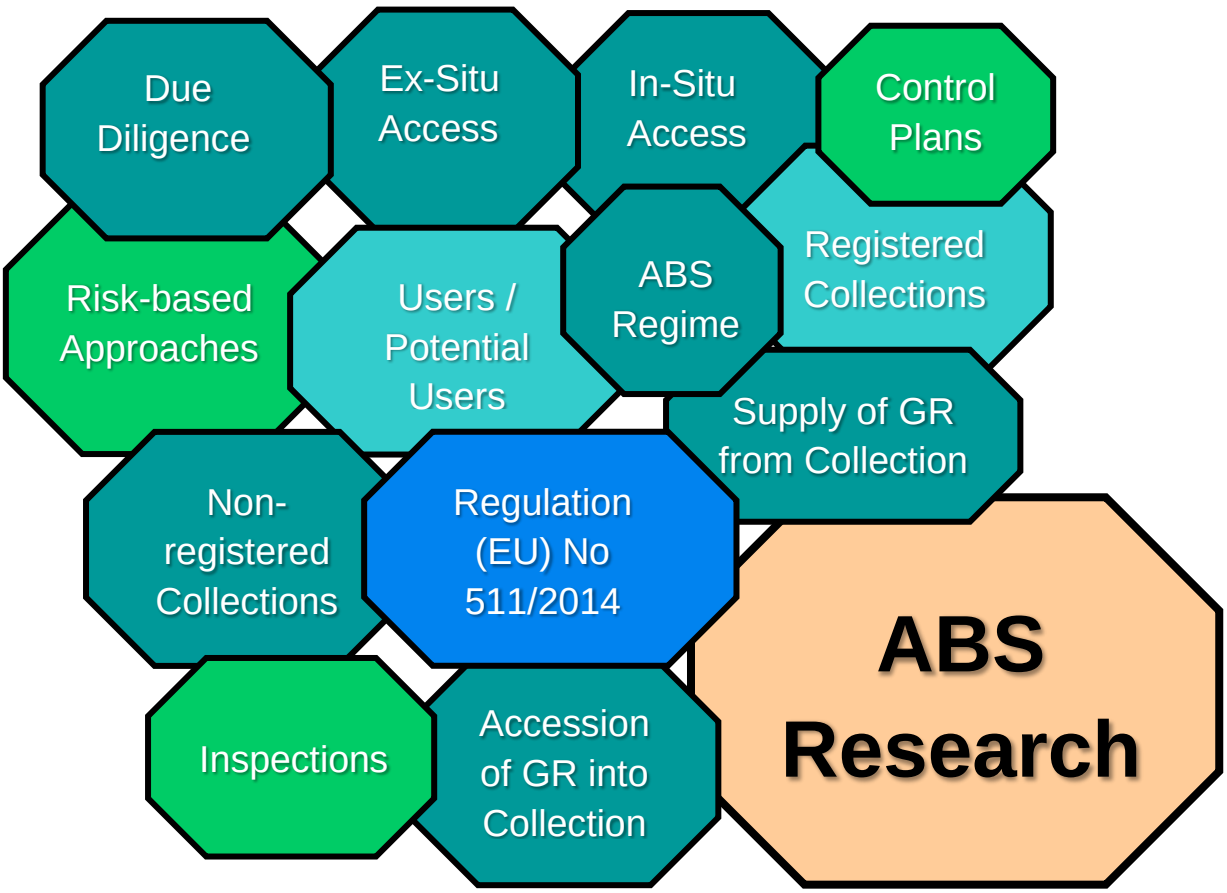
**Ute Feit, Dagmar Fritze, Thomas Greiber,
Dunja Martin and Elizabeth Karger (Eds.)**

First Meeting of the European Competent National Authorities Implementing the Nagoya Protocol and the Corresponding EU Regulation

Final Report



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First Meeting of the European Competent National Authorities Implementing the Nagoya Protocol and the Corresponding EU Regulation

Report of an International Meeting hosted by the Nagoya CNA-Unit of the German Federal Agency for Nature Conservation on the Isle of Vilm, Germany, 20 - 23 March 2017

Editors
Ute Feit
Dagmar Fritze
Thomas Greiber
Dunja Martin
Elizabeth Karger

BfN
Federal Agency for Nature Conservation

Cover picture: Anette Pahl

Editors' addresses:

Dr. Dagmar Fritze
Dunja Martin (LL.M.)
ABS-Compliance & Consulting
Möwenkamp 9, 30916 Hannover-Isernhagen
E-Mail: d.martin@abs-compliance.de

Thomas Greiber (LL.M.)
Federal Agency for Nature Conservation
Division I 1.4 "Competent National Authority for the Nagoya Protocol"
Konstantinstr. 110, 53179 Bonn
E-Mail: thomas.greiber@bfn.de

Elizabeth Karger
Hermann-Köhl-Str. 10, 93049 Regensburg
E-Mail: elizabeth.karger@posteo.de

Scientific Supervision:

Ass. iur. Ute Feit
Federal Agency for Nature Conservation
Division I 1.4 "Competent National Authority for the Nagoya Protocol"
Isle of Vilm
18581 Putbus/Rügen
E-Mail: ute.feit@bfn.de

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List of Abbreviations

ABS	Access and Benefit Sharing
ABSCH	ABS Clearing-House
BGCI	Botanic Gardens Conservation International
BIO	Biotechnology Industry Organization
BMS RI	BioMedical Science Research Infrastructure
BRC	Biological Resource Centres
CBD	Convention on Biological Diversity
CEN	Comité Européen de Normalisation
CETAF	Consortium of European Taxonomic Facilities
CIESM	The Mediterranean Science Commission
CNA	Competent National Authority
COP-MOP2	Second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol
CRO	Contract Research Organisations
DFG	German Science Foundation (Deutsche Forschungsgemeinschaft)
DSI	Digital Sequence Information
DSMZ	German Collection of Microorganisms and Cell Cultures
EC	European Commission
ECCO	European Culture Collections' Organisation
ESFRI	European Strategy Forum for Research Infrastructures
ERIC	European Research Infrastructure Consortium
EU	European Union
EUTR	EU Timber Regulation
IDA	International Depositary Authority
IJSEM	International Journal of Systematic and Evolutionary Microbiology
IJSB	International Journal of Systematic Bacteriology
IRCC	Internationally Recognized Certificate of Compliance
ISO	International Organization for Standardization
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for the Conservation of Nature
JBO	Japanese Bio-Industry Organisation
MAT	Mutually Agreed Terms

METI	Japanese Ministry of Economy, Trade and Industry
MIRRI	Microbial Resources Research Infrastructure
MTA	Material Transfer Agreement
NFP	National Focal Point
NGO	Non-Governmental Organisation
NP	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization
OECD	Organization for Economic Co-Operation and Development
PIC	Prior Informed Consent
R&D	Research and Development
RG	Risk Group
UC	User Compliance
UPOV	International Union for the Protection of New Varieties of Plants
WFCC	World Federation for Culture Collections
WHO	World Health Organisation

Introduction to the Meeting

Ute Feit, Ellen Frederichs, Thomas Greiber

Federal Agency for Nature Conservation, Germany

It has been a long road from the start of the negotiations on Access and Benefit Sharing (ABS)[1] leading up to the adoption of the Convention on Biological Diversity in 1992, the development of the Bonn Guidelines in 2001 and the adoption of the Nagoya Protocol in 2010 to the point where we now have binding obligations for the implementation of the ABS regime in the European Union (EU). The time has finally come where ABS needs to move from theory to practice and the Competent National Authorities (CNAs) will play a key role in this regard.

Two regulations have been enacted to implement the compliance measures of the Nagoya Protocol in the EU: Regulation (EU) No 511/2014 (ABS Regulation), which focuses on the due diligence obligations of users, monitoring of user compliance, conducting checks, registration of collections and recognition of best practices; and Regulation (EU) 2015/1866 (Implementing Regulation), which provides detailed rules regarding the register of collections, monitoring user compliance and best practices.

The implementation of these regulations requires a multi-facetted approach, including amongst others the following activities: user identification and awareness-raising, cooperation and exchange of information between EU member states and also provider states, interaction between EU member states and the EU Commission, development and implementation of administrative procedures, training of staff, data management etc.

Now that many of the EU member states have developed national implementing legislation and established their CNAs, there is a great demand for information sharing between the responsible authorities on technical and structural processes as well as on early implementation experiences. This exchange promotes not only the development of these processes but also fosters joint learning, mutual support and harmonization among the member states.

Against this background, the German CNA – a designated unit at the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) – organized a first informal meeting of the EU CNAs implementing the Nagoya Protocol and the corresponding EU regulations. The meeting took place from 20 to 23 March 2017 at the branch-office of the BfN, the International Academy for Nature Conservation, located on the Isle of Vilm, Germany.

Purpose of the Meeting

The purpose of the meeting was to provide for the first time a platform for the EU CNAs to identify and discuss implementation challenges and possible solutions with respect to any of their designated tasks under the regulations, including receiving due diligence declarations, processing applications from collections for inclusion in the EU register and verifying fulfillment of the criteria for registration, checking and enforcing user compliance as well as imposing sanctions for infringements, cooperating with CNAs in provider states, and advising users and collections.

[1] Access and Benefit Sharing (ABS) refers to access to genetic resources and fair and equitable sharing of benefits arising from their utilisation, which is the third objective of the CBD.

