee/do not know: 5**	**Negative effect: 4** ▪ Big impact because of the restricted access to data (3) ▪ Adds barriers to research, discourages work (1) **Do not know: 1** **No effect: 2**
	Ideas about implementing a system	Cannot foresee/no idea: 7 Cannot imagine a system without major negative effects on basic research and taxonomy: 1 At least basic (i.e., not applied) research should be exempted: 1 "Have access to material and sequences in the same PIC/request: 1 Protect deposited sequences for limited period in a database, during which access is controlled: 1 Use of genetic sequences for non-profit activities such as identification (using public reference sequences) should be out of scope; catalogue of uses may be useful (GV: do they mean indicating in/out of scope? I think yes): 1 Some system for traceability: 1 ("There should be some way to check the DSI deposit and use").	No answer: 4 Multilateral approach (easy access and distribution of funds to global biodiversity projects) (2) National repositories allowing countries to control their DSI (1).

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-D-1/ ORG-D-1	**ABS info in strain catalogues** Are collections providing sufficient ABS-related information on their holdings in the online strain catalogues? **What is missing**	**Yes: 15** ▪ "Some CCs are more aware about the information they shall provide and some others have less knowledge and provide less information."; ▪ " …when I browse culture collections catalogues I usually do not see much ABS-related information anyway." **Could be improved: 2** • "Not always easy to find the info. Perhaps a specific field in the database related to Nagoya with a clear statement (compliant or not with Nagoya)" **Not sure/ do not know: 5** **Some collections yes, some no: 1** ▪ **What use is allowed / not allowed** (especially commercial purposes, patent, industrial use). ▪ **Strain affected or not affected by ABS legislation**	**No answer/do not know: 4** **Yes: 3**
IND-D-2/ ORG-D-2	**Registered collection** Would the status of the collection being registered or not-registered under the EU Regulation influence your choice of mBRC for ordering strains?	**Yes: 13** ▪ The choice to order may also depend on the price per strain (several) ▪ Increases confidence in collections (1) ▪ Higher price would not be a problem (1) **No: 8** one interviewee remarks "will use internal strain as alternative" **Do not know/not aware: 5**	**No answer/do not know: 3** **Yes, positive impact: 2** **Maybe: 2** ▪ Could be, but only because users may perceive these as CCs with higher quality, which is not necessarily true, even regarding the information about NP issues (1)
IND-D-3	**Collections' response to queries** on ABS-related information about their holdings	**Good experiences: 17** ▪ Helpful, referred to other persons when needed (1) ▪ " …although the collections always state that they are not responsible for the accuracy of the information or the interpretation of the ABS laws **Not good experiences: 1** (incorrect answer was given but the case was solved with help of the relevant Competent National Authority) **No experiences: 2**	

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-D-4	**Awareness about involvement of collections with national authorities on ABS in your country**	**No not aware, or not sure: 16** **Yes: 6**	
IND-D-5	**How should collections be involved?**	Summary of responses: Most interviewees see a role for CC in **providing support** and /or ABS information to users, e.g., by **more pro-actively (than currently) disseminate such info (or changes in field of ABS) to their clients.** Importance of the current level of informedness of several collections was mentioned. Further suggested roles for CC: ▪ **Understand better the need of customers**, and provide advise on ABS ▪ **Influence the legislators**, CCs should represent the National Authorities ▪ **Be the users' reference** for information about Nagoya ▪ **Act as intermediary between the users and the National Authorities**, as CCs are aware of the problems that the users face." ▪ Umbrella agreements between CC and provider countries for all deposits originating from those countries. ▪ Act as competent authorities and give trustable information, without transferring the responsibility to the user. ▪ All the collections in a country should meet to discuss at national level and try to identify the needs and the current knowledge on ABS. "Provide short booklets to help clients/research centres understand ABS and related concept when they request access to genetic resources."	