The meeting was thus an important step towards fulfilling the member states obligations under Article 12 of the ABS Regulation in terms of cooperation. Furthermore, it sends an important signal to the international community as it underlines the serious efforts made in the EU to operationalize the Nagoya Protocol and thereby achieve Aichi Target 16 of the Strategic Plan for Biodiversity 2011-2020 under the Convention on Biological Diversity (CBD) as well as the UN Sustainable Development Goals, in particular Goal 2.5.

Participants and Workshop Format

ABS experts from 17 EU member states and the Commission joined this first meeting to discuss legal and technical developments arising from the establishment of the CNAs and the implementation of the above-mentioned EU regulations.

The workshop was primarily addressed to representatives of the CNAs of the EU member states. Additionally, some representatives from collections were also present to provide technical expertise.

The meeting was treated as an informal technical workshop, the aim of which was to exchange ideas and not to reach (political) consensus on individual issues. The informal setting of the meeting was seen as a major advantage as it gave participants the opportunity to speak freely.

Key Issues

The core topics of the meeting were the development of so-called "risk-based" controls and the registration of collections, which are special ABS compliance tools foreseen under the EU ABS Regulation. The meeting was therefore divided into two thematic areas.

A major focus of the first day of the meeting was on institutional structures and procedures for user compliance checks, which are to a great extent still in the development stage in all EU member states. Important points discussed under this item were the concrete identification of users as well as the possible format and content of “control plans” including the understanding of the concept of “risk-based” approaches (Article 9 of the ABS Regulation).

The discussions showed that many CNAs are finding it challenging to develop appropriate and practical measures for the identification of potential users of genetic resources and at the same time to raise awareness amongst different user sectors. The session also indicated the technical complexities of successfully implementing compliance checks given the limited human resources and the remaining legal uncertainties which were identified by all CNAs as major challenges.

However, the participants were able to gain useful ideas and suggestions for future implementation, either based on theory or experiences drawn from first ABS inspections or the implementation of other legislation such as the EU Timber Regulation[2].

The second day of the meeting concentrated on the concept of registered collections as foreseen in Article 5 of the ABS Regulation. The session provided a general overview of the different typologies and mandates of collections as well as the perceptions of some EU member states regarding their existing collections. Furthermore, the expectations of the en-

[2] Regulation (EU) No 995/2010, OJ L 295/23.

visaged register of collections were discussed, accompanied by use cases, possible approaches and tools. Last but not least some of the problems with establishing a sound registration process and difficulties faced by collections in meeting the registration requirements were identified.

The participants concluded that collections play a fundamental role in the implementation of the Nagoya Protocol in the EU. A rapid application process for as many collections as possible to become certified as "trustworthy" sources of genetic resources would therefore result in greater legal certainty for users. However, it became also clear from the discussions that collections still need incentives to apply for registration and at the same time practical guidance to prepare and accelerate this process. In this context, the CNAs play a critical role.

In order to support all players involved a draft awareness-raising tool was presented which was inspired by the ABS Manual of the European Strategy Forum for Research Infrastructures (ESFRI) project MIRRI[3]. This manual could inform and support collections in the implementation of the EU ABS Regulation in the future.

Outcomes

The participants agreed that the meeting was extremely useful, providing insights into current activities and first achievements of the different CNAs, as well as highlighting those areas where more work needs to be done. It was clear from the discussions that the implementation process has only begun and that most CNAs are in a similar position in terms of the progress already made.

A key outcome of the meeting was the great need and willingness for sharing information and supporting materials. Although all CNAs profited from this exchange, it was particularly helpful for those CNAs that have fewer human resources devoted to the implementation of the EU regulations. It was also noted that this type of cooperation between member states is an important and valuable part of the work at the EU level as it helps to avoid duplication of work and at the same time promotes consistency and harmonization.

Many participants highlighted the need to build strong networks between the CNAs, to communicate regularly and to continually share information on achievements, common problems, possible ideas, tools etc. while many processes are being implemented for the first time and open questions and uncertainties still need to be addressed. The idea of creating an online discussion forum (similar to the one used in the biosafety field) was therefore recommended and has been established in the meantime as an indirect result of the meeting.

It was also suggested that the CNAs should meet for an informal workshop at least annually in the future and that more frequent interim-meetings would be helpful as well. After the workshop, it was therefore decided to organize such interim-meetings of the CNAs on a regular basis back-to-back with ABS expert meetings.

A number of participants expressed the wish to revisit the same topics again at the next CNA meeting. By that time, the CNAs will have made more progress and gained more experiences that can be shared. In addition, participants proposed that the following topics could be

[3] The "Microbial Resource Research Infrastructure" – short MIRRI – has the mandate to provide researchers with easy and efficient access to the best microbial resources, services and data in Europe. See MIRRI ABS Manual under www.mirri.org/news-and-events/archive/archive/2016/december/article/abs-manual-abs-clearing-house.html.

discussed in future CNA meetings:

- Identification and understanding of user groups
- Control plans
- Inspections including their scope and the resources dedicated to them
- Experiences from infringement procedures
- Sanctions and penalties imposed for non-compliance in different member states
- Collections
- Concrete case studies
- Best practices
- Capacity-building and awareness-raising
- National legislation in the individual EU member states
- Legislation in provider countries
- Traditional knowledge

Other suggestions included the dedication of more time for discussions and working groups on specific topics, as well as the direct involvement of users from different sectors and collections.

The overall feedback received at the end of the meeting was very positive. The participants appreciated the constructive atmosphere and spirit of cooperation among the CNA-representatives as well as the perfect working conditions on the island of Vilm.

Documentation of the Meeting

The meeting resulted in the documentation at hand. Its objective is to highlight the challenges of CNAs associated with this new chapter of on-the-ground ABS implementation and at the same time the progress that has already been made in terms of operationalizing the Nagoya Protocol and the corresponding EU ABS Regulation.

The main contents of the meeting report are the summary of the meeting and the abstracts of the presentations held by different participants. The contributions are followed by a summary of the discussions which took place during or after the presentations.

These workshop proceedings, including the collected views on different issues, are published for the benefit of both CNAs and other ABS stakeholders to support the European CNAs in the implementation of the Nagoya Protocol and the corresponding Regulation (EU) No 511/2014.

The meeting report as well as further information on the Nagoya Protocol and its implementation can be found on the BfN website at www.abs.bfn.de.

Summary of the Meeting

Dagmar Fritze and Dunja Martin

ABS Compliance & Consulting

Ute Feit and Elizabeth Karger

Federal Agency for Nature Conservation

The following summary provides a brief overview of the content of each session of the meeting and the main issues raised in the discussions. Further details of the discussions can be found directly following the contributions of the speakers.

As the CNA meeting was informal and issues were discussed openly and without participants stating any fixed or agreed-upon positions, this summary and the discussions which appear after each contribution are based on the authors' notes and therefore may not fully reflect the opinions or concerns of the participants.

Opening of the Meeting

UTE FEIT opened the meeting and welcomed the participants to the Isle of Vilm. A short history of the development of the ABS regime was provided and an overview of the implementation of the Nagoya Protocol in the EU and Germany. The emphasis of the presentation was on taking ABS from theory to practice, which poses a multi-facetted challenge for the CNAs. The role of the meeting in providing a platform for the CNAs to identify and discuss the challenges as well as possible solutions was highlighted.

1. State of Play

In the first session, ALICJA KOZLOWSKA presented the decisions of the 13th meeting of the Conference of the Parties to the Convention on Biological Diversity (COP13) and the 2nd meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP2) which are relevant for the work of the CNAs. Decisions relating to institutional structures, the ABS Clearing-House, awareness-raising and capacity-building were identified as being relevant. Reference was also made to more controversial issues such as synthetic biology and digital sequence information (DSI), which may impact upon the material scope of the Nagoya Protocol in future and therefore also have implications for the activities of the CNAs. The discussion focused on the issue of DSI and the process for dealing with it.

2. Development of Control Plans

This session was focused on the development of control plans, including the structure, content etc. THOMAS GREIBER began by speaking about risk-based control plans, which need to be prepared by the CNAs, and a possible structure for these plans. In the discussion, the need for a pragmatic approach to controls was highlighted, especially considering the limited resources available to the CNAs for conducting checks. The potential to learn from implementation of other regulations with due diligence obligations such as the EU Timber Regulation was also noted. KATIE BECKETT talked about the approach of the United Kingdom with

respect to the control plans and how Regulatory Delivery takes the level of hazard and the likelihood of non-compliance into consideration when assessing risk. The UK implementing legislation was introduced and suggestions were made about how compliance visits might be conducted. The discussion focused on the role of awareness-raising activities, some of the challenges associated with reaching users and the value of communicating with users for both gaining valuable information and increasing transparency of CNA activities. Finally, the issue of compliance within universities was discussed. LUDO HOLSBEEK presented the ABS competences in Belgium, which are distributed among the federal and regional levels, which will lead to differing approaches to ABS in Belgium. He further explained that the Belgian collections fall under the individual competences of the different federal or regional ABS authorities. Problems which could potentially arise as a consequence of these differing responsibilities were addressed. The discussion focused on the uncertainty surrounding the scope of the controls required by the ABS Regulation.

3. Identification of Users

KATIE BECKETT presented the various strategies employed in the UK to identify users and the results of a study about UK users. In the discussion, the difficulty associated with establishing and updating databases with user information was highlighted. The usefulness of existing databases, which have been established for other purposes, and the ability of CNAs to access the information stored in these databases was touched upon. ELKE ZIPPEL AND SEBASTIAN GARDT presented the results of a study which aimed at identifying users of genetic resources in Germany. The analysis focused on an internet based approach where ABS relevant information was automatically extracted from publicly available databases, the homepages of companies, etc. The goal was to develop a tool which enables an assessment of whether a given organisation is potentially using genetic resources or not. The need to have expert interpretation of data and the problems relating to the data themselves in terms of being current, correct and having informational value were discussed. KATILEENA LOHTANDER-BUCKBEE presented the Finnish implementing legislation and the institutional arrangements which have been put in place, including the requirement for users of genetic resources, which are within the scope of the Nagoya Protocol, to notify the competent national authority when these resources are imported to Finland. The discussion focused on accessing information about applicable ABS legislation and the ABS Clearing-House, and the extent to which this is useful for CNAs and users.

4. Risk-based Approaches and Criteria

In this session, THOMAS GREIBER noted that no guidance has been provided by the regulations in terms of implementing a risk-based approach to compliance checks. A possible step-wise process for the development of a risk-based assessment and criteria was presented. In the discussion, the scope of the checks and the challenges associated with getting the data needed to develop such a risk-based approach were raised. MICHAEL KEARNEY talked about the risk-based approach in the UK, noting that the checks usually start with low-risk sectors and users so that inspectors can build up their understanding of sectors and users. The issue of awareness levels within different sectors and the value of awareness-raising and capacity-building were also raised. Participants discussed the type of information about a company and its structure, which may help to determine the risk of non-compliance. EVA JUUL JENSEN spoke about how Denmark has raised awareness amongst users and the preparatory work which has been done for the checks. In Denmark, implementation has

also drawn on experience gained from the implementation of the EU Timber Regulation. In the discussion, participants spoke about which sectors need to be checked and how CNAs can get data about the users in their country. Finally, Linda Wassink-de Ligt presented the risk-based approach taken in the Netherlands. This included how to identify risks of non-compliance, matrix for assessing risk and what further activities will be taken by the CNA.

5. Control Approaches and Processes – First Inspections

In this session, participants spoke about their impressions from the first inspections conducted in their respective countries. In his presentation, PETER MAŇKA described the implementation of the EU ABS Regulation in Slovakia, including the national legislation and institutional structures which have been put in place. The outcomes of the first checks in Slovakia were presented, with use of genetic resources in Slovakia predominantly taking place in publicly funded research institutes. In the discussion, the benefits of cooperating with research institutes and the establishment of creating baselines was noted. ELLEN FREDERICHS elaborated on a possible stepwise-approach to conducting inspections and noted the value of developing a checklist and a manual for inspectors involved in on-the-spot checks as well as the possible content of a protocol for on-the-spot checks was also provided. In the discussion, questions were raised about the extent of checks, the potential flow of information about non-compliance to provider countries and confidentiality of documentation held by users. Finally, LINDA WASSINK-DE LIGT presented the experience of the Netherlands regarding the inspections that have been conducted so far in the plant breeding sector. Information about identification of users and the types of information requested were provided as well as how the inspectors prepared for and conducted the inspections. The discussion started with the outcomes of the checks and then moved onto the issue of the cut-off point for new genetic resources.

6. Lessons Learned from a German Expert Study: Typologies and Mandates of Collections

In this session, DUNJA MARTIN described the different types of collections, the types of genetic resources collected, the temporal scope of the collections' existence, their financial sources and their overall mandate. The relevance of ABS for the different collections needs to be analysed taking into account their academic, industrial, public or educational mandates and their different purposes. DAGMAR FRITZE then described microbial service collections in more depth. These collections may be one of the most likely candidates to become registered. Emphasis was placed on why and how microbial genetic resources enter these collections, what is done with these microbes and why and how they leave the collection. Typical services and cooperation within the sector were described. An ABS relevant result of these services and cooperation, namely, the multiple, simultaneous existence of subcultures of one and the same microbial strain was highlighted. DAGMAR FRITZE continued with the complex framework of laws and regulations which influence the daily work of microbial collections. It was noted that the ABS regulations are only one of many relevant regulations. Background information on the nature of microbial genetic resources and their diversity was provided. The various reasons why researchers deposit their microbial strains with service collections were also described. Generally, published data can only be verified if the relevant biological material is also available for comparison and further study. After this, the core types of work with microbial genetic resources were described, which revolve around the agreed minimum requirements for checking viability, purity and authenticity. This core work is

considered to be outside of the scope of Regulation (EU) No 511/2014. Overall compliance by microbial culture collections is determined by numerous international, regional and national laws and regulations as well as voluntary international, regional and national standards and codes of practice. It was stressed that service culture collections, in fulfilling their mandate, need to reconcile scientific demands for open unimpeded access to microbial genetic resources while ensuring that access to that material is legitimate. The ever more regulated framework puts substantial administrative burdens on these collections and entrusts them with ever increasing responsibility.

7. Discussion and National Perceptions

Some questions were disseminated prior to the CNA meeting in order to prompt discussion about perceptions of national collections and existing ABS approaches. AMBER HARTMAN-SCHOLZ described the experiences of a German microbial collection, which exchanges large amounts of genetic resources on a worldwide basis for both academia and industry. The experiences of this collection in terms of working towards an application to become a registered collection were discussed. This collection has begun an initial assessment of their compliance with Regulation (EU) No 511/2014 in preparation for submitting an application for inclusion in the register. This has been done to be able to decide on which resources are to be included for registration and to demonstrate their ability to apply standardized procedures and to fulfil other requirements of Article 5. Challenges identified include compliance with Article 5(3)(b) and the assessment of depositors' documentation accompanying the genetic resources. While IT solutions are being implemented to ease the logistical and legal workload, it remains unclear to which extent the collection will be expected to legally verify the Nagoya-related documentation provided by depositors. Because of the large numbers of deposits received from a wide variety of countries, a "de minimis" check on behalf of the collection is considered to be reasonable. It was further noted that the collection can only expect users to fulfill their due diligence by reading the relevant documents, adhering to the relevant terms, and report on their activities as envisioned in Article 7(1) and (2). The collections themselves cannot enforce the terms specified in the documents themselves. FLORENCE HERVATIN-QUENEY outlined the national institutions and responsibilities in France for processing applications from collections to be entered into the European register of collections and for conducting the corresponding verification checks on registered collections. The activities and responsibilities of the expert committee, which was established by the Ministry of Research and which is responsible for assessing these requests, monitoring the management procedures at collections and analysing whether good practices have been implemented, were also described. Many of the activities of these experts are carried out using an electronic platform which has been created to store all relevant requests, correspondence and information. ZSUZSANNA UJJ outlined the implementation of the EU ABS Regulation in Hungary, including the various organizations and their responsibilities. The checkpoints, the penalty system, the status of the control plan and future plans for access legislation were explained. The different types of Hungarian collections were described together with their ABS relevant activities. Issues such as varying standards for documentation, level of ABS knowledge of staff and potential consideration for registration were addressed. Emphasis was placed on the fact that capacity-building is the most important activity and that awareness–raising workshops are being organized. BOŻENA HACZEK presented the results of an analysis of Polish collections of genetic resources and the results of a survey, which was conducted to assess the Polish collection holders' level of awareness about the Nagoya Pro-

tocol and the Regulation (EU) No 511/2014 and their interest in potentially being included in the EU register.

8. Development of a Register of Collections and Expectations

ALICJA KOZLOWSKA introduced the concept of registered collections as well as the reasons why this compliance tool was incorporated into the regulation. Regulation (EU) 2015/1866 was explained as completing the legal landscape on registered collections in the EU in that it defines which information needs to be put on the register, the rules concerning application and provides guidance for member states concerning possible ways of verifying collections. It was remarked that the ABS Regulation provides an important incentive for users of genetic resources to obtain genetic resources from registered sources, specifically that "the user is considered to have exercised due diligence as regards the seeking of information as far as resources from (the relevant, registered part of) that collection are concerned" and that "the obligation to supply the genetic resources together with all the relevant information rests with the holder of the registered collection". However, the incentive for collections to become registered is not as strong. It was noted that there is limited interest among collections in becoming registered and many are still carrying out business analyses of the potential effects of registration. The importance of interpreting and implementing the ABS Regulation in a harmonised way throughout the EU was noted.

9. Towards a Registration Process: Use Cases, Approaches, Tools and Problems

DUNJA MARTIN started this session with use cases in which the scope of the EU ABS Regulation and the resulting due diligence responsibilities were considered. A detailed workflow of the related decision-making process was shown. The responsibility of collections in balancing the interests and obligations of all involved players was then illustrated. DAGMAR FRITZE continued with general and sector / domain specific ABS models, guidelines and tools and the relevance of federations and associations for the ABS related work done by collections. The complexity of collection work was elucidated, including the highly regulated areas of access to, distribution of and use of genetic resources. The need for cooperation and coordination among the involved institutions as well as the need for sharing of experiences was highlighted. The design of standardised conditions for the deposit or acquisition of genetic resources as well as for their handling and supply, could be a basis for a confidence-building system to facilitate access and exchange. Voluntary agreements of more recently formed associations such as the Consortium of European Taxonomic Facilities (CETAF), of funding agencies and bioindustries were explained. The long tradition of cooperation among microbial service collections on the global (World Federation for Culture Collections – WFCC) and regional levels was noted, with Europe being highlighted in more depth (European Culture Collections' Organisation – ECCO). Details of the WFCC Guidelines, the ECCO Core Material Transfer Agreement (MTA) for the Supply of Cultures and other European projects and their relevance for ABS were described. Challenges and problems arising out of the ABS regulations were pointed out and some possible approaches to solutions addressed. Finally, DUNJA MARTIN explained the capacities expected of registered collections. A detailed matrix of requirements, tools and possible impacts of registration was displayed. Aspects such as accession conformity and due diligence obligations were highlighted and a detailed overview of the impact of registration for collections was provided. Additionally, a suggested step by step approach towards the registration for both collections and CNAs was outlined.

10. Working Groups

In short breakout sessions, a number of model cases of activities and processes related to genetic resources from the daily work at microbial culture collections were presented and discussed. These were selected to highlight the three main situations of work with genetic resources at collections: (1) the entry of genetic resources into the collection (2) the internal processing of genetic resources (3) the leaving of / supply of genetic resources from the collection. The aim was to discuss these issues and come to conclusions as to whether the activities fell under the scope of the Regulation (EU) No 511/2014. For those cases falling within the scope of the EU ABS Regulation, further discussion took place regarding the due diligence consequences for the collection and/or other players and what would be expected from them.

11. Presentation of a German Technical Analysis of Implementation Options for Collections and their Users

DUNJA MARTIN provided a short description of the Microbial Resource Research Infrastructure (MIRRI), their members and membership criteria as well as their ABS policy. The MIRRI Best Practice Manual on Access and Benefit Sharing was used as a starting point for the presented technical analysis. The document was analysed to reveal the extent to which the needs of collections, academia, users and legislators (on the EU level and nationally) were met under the present conditions. In this gap analysis, other collection guidelines were also included in order to complete the picture, to be able to develop options for collections and their users and to identify presently given limitations in the Manual from the viewpoint of other domains and collection types. DAGMAR FRITZE presented the draft technical study. The study resulted in a concept that can serve as guidance, offering instructions to support collections and their users. At the same time, this study was envisioned to support the CNAs. In the draft document, some background information is provided on the typology of collections and their users, as well as the scope of Regulation (EU) No 511/2014. To help with the necessary interpretation of collection activities and whether they are within the scope of the regulation, related excerpts from the EU ABS Regulation and from the European Commission Guidance Document (2016/C 313/01) are included. Typical use cases of different types of work with genetic resources are described in the analysis together with an interpretation of whether these are within scope and the related aspects of due diligence. The main body of text provides detailed descriptions of the daily activities of a collection and the relevance of ABS. The annexes include detailed flow diagrams that visualise the complete life-cycle of genetic resources. It was explained that the document is structured in such a way that it can be expanded to apply to collections in other domains and with other types of genetic resources. DUNJA MARTIN then described the aspect of a value chain for genetic resources as a further reason for the study. For scientists working with genetic resources, their value increases once they have been processed and preserved in a collection. However, a prerequisite for this added value is the availability of information and documentation at each stage. To prove compliance with the legal requirements that apply to genetic resources, a collection will have to compile all relevant information at the time of deposit, preservation and supply of the genetic resource. Information and documentation may be partly public (Prior Informed Consent – PIC, Mutually Agreed Terms – MAT, Material Transfer Agreement – MTA) and partly confidential (laboratory and customer statistics), meaning disclosure will be subject to data privacy protection. However, all information will have to be made available for the purpose of compliance checks by national / legal authorities. Next, DAGMAR FRITZE ad-

dressed the relationship of the technical analysis to the EU sectoral Guidance Documents. While the EU Guidance Documents focus on utilisation of genetic resources in the sense of Regulation (EU) No 511/2014, the draft technical analysis presented here focusses on access to genetic resources before use. Additionally, it is strongly oriented towards providing practical advice and instructions for activities of relevance to ABS. Then, the various existing and emerging challenges for collections were highlighted. It was explained that with many collections, the scientific and legal compliance regimes already result in shortage of equipment, infrastructure and personnel. With the additional ABS regulations, collections fear that compliance may result in overwhelming administrative duties and ever more constraints on their human resources and finances. An additional challenge is posed by having PIC and MAT which are sometimes too restrictive and by having uninformed depositors. The potential negative consequences of these challenges were explained. Possible approaches were presented to find solutions for these challenges, including involving all stakeholders in dialogues and education, awareness-raising and creating incentives to relieve collections of the heavy burden of compliance and to support them on their way to the central and special role as registered collections as foreseen by Regulation (EU) No 511/2014.

Final Session: The Way Forward

At the final session, all participants were offered the opportunity to give feedback on the meeting and to make suggestions about whether further meetings should be held and what topics should be covered. The participants took this opportunity to thank the organizer for the meeting. The high quality of the presentations and the discussions was highlighted. Participants made many suggestions regarding possible topics. Some participants expressed the need to revisit the similar topics again at the next CNA meeting as the CNAs will have made more progress by that time and will have much more experience to share. However, exactly which topics will be discussed in future and whether new topics would be included on the agenda was not decided.

1. State of Play

Results of COP-MOP2 Relevant for Implementation of the Nagoya Protocol in the EU and the Work of the Competent National Authorities

Alicja Kozlowska

European Commission

This presentation reflected briefly on the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP2), which took place from 2-17 December 2016 in Cancún, Mexico, and the relevance of the decisions taken by COP-MOP2 for the work of the competent national authorities in the EU.

It was the first time that concurrent meetings were organized for the CBD (COP13), the Cartagena Protocol on Biosafety (COP-MOP8) and the Nagoya Protocol (COP-MOP2). The organization of the meetings in this way facilitated discussion on cross-cutting issues, such as the budget, financial mechanisms, subsidiary bodies etc. and it also substantially helped with the handling of overlapping issues, such as synthetic biology and digital sequence information. COP-MOP2 took 14 decisions, most of which were concerned with institutional aspects underpinning the implementation of the Nagoya Protocol, for example, on progress towards achievement of Aichi Target 16, the ABS Clearing-House, the Compliance Committee, assessment and review of the effectiveness of the Protocol, capacity-building and awareness-raising. COP-MOP2 also dealt with some more controversial issues which touch upon the scope of the Protocol (NP. 2/14 and the related CBD decision XIII/16 on digital sequence information, NP. 10/14 on the global multilateral benefit sharing mechanism and criteria for the recognition of "specialized international ABS instruments").

Some of the decisions taken by COP-MOP2 have direct relevance for the work of the competent national authorities in the EU. Decision NP. 2/1 on progress towards achievement of Aichi Target 16 calls on the Parties to strengthen their efforts to put appropriate institutional structures in place for the implementation of the Protocol. In the EU, not all member states have designated a competent national authority which will be responsible for the implementation of the EU ABS Regulation, meaning that not all appropriate structures are in place and additional efforts in the EU are needed. Decision NP. 2/2 on the ABS Clearing-House calls on the Parties (and non-Parties) to place all relevant information on the ABS Clearing-House, such as access laws, permits, checkpoints and checkpoint communiques. Any information that has not yet been published about checkpoints, competent national authorities etc. as well as any due diligence declarations already received by competent national authorities should be put on the ABS Clearing-House. Decision NP. 2/4 on the assessment and review of the Protocol is also relevant for the competent national authorities as any assessment will be built upon the national interim reports that are due by 1 November 2017. Decisions NP. 2/8 on capacity-building and NP. 2/9 on awareness-raising are also pertinent as capacity-building and awareness-raising are also key challenges in the EU.

During COP-MOP2, those issues not resolved during the negotiation of the Protocol re-emerged. Thus, we saw the temporal scope of the Protocol featuring heavily during discussions on the global multilateral benefit sharing mechanism (NP. 10/14). Decision NP. 2/14 on digital sequence information (DSI) is a reflection on the speed of technological developments in recent years and also touches upon unresolved issues relating to the material scope of the

Protocol. The relevant decisions taken by COP13 and COP-MOP2 have established a process to look at this issue further. In the longer term, this may have relevance for the competent national authorities in the EU, with future decisions on DSI potentially impacting on the scope of application of the Protocol.

Finally, it was noted that there is a need to better communicate the efforts already made in the EU to implement the Protocol.

Discussion

In the discussion, the main focus was on the issue of DSI, although it was acknowledged that other outstanding issues need to be considered, including the criteria for specialized instruments and the global mechanism. So far, no substantive decision has been made about DSI. Only a decision has been made on how to proceed with the issue. It was noted that information gathering is needed so that a clear and informed decision can be made and an EU submission can be prepared. From the discussion, it became clear that the issue of DSI requires thorough consideration. Several participants noted the value of consulting industry and other stakeholders about the DSI issue as well as keeping them up to date on the outcomes of the COP-MOP, the CNA meeting etc. During the discussion, it was suggested that the member states should consult with stakeholders and take their views into account, although the position communicated to the European Commission ultimately reflects the views of the member states themselves.

The potential use and commercialization of pre-Nagoya Protocol genetic resources in the European Union in the absence of PIC and MAT was also raised. Norway's submission on the creation of a voluntary mechanism for such situations was referred to. However, it was suggested that the establishment of such a mechanism may involve the investment of large amounts of money with few benefits ultimately flowing to the provider countries.

2. Development of Control Plans (Structure, Content etc.)

Development of Control Plans in Germany

Thomas Greiber

Federal Agency for Nature Conservation, Germany

According to Article 9.1 of the Regulation (EU) No 511/2014 (hereafter referred to as the "Basic Regulation"), each EU member state is obliged to carry out checks through its competent national authority/ies in order to verify whether users of genetic resources are in compliance with their obligations to exercise due diligence (Article 4 of the Basic Regulation) and to file due diligence declarations (Article 7 of the Basic Regulation). To implement this, the competent national authorities in EU member states have to develop so called control plans which need to be:

- periodically reviewed,
- risk-based (Article 9.3 (a) of the Basic Regulation), and
- distinguished from situations where more concrete information on non-compliance is available (see Article 9.3 (b) of the Basic Regulation).

It could be argued that these risk-based control plans will become the "regular" trigger of compliance checks, while substantiated concerns raised by provider states or other third parties (Article 9.3 (b)), such as NGOs or competing user institutions, might represent a more "exceptional" scenario for checks, as the relevant information will be provided or collected in an ad hoc manner.

The question therefore arises as to what could or should be the content of the risk-based control plans. Neither the Basic Regulation nor the Implementing Regulation (EU) 2015/1866 or the EU Guidance Documents to Regulation (EU) No 511/2014 provide any indications in this regard. Below, a possible structure for these plans will be presented together with a brief explanation of the proposed content.

Legal Basis

In the first section of the control plan, the legal basis and objective of the plan could be stated in order to introduce the subject matter at hand, including:

- the Nagoya Protocol,
- the Basic Regulation,
- applicable national implementing legislation, and
- the principles of access and benefit sharing in general.

Such explanations will serve as an introduction and help to provide the necessary background and to build the case for the following sections.

Institutional responsibilities could also be clarified upfront, i.e. the competent authority/ies in the particular country, which is / are designated by the EU member state in accordance with Article 6.1 of the Basic Regulation, could be identified.

Furthermore, according to Article 9.2 of the Basic Regulation, compliance checks need to fulfil certain criteria. EU member states only fully meet their obligations under Article 9.1, if their compliance checks are:

- effective,
- proportionate, and
- dissuasive.

These terms are not defined anywhere in the EU regulations. Therefore, they could be concretised and an explanation could also be provided on how and why these requirements are met.

Risk-based Approach

In the following section, the concept of risk-based approaches could be introduced and explained in a more general sense. In this context, it could be argued that the basic objectives of risk-based controls are to:

- ensure more frequent controls of high risk users than of low risk users, and
- avoid purely random compliance checks.

Against this background, a description could be provided of what kind of approach is proposed for the specific control plan. One option in this regard could be to adopt a risk-based approach comprising two pillars:

- Sector specific risk assessments – analysing the risk of non-compliance in the different sectors based on e.g. awareness levels, performance etc. of all users in a particular sector.
- User specific risk assessments – evaluating a set of risk criteria which can be applied to individual users.

To conduct the assessments, however, a certain amount of groundwork will be necessary, including:

- determination of the related risk levels – deciding whether a two-level assessment “low-high”, a three-level assessment “low-medium-high”, or other risk levels will be applied,
- identification and definition of the sectors (e.g. in line with the differentiations made in the seven EU sectoral Guidance Documents), and
- classification of the users – assigning each user to one or more user sectors.

Risk Analysis

After applying the general risk-based approach described above, a risk analysis could then be done. This risk analysis would be the core of the control plan and provide a systematic process which makes complex relations regarding the utilization of genetic resources and associated traditional knowledge transparent, identifies existing knowledge gaps and uncertainties in view of e.g. sector specific research and development activities, and evaluates the relevant risks.

However, before a risk analysis can be conducted, it is necessary to

- identify concrete risks of non-compliance (if possible),

- evaluate and adapt (if needed) given risk factors based on past experiences and new Information,
- determine the individual risk factors to be applied in the sector specific and user specific risk assessments during the upcoming control period, and
- explain and justify each risk factor in the concrete context.

Control Plan

The actual details of the checks need to be rolled out at the very end of the control plan in order to specify the way forward. Such details would include specification of:

- the number of checks to undertake in total in the given control period (e.g. 100 checks),
- the percentage of compliance checks for each risk level (e.g. 70 % high risk, 10 % medium risk, 10 % low risk, 10 % random),
- the distribution of compliance checks by specific sector, and
- the selection of users within each sector based on individual risk factors and / or as follow-up checks.

Finally, statistical data could be provided, such as the percentage of users checked based on the total number of potential users within the country. It might be important to document these figures in order to determine whether the compliance checks undertaken within a specific control period can be considered effective, proportionate and dissuasive as foreseen by Article 9.3 of the Basic Regulation.

However, it is important to note that there is not one single way to develop a risk-based control plan. Its specific structure and concrete content are not defined in the Basic or Implementing Regulations. Furthermore, while risk-based control plans also need to be developed in other contexts[4], the approaches taken for the implementation of other regulations cannot be simply copied but need to be adapted to the specific context of the Nagoya Protocol, the issue of access and benefit sharing and the utilization of genetic resources and associated traditional knowledge.

Discussion

In the discussion, it was generally acknowledged that most CNAs have limited resources to devote to the compliance checks. The lack of human resources could potentially limit the number of checks conducted each year to just a small percentage of users. The question was then raised as to whether this would be sufficient. The point was made that the risk-based approach to compliance checks, which is required by the ABS Regulation, does not demand that CNAs check all users. It was suggested that some users and sectors will potentially self-regulate and comply whereas others will not and therefore, compliance checks should focus on those non-complying users or sectors.

The need for a feasible and pragmatic approach was highlighted and therefore a step-wise

[4] See e.g. Regulation (EU) No 995/2010 laying down the obligations of operators who place timber and timber products on the market as well as Regulation (EU) No 2017/821 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas.

approach was suggested, in which on-the-spot checks would form the last step. One representative suggested that the CNAs have the discretion to choose whether to conduct on-the-spot checks or not, with the ABS Regulation stating only these checks “can” be conducted and not that they “must” or “shall” be conducted. On this basis, it was argued that it would be sufficient for CNAs to only check documentation in order to fulfil their obligations.

The issue of CNAs investigating substantiated allegations of non-compliance was also raised. One representative suggested that CNAs have some discretion in terms of what they investigate because the CNAs have to decide what is a substantiated allegation and what is not. Another representative suggested that some commercial actors could potentially make allegations of non-compliance against their commercial competitors. The possibility of this happening is something which most CNAs had not considered. However, the argument was also made that many users of genetic resources will be unsure of their own compliance status and therefore would be unlikely to make allegations against others.

The discussion then turned to experience gained from the implementation of the EU Timber Regulation. It was suggested that this experience could be useful for ABS compliance but that it would be necessary to keep in mind the differences between the regulations and to identify those aspects of compliance which are really transferable. Experience from the implementation of the Timber Regulation indicates that some companies take a very cooperative approach with regulatory authorities because this is thought to reduce the risk of being checked.

Development of Control Plans: Approaches and Experiences in the United Kingdom

Katie Beckett

Department for Business, Energy and Industrial Strategy

A control plan is a documented description of procedures, checks or assigned activities that are necessary to verify compliance, and in the context of the workshop, compliance with the EU ABS Regulation. A control plan, also referred to as an enforcement strategy/approach, should be risk-based and proportionate, ensuring that the regulator operates in a consistent and transparent manner, while being accountable for actions taken and methods employed. In the UK, Regulatory Delivery has recently published updated enforcement policies at an organisational level and it is from this overarching framework that the ABS control plan will be developed.

When conducting a risk-based analysis of regulated entities, Regulatory Delivery takes the hazard and the likelihood of non-compliance into consideration. The level of hazard will generally be determined by the nature of the harm it may cause, while the likelihood of non-compliance can be based on factors such as experience, complexity of compliance, market drivers and the level of awareness. For example, a multi-national pharmaceutical company may be considered to have a high hazard factor (non-compliance could cause significant harm) but a low likelihood of non-compliance (they have significant capacity to put the right measures in place; regulatory / legal / scientific teams with the right training in place). Different sectors, sub-sectors and users can then be plotted on a chart to indicate those considered to be high risk (high hazard and high likelihood) and those with a lower risk profile. This method can be used to identify the priority areas and inform the development of enforcement programmes.

In the UK, Regulatory Delivery has the authority to enforce the EU ABS Regulation through the UK Statutory Instrument, The Nagoya Protocol (Compliance) Regulations 2015. The Statutory Instrument lays out the civil and criminal sanctions that are available for cases of ABS non-compliance, and part of the role of the control plan is to ensure that these sanctions are applied in a proportionate manner. It is also important that a control plan has sufficient flexibility within it to deal with unexpected and potentially high priority allegations that may be received. Under current processes, Regulatory Delivery has procedures in place for the receipt and processing of allegations.

In the final slide of the presentation, ideas were presented on the content of an enforcement visit, and the topic areas to be discussed with the regulated entity. This, for example, could include discussions around their understanding of the legislation, any policies they may have in place, guidance and training for staff, and a review of activities that may be considered within scope. Where genetic resources have been utilised, Regulatory Delivery would be interested in evidence of due diligence having been exercised, along with a record of any decision-making process and supporting justifications.

Discussion

In the discussion, it was noted that the CNAs are faced with the challenge of identifying users and making those users aware of their obligations under the EU ABS Regulation. The gen-

eral impression among the CNAs seems to be that many users lack awareness of their obligations. However, experience gathered by CNAs so far suggests that there is a general willingness amongst users to comply with the regulations, if they know what is expected of them.

The discussion then addressed awareness-raising, which has been a major activity by many of the CNAs so far. It was acknowledged that due to the sheer number of potential users that it is virtually impossible to communicate directly with all of them. Workshops conducted with umbrella organizations has proved to be an effective way of ensuring that information potentially filters down to users at all levels. It was noted that conversations held by CNAs with umbrella organizations and users were useful for getting information about the various sectors, building up understanding of user activities and understanding potential compliance issues.

It was noted that some users or potential users may be reluctant to ask CNAs questions for fear of being targeted for compliance checks. Participants noted the challenge of communicating that it is not only the role of the CNAs to conduct checks but also to provide assistance to users. One representative noted that taking a supportive, open-door approach to users, where questions about compliance requirements were not used as a trigger for compliance checks, promotes good relations with users.

The suggestion was also made that reporting by compliance authorities on the implementation of regulations increases transparency and awareness within industry about compliance measures. Experience of implementing other regulations has shown that this type of reporting can improve relations between authorities and industry actors and can also help industry with their own compliance.

The issue of compliance by universities was also raised during the discussion. It was noted that universities may find compliance particularly challenging as these institutions are not always informed about the activities of all the researchers and students on campus. One representative noted that some universities are already putting systems in place to address compliance with the ABS Regulation whereas other universities have never heard of the Nagoya Protocol. It was proposed that similar systems could be put in place in all universities in order to ensure compliance with the regulations and therefore, an online forum or platform would be useful for facilitating exchange of information, experiences and tools between universities, so that the duplication of work can be avoided.

Development of Control Plans in Belgium

Ludo Holsbeek

Flemish Government, Department of Environment, Nature and Energy

The implementation of the Nagoya Protocol and the EU ABS Regulation suffered some delay in Belgium as a result of discussions on the distribution of competences between the federal and regional levels. However, the Belgian inter-ministerial platform eventually reached an agreement on the different responsibilities. Access-rules on land will be dealt with by the regional authorities, whereas access to marine samples fall within the competence of the federal environmental services. Access to collections is dealt with at the regional level, with the exception of the five federal collections, which will be dealt with at the national level. All due diligence declarations relating to research and development (R&D) will be received by the regional authorities, which will also organize the controls and enforcement of the users' PIC and MAT obligations. A single Belgian web portal will bet set up to inform users of incoming or outgoing samples. The intra-Belgian coordination will meet on a regular basis to coordinate efforts and fulfill reporting duties.

In terms of access to samples for R&D and the conditions of use, the Flanders region has already decided that access to its genetic resources under the Nagoya Protocol is free. Evidently, users will have to comply with regional nature and species protection laws when sampling protected plant and animal species or when sampling in protected areas. The Wallonia and Brussels regions still have to decide on access rules and possible conditions for use of genetic resources. The same applies to marine samples, where the federal government will decide on the possibility of imposing PIC and MAT obligations. Whether PIC and MAT will apply to batches of samples or might be subjected to "light" MAT with only the duty to inform the government of the outcome of R&D will be decided shortly. Also in Wallonia, Brussels and areas subject to federal jurisdiction, all existing nature and species protection laws and sampling rules will continue to apply.

Sectoral meetings with stakeholders and academic institutions are ongoing. It is already clear that users have great difficulty with getting in contact with the competent national authorities of provider countries in order to get information on PIC and MAT obligations. There is also a major demand for legal certainty, especially with regard to the use of the ABS Clearing-House. If a provider country does not state the relevant legal obligations on the ABS Clearing-House, it will be impossible for users to comply with due their diligence obligations, or for that matter, for authorities to organize controls. Stakeholders are urging the Belgian authorities to take up this issue at the European and Protocol level.

As of March 2017, no on-site controls had been carried out. Each of the competent authorities still has to compose lists of possible users and to develop risk-based control schemes.

Discussion

During the discussion, it became apparent that there is some uncertainty about the scope of the controls required by the EU ABS Regulation. One suggestion was made that the CNA should check the MAT. A theoretical example was provided in which commercial use of genetic resources is taking place but the MAT explicitly prohibits this. This would be a clear breach of the MAT and it was suggested that the provider country could be notified by the

CNA. The alternative interpretation suggested was that CNAs do not check for compliance with MAT but only whether MAT has been established. This led to further questions about what happens if there is no MAT e.g. in the case of biopiracy. The discussion then focused on the ambiguity of the regulation in terms of imposing sanctions on users for the failure to obtain MAT or for non-compliance with MAT. It was put forward that it is possible to impose criminal sanctions e.g. for a major breach of MAT. However, it was also argued that CNAs are not responsible for enforcing the contractual obligations in MAT. Enforcement of those obligations would fall to the parties to the contract and would be pursued in the civil courts by those parties. Finally, it was noted that Article 9(4)(c) of the EU ABS Regulation is very broad and it is not clear how non-compliance would be sanctioned.

3. Identification of Users and Data Management

Identification of Users: Experiences from the United Kingdom

Katie Beckett

Department for Business, Energy and Industrial Strategy

In preliminary assessments and through direct engagement with users of genetic resources from a range of sectors and sub-sectors, it is apparent that there are different categories of users. There are those that are aware of the ABS legislation and who want to comply, those who are aware but would rather be unaware, and those who are genuinely unaware of the EU Regulation, and perhaps even of ABS more broadly. Regulatory Delivery has been working across the UK to identify the user groups that are active in R&D on genetic resources. This has been achieved through awareness-raising activities, which often lead on to subsequent user group engagements and highlights relevant organisations and activities. Regulatory Delivery has also actively published articles in a range of press and media channels including trade magazines, blogs and through social media. The ABS Clearing-House has an important role to play in the identification of users, particularly through the application of Internationally Recognized Certificates of Compliance (IRCCs) which highlight when a new user has accessed a genetic resource from a Party to the Protocol. The ABS Clearing-House also provides an opportunity for information sharing between provider and user countries which can support the identification of users of genetic resources. Provider and user countries should be encouraged to share this information to support implementation. Likewise, the sharing of information between EU member states is another important tool in the identification of users and user groups. It is quite possible that there will be users who are active in more than one member state and more than one Competent National Authority may have applicable obligations in regard to compliance checks.

The Department for Environment, Food and Rural Affairs (Defra) previously undertook a study (conducted by One World Analytics) to develop a UK company index, identifying all those companies within the UK that have filed a patent which makes reference to a genetic resource. The work was based on a review of UK international patent activity and subsequently linked the intellectual property (IP) information to company websites and the UK registry of companies “Companies House”. These potential users of genetic resources have also been mapped across the UK and this is now positioned as a tool which can be used by Regulatory Delivery in its enforcement activities. It is, however, important to note that the information included in the first data collection can quickly become out of date, as contact information and company names change etc. It is also worth noting that not all the companies identified will be in scope of the EU ABS Regulation and that a deeper review of companies should be undertaken to provide a basis on which to approach them. The database is currently under review where any critical updates will be identified and addressed.

Other methods to be employed in the identification of users include the development of project approaches, where topics such as sector, sub-sector, ingredient category or geographic location are selected and focus is given to that user group area for a defined period (or a defined number of companies / organisations). This is an approach that is used by the EU Timber Regulation, providing an opportunity to learn from colleagues within the team. Phytosanitary certificates have been identified as a potential source of information for the identification of those entities importing plant material from outside the EU. In this regard,

Regulatory Delivery could partner with organisations responsible within the UK for overseeing plant and animal imports including the Animal and Plant Health Agency (APHA) as well as Plant Health Inspectors within the UK. A final method for the identification of users will likely be through allegations received, whether from other active companies (possibly competitors), NGOs or other interested parties. Regulatory Delivery has processes in place to review and respond to such allegations as and when they are received.

Discussion

In the discussion, the challenges associated with data management were highlighted. Although some user studies have already been conducted, a major issue is that the data becomes outdated very quickly. Particularly data relating to names, addresses etc. change quickly, making it extremely difficult to find users at a later point in time. It was suggested that there needs to be a rolling update of this data but this is regarded as being a major challenge for CNAs. The need to manage this data in such a way that they are consistent and useful was also highlighted. One representative suggested that user databases could also be extended to reflect whether a person or institute is a user of genetic resources, what type of engagement the person or institute has already had with the CNA etc.

The discussion then turned to the various databases, which may have information relevant for ABS compliance and identifying users. A number of issues relating to access to these databases were raised. Although databases may exist, e.g. which relate to the import of certain species for research purposes, data protection laws may prevent access to this information. Experience from different member states indicates that authorities cannot necessarily access information held by other government authorities, e.g. customs. It was pointed out that even if information can be accessed, there may still be questions relating to personal liability if the information is used or misused.

The relevance of all databases for ABS compliance is also not yet clear. It was noted that information is often available on who receives research funding at either the EU or national level. However, it does not mean that utilization of genetic resources takes place within the meaning of the regulations just because research is conducted. Patent databases were also mentioned. These databases may be accessible but it was noted that they may fail to capture certain users e.g. researchers doing basic research who do not file a patent. Furthermore, it is not always clear from a patent whether actual use within the meaning of the EU ABS Regulation took place. Finally, it was noted that some patents refer to genetic resources but no research was conducted on the genetic resource.

Identification and Evaluation of Potential Users of Genetic Resources

Sebastian Gardt

Global Nature Fund, Bonn

Dr. Elke Zippel

Botanical Garden and Botanical Museum Berlin – Dahlem (University of Berlin)

One of the great challenges for the European Competent National Authorities when implementing the Nagoya Protocol and the corresponding EU ABS Regulation is to get the most complete overview possible about the users of genetic resources in their respective countries. To meet this target, it is important to develop mechanisms for the identification of potential users as well as a method to estimate the likelihood that these users fall within the scope of the EU ABS Regulation. As there is a broad range of different uses of genetic resources in the various sectors and fields of the life sciences (biotechnology, pharma, cosmetic, food & beverages, biocontrol, plant and animal breeding, horticulture, research), it is difficult for outsiders to detect these uses and the users. Methods to detect users and to estimate potential use in the sense of the EU ABS Regulation should also be reproducible for non-experts, e.g. staff of the various administrations who are working on the implementation of the Nagoya Protocol and the EU Regulation.

Identification of Potential Users of Genetic Resources

1. Sources of Indications of Potential Users

The most important source of lists of users of genetic resources is the internet. However, due to the fact that the sectors are not homogenous and not all users of genetic resources are well organized in associations or business networks, it is not easy to get a complete picture of the potential users in a given sector. Therefore, we must have a narrow focus when searching for sources in the specific sectors to find the names and addresses of potential users as well as background information about them. Such sources are more or less available, such as lists and databases which have been collected and maintained by ministries and associations. In Germany, some (industrial) sectors do have well organized associations, which provide the names, addresses and some other data about their members online. In the best case, we can find databases on the web like www.biotechnology.de, which probably lists most of the companies involved in biotechnology in Germany and which includes more or less all of the contact data and short descriptions of the companies. Further sources of information are the associations in particular sectors, e.g. pharmaceutical or biology associations as well as lists of participants from national and international congresses, if available. The most important sources which we used are:

- Online company-databases of the specific sectors e.g. biotechnology, pharma, cosmetics
- Member lists of industrial and scientific associations e.g. chemical industry, plant-breeding, biocontrol
- Excellence clusters e.g. “biotech-regions“

2. Data Harvesting from Web-based Databases

The web provides data about potential users in a way which necessitates a lot of copy and paste steps to transfer all of the data manually into an Excel sheet or other database. Since manual copying of information is very time-consuming and error-prone, we decided to develop a tool to get data from big internet databases automatically. Sometimes it is possible to use collections of company names or weblinks to perform an automated macro-based web search to build up an Excel-based data source. Some of the sources mentioned above list companies or research institutes together with a good set of data including email address, telephone number, web address and even a short description of the institutions' research activities and products. If this information is well structured (e.g., www.gelbeseiten.de) and based on a special code which can be read electronically, it is possible to use such databases for compiling a user list from web sources. The relevant data about potential users can be extracted and entered into a simple Excel sheet in the preferred form and structure.

Using four different Excel tools (macros) and a self-defined input (e.g., company name), data can be extracted from existing databases on the internet. For example, if the name of a company is known, the Excel macro can be used to read the company's address, web page, telephone number etc. with just a few clicks. An existing list of company names can be filled with additional data very quickly. However, the configuration and customization of the macro may take some time and this is usually only worth doing for at least a few hundred companies. Using the macro can save a lot of time, if the database consists of more than around 250 entries.

To work with such a macro it is necessary to:

- Understand the structure of the database (HTML-code)
- Program an Excel macro (depending on the HTML-structure of the database)
- Perform "Webcrawling" in the database to get data with help of the macro (address, keywords, website etc.)
- Smooth the data manually
- Add data that could not be transferred automatically

An example of such a macro and a detailed manual on how to program it can be made available on request.

We used the internet to find companies from within each sector. The outcome is a list of about 3,800 companies and institutes in Germany.

Risk-based Approach

1. Google Scores

With the method mentioned above, potential users can be found just by looking for companies and institutions which probably belong to a certain sector, but no conclusion can be drawn about actual use of genetic resources in the first instance. To enable a risk-based approach for the control of users, it is essential to get an impression about whether a given company or institute is likely to be a user of genetic resources within the meaning of the Nagoya Protocol, i.e. genetic resources are used for research and development.

We have developed an easy google-based macro to get a first estimation of the likelihood

that a given company or institution could use genetic resources. This macro checks whether special keywords are connected with a given company and whether there are indications of the use of genetic resources. The macro calculates a value ("Google Score"), which can be regarded as an indication of the use of genetic resources (high value) or not (low value). The information provided by this method is still limited because the method is based on a simple Google search approach and can include errors and misleading information from time to time. The method cannot detect the use of genetic resources in detail and it cannot give information about whether an institution uses genetic resources in the sense of the Nagoya Protocol or the EU ABS Regulation. However, our first tests led to strong correlations between the manual estimation of use and the macro for the biotechnology, plant and animal breeding, cosmetics and biocontrol sectors.

It is important to have in mind that companies may have websites that do not contain clear information about the company profile or the web does not provide any information about a company. Such companies cannot be identified as potential users through the Google-based search, so it is important to also look closely at those companies whose Google Score does not suggest that they use genetic resources.

With the same technique, it is possible to check whether a company or institution is listed as having one or more patents in the Google Patent Search database. The Google Patent Search contains a database of over 87 million patents from 17 patent offices worldwide. We can determine whether a company has any patents registered with one of the 17 patent offices using a specific company search on the Google Patent website. If a company or institute that works with genetic resources is listed in the Google patent database, this is an indication that this company or institute conducts research and development and is probably a user of genetic resources within the meaning of the Nagoya Protocol. Our "Patent Score" can only have one of two scores. A one means that a patent has been claimed by the company, whereas a zero means either that no patent has been claimed by the company, the patent is not listed on Google patents or some error has occurred. However, the Google Patent Search cannot stand alone as a method to define potential users of genetic resources because no result (no hits) does not mean that the given company does not use genetic resources.

With the Excel macros, we can run an evaluation of hundreds of companies within a few minutes. The combination of these macro-based methods can help to quickly exclude companies which are not involved with genetic resources in any way. It therefore provides a first rough estimation as to whether a company is a potential user of genetic resources.

2. Manual Estimation of the Risk

The Google Score and the Google Patent Search provide a first impression about whether an institution works with genetic resources. However, before checking an institution, you have to go more into detail. To assess whether a company is actually using genetic resources, i.e. performing research and development, it is, of course, necessary to have a basic understanding of the Nagoya Protocol and the EU ABS Regulation. It is also essential to have basic knowledge about the concept and delimitation of genetic resources as defined by the Nagoya Protocol and recent research methods used in the life sciences and other (applied) fields which use genetic resources or their derivatives (e.g. enzymes in metallurgy) for industrial purposes.

Therefore, we are developing short sector-specific manuals including a questionnaire to es-

timate the likelihood that an institution is using genetic resources in the sense of the Nagoya Protocol. These manuals can be used by people who are not experts in the life sciences. However, it would be helpful if the person completing the questionnaire has basic scientific background knowledge.

As mentioned above, a number of companies do not reveal their precise activities on their websites. Therefore, these companies cannot be identified as potential users of genetic resources with technical methods or by non-experts. In many cases, only insiders or experts will be able to assess whether these companies use genetic resources or not. When planning controls these companies should therefore also be taken into account in addition to those companies which are likely to be using genetic resources.

Discussion

Data analysis was identified in the discussion as presenting a major challenge for the CNAs. It was noted that there are potentially thousands of users, meaning that the amount of data is impossible for individuals to analyse manually. However, the difficulties with developing a computer-based system which can accurately assess information about a person or institute and determine whether use within the meaning of the EU ABS Regulation is taking place were highlighted. It was pointed out that although a person, especially experts, can get a sense from a website, the type of work done by an institute based on their publications etc., a computer based system cannot do this. It was also noted during the discussion that tools for identifying users also have to be appropriate for people who are not necessarily experts on biotechnology or pharmaceuticals etc.

The Finnish ABS Legislation

Katileena Lohtander-Buckbee

Finnish Environment Institute, Finland

Mari Rusanen

Natural Resources Institute, Finland

The Finnish Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity (394/2016) came into force in 2016. The main aspect in the legislation is the free access of Finnish genetic resources. However, PIC and MAT must be acquired for traditional knowledge of the Sami people. The National Focal Point is the Finnish Environment Institute and the competent national authorities are the Natural Resources Institute Finland (agricultural and forest genetic resources) and the Finnish Environment Institute (all other genetic resources).

Umbrella organisations of the bio-based industry have been kept informed throughout the implementation process and a notice describing the user's obligations was sent to the directors of various research institutes. Press releases were also issued and national ABS web pages were published when the new legislation came into effect.

The Finnish legislation contains a potentially problematic section, i.e. section 5, according to which a user who imports genetic resources or traditional knowledge that are within the scope of the Nagoya Protocol shall provide notification to the competent national authority within one month of the import date. This may result in an enormous amount of notifications and consequently there is a need for a national database/register in Finland.

Discussion

It was noted in the discussion that Finland has taken a different approach to other member states by having an additional declaration which needs to be made when genetic resources are imported to Finland. Although this is not a compliance check per se, it was regarded as being a useful strategy for identifying users of genetic resources.

In addition, the challenge faced by collections in terms of getting information about which provider countries have access legislation was raised. It was noted that access and benefit sharing legislation should be on the ABS Clearing-House. However, the fact that information on the ABS Clearing-House is sometimes incomplete or inaccessible due to language barriers was pointed out. Due to these present limitations, it was acknowledged that it may not be possible for users of genetic resources to rely on the information provided in the ABS Clearing-House at present.

4. “Risk-based” Approaches and Criteria

Suggestions for the Development of Risk-based Approaches

Thomas Greiber

Federal Agency for Nature Conservation, Germany

Articles 9.1 and 9.3 (a) of the Regulation (EU) No 511/2014 (hereafter referred to as the “Basic Regulation”) oblige the competent national authorities of EU member states to undertake checks on user compliance in accordance with periodically reviewed plans, using a so-called risk-based approach. Neither the Basic Regulation nor the Implementing Regulation (EU) 2015/1866 further define the term “risk-based approach” or explain what it may imply. Nevertheless, the following general observations can be made, which may help to better understand and frame such approaches:

- Compliance plans and user checks and therefore also risk-based approaches need to focus on compliance of users with their due diligence obligations under Article 4.1 as well as Articles 7.1 and 7.2 of the Basic Regulation.
- The requirement to develop and apply risk-based approaches indicates that the competent national authority/ies of EU member states are not expected to check all users within their country. Most likely, this would also be impossible given the limited (human and financial) resources of the EU competent national authorities on the one hand and the often high numbers of potential users of genetic resources on the other hand.
- Instead, through the development of risk-based approaches, a selection is supposed to be made in order to concentrate specifically on those cases where a greater danger of non-compliance is foreseen.
- Consequently, a risk-based approach is meant to be an instrument to concentrate on particular users and to prioritize resources.

It is important to note that there is not one single risk-based approach or one way to develop it. Instead, different paths may be followed. Below, one suggestion will be presented and further explained, noting that it should be read only as a theoretical concept.

Development of Risk-based Approaches

So far, there has been no experience with compliance checks and the development and application of risk-based approaches in the context of the Nagoya Protocol, access and benefit sharing (ABS) or the Basic Regulation. Furthermore, there is no specific information available about which types of uses, individual users and / or user sectors may present a higher or lower risk of non-compliance with the due diligence obligations, and how the risk of non-compliance could be assessed.

Therefore, reference points for risk-based compliance assessments as well as risk factors basically have to be developed from scratch, starting with their theoretical development as a first step. In the second step, risk-based approaches and risk factors may then be tested in practice. Only in the third and last step will ongoing adaptation and specification of the reference points and risk factors be possible. With each subsequent series of checks, more data will be available about the sectors, users and uses together with the outcomes and experi-

ences of the checks themselves. This information can then be used to further assess and adapt the plans as well as their reference points and risk factors.

Risk-based Assessments

There are two different reference points for risk-based compliance assessments, which could be applied separately or in combination.

- Sector specific assessment

A risk assessment could focus on the different sectors and their respective risks of non-compliance. First of all, this would require the user sectors to be distinguished from one another. The following 8 sectors are often referred to: pharmaceutical, cosmetics, food and feed, animal breeding, plant breeding, biotechnology, biocontrol and bio-stimulants and basic research.

Furthermore, individual users would need to be assigned to one or more of these sectors. This could be one of the tasks to be undertaken by the competent national authority/ies when developing a database of potential users. Potential users could also be asked directly, e.g. through an anonymous user questionnaire, to identify one or more sectors to which they belong according to their own judgment.

The actual assessment of each sector could start based on the results of an anonymous user questionnaire, through which knowledge and awareness of the different sectors could be "tested". Such an assessment would then need to be continuously updated and adapted based on analysis of the outcomes of future compliance checks.

- User specific assessment

A risk assessment could also focus on the user and its individual risk of non-compliance. For this, specific criteria and characteristics would need to be developed which might relate to compliance and non-compliance. Examples could include: performance of the user in previous compliance checks; existence of internal ABS policies and processes or sustainability strategies, as well as other dynamic factors which may be influenced by the user; different user-related sources of information such as due diligence declarations or reports from patent offices; estimation of seriousness of non-compliance (e.g. high impact in the case of commercialization).

Stepwise Approach to User Compliance Checks

On this basis, user compliance checks could be initiated in a stepwise manner. In the first step, the identification of potential users would take place, leading to a user database as a critical starting point.

In the second step, a general user survey could be undertaken, sending out an anonymous questionnaire to all potential users listed in the database. Questions should be selected and formulated in a way to raise ABS awareness and at the same time test ABS knowledge within the different sectors.

Only in the third step would the actual user checks start. Due to lack of risk-related information at the beginning, the first cycle of compliance checks could be based on an entirely random selection of users. Only the following control cycles would then be based on sector and / or user specific assessments, taking into account the results of the user survey and the

first round of compliance checks, but also the probability of being an actual user in the sense of the Basic Regulation.

In the first round of risk-based compliance checks, different percentages of checks could be allocated to different risk levels in order to verify the previous risk assessments, e.g. 60 % of the users to be controlled could be selected from high risk sectors, 10 % from medium risk sectors, 10 % from low risk sectors, and 20 % could be selected randomly. Within each sector, users would be identified based on specific user factors.

Discussion

The discussion began with a question about the scope of the controls, which sectors will be checked and how the checks will be conducted. For practical reasons, it was noted that Germany will take a step-wise approach to compliance, meaning that the check will start with checking documentation and be followed by on-the-spot checks if necessary. The amount of information which will be requested still needs to be clarified. It was suggested that CNAs have to strike a balance between being thorough but also efficient so that compliance does not become too burdensome on either the CNAs or the users. One representative suggested that users are already concerned about how long compliance checks could potentially take.

Lack of data for the initial risk-based checks was acknowledged to be a problem. One suggestion was to conduct some random checks in order to gain experience and information about users and then to use this data as the basis for risk-based checks in future. Without data about the users and compliance risks, it is challenging for CNAs to select users to check using a risk-based approach. The question was then raised as to whether this random approach to checks is justifiable for the first cycle of checks from the point of the view of the EU ABS Regulation.

The suggestion was made that it would also make sense to conduct the first cycle of checks within only one sector. The reason for this would be that word would spread within the sector that compliance checks are taking place, which may encourage users to take voluntary measures to ensure compliance with the regulation.

The suggestion was made that compliance within the biotechnology sector would be most important because this sector underlies many of the other sectors. Although it should not be assumed that there is non-compliance within the sector, it was acknowledged that the potential impact of non-compliance within the biotechnology could be quite high and far reaching and therefore it makes sense to check it first.

Continued awareness-raising was highlighted as being important, particularly within the feed and food sector.

Finally, a question was raised about how resources should be divided between scoping i.e. who to check, and the actual checks. At this early stage, it is not really clear how CNAs will use their resources. It was noted that as a first step, it is necessary to ensure that data about the users are complete and accurate so that users can be reached. It was noted that subsequent user studies could then provide insight into ABS awareness levels within different sectors and to also identify the needs of the users in those sectors.

Risk-based Approaches and Criteria: The UK Approach

Michael Kearney

Department for Business, Energy and Industrial Strategy

When implementing a new piece of legislation, Regulatory Delivery generally begins by engaging with businesses that are known to be compliant or businesses with a low likelihood of non-compliance, as well as any government or public-sector bodies which are within scope of the regulation. The intention is to develop our understanding of how the legislation should be applied and what "compliance" looks like in an environment where any failures can be dealt with positively. As well as building our expertise in a "safe" environment, we also ensure that the government is meetings its regulatory obligations and so avoid potentially embarrassing publicity surrounding public-sector non-compliance. By engaging positively with market leading companies, we often pick up useful information about trends within the sector and where particular risks or challenges may lie.

Once this initial cycle of low-risk enforcement visits has taken place, individual officers are usually better informed about how the legislation works and what companies can and should do in order to comply with it. We better understand the nature of business practices, the type of language used within particular sectors and this means that we can approach enforcement with greater levels of confidence and with a range of practical examples that can be used to advise those organisations that may be struggling to comply.

Whilst this approach does not deliberately delay the implementation of the legislation, focussing initially on low risk companies does allow those companies that are less well prepared more time to adjust their processes. Notwithstanding this, engaging with well-prepared or "compliant" businesses still yields worthwhile enforcement outcomes, as in most cases there is scope for businesses to improve their approach and become more compliant.

Undertaking risk-based market surveillance activities requires a degree of familiarity with the sectors concerned and an understanding of where awareness of the legislation or compliance levels may be low. In order to gain a well-informed picture of the risk landscape within which we are operating, it is useful to undertake a wide and comprehensive programme of engagement and awareness activities. By speaking to different sectors, hosting or attending seminars and undertaking other forms of outreach work, you raise awareness of the legislation but also provide a forum through which information will flow to you about the market you are regulating.

It is often the case that where a particular sector is unaware of the legislation or is opposed to it, they will tell you so directly – and challenge you. Any such challenges or negative feedback can be an indicator of a lack of compliance or meaningful engagement, both of which can inform your subsequent intervention choices. The nature of the sector concerned can also be indicative of likely compliance levels, with well represented and well organised sectors better placed to meet their regulatory obligations than fragmented and ill-informed sectors.

Throughout the engagement process, it is possible to build an impression of the complexion of the sector in terms of company size, value of commercial activities and the extent to which any available resources may be directed towards compliance activities