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-E-1/ ORG-E-1	**Role for MIRRI** What could MIRRI provide you in this respect?	**More information on ABS rules and NP: 12** **More harmonization across Europe of information and procedures: 5** **Foster collaboration (between users and CC): 1** **No ideas: 3.** Main remarks made: ▪ "Simplified information and guidelines about ABS" ▪ "**Information about NP implementation in different countries from one contact point** would be better than going one by one. This is a very attractive point." ▪ "MIRRI is a great project to have access easily to collections that we don't know. It can help to be aware of all collections. It will be easier if MIRRI homogenize the regulations to facilitate the exchange between the European countries. When we have a European collection like MIRRI it will be easier to connect with the International collections." ▪ **More info about country laws**; ▪ **Giving consultancies**; ▪ **Giving alert in changes of the status about ABS**. ▪ **Publish a newsletter about ABS and the rules of NP**"; ▪ "**Provide clear info in the MIRRI catalogue**. With dissemination and in-depth activities and by creating pages on the website". ▪ "**Provide legally acquired strains**".	**No answer: 1** **Sharing information: 5** (infographic documents, training, workshops, consultancy…) **Acting as intermediary in the request for permits, lobbying to harmonize procedures and forms across countries: 1**

Question ID	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-E-2/ORG-E-2	**Paid MIRRI consulting service** Would you be interested in paying for a consulting service to help you/your organization to comply with NP?	**Yes: 12** **Yes, but consider that it should be for free, at least for public institutions: 8** (number overlaps in part with below answer) **Not sure: 5** (including "maybe in future") **No: 6** Selected remarks made: - Interesting service, but academia depend on data for free. Afraid of more pay-walls, for which permission may not be granted or funds lacking. - If paying for such a service, it must have clear added value (compared to for-free alternatives) - Some institutions already pay internal ABS specialists, so unlikely they would also want to pay for MIRRI advice.	**Eventually: 3** (depending on fee and usefulness of the information provided) **Yes: 2** **No: 1** (no budget for this and availability of the service in house) **No answer: 1**
IND-E-3/ ORG-E-3	**Training courses (paid)** Would you be interested in paying for training courses on NP and ABS?	**Yes: 21** **No: 4** **Not sure: 1** Remarks: "Yes. It could be a way to give information to a large number of people, and if the institute pays for courses it will be taken more seriously by people. For example a webinar (round table) dedicated to touch the maximum of number people, can give the chance for interaction through many questions from people and knowledge exchange."	**No answer/do not know: 2** **Eventually: 2** (cost) **Yes: 1** **No: 2** (1 no budget, 1 do not think that he will receive valuable info)

Question ID6	Question(s)	Individual Researchers (Public 13, Semi-public 4, Private 9 interviews)	Organisations (7 interviews)
IND-E-4	**Needs** Can you tell us more about your specific need as regard NP and ABS?	- **More info on ABS regulations in other countries** (2+), " visible contact points to go for information about NP implementation in microbiology research". - "Provide **short booklets** to help clients/research centres understand ABS and related concepts, and training - **Advocate/convey the message about needs of users of GR to the policy makers, authorities etc.** - "Everything that restricts basic science should be relieved. **There should be approved, standardized access to GR from any country for basic science and non-commercial purposes.** A general requirement for it could be that work done on the GR should be open access, and perhaps be published within a certain time. In practice, it is very difficult to change this, as countries take their own decisions and do not seem to care much about the negative consequences of their policies for their own researchers and national science development". - **Quicker procedures for obtaining PIC.** - **"Guarantee that the information obtained from CCs or MIRRI is trustable".** - **More info on ABS regulations in other countries, Alert system of changes and news;** - **Access to validated info about national ABS procedures;** - **Faster processes, more legal certainty;** - **strain label of compliance for NP**.	
ORG-E-4	**What could in your opinion be done (more) by culture collections or MIRRI** to support ABS practices and compliance to the Nagoya protocol for your members?		**Awareness raising and provision of information: 3** **No answer/do not know: 2** **Act as intermediary in the request of permits to the NCA: 1** **Lobbying with other organizations to simplify and harmonize national procedures: 1**

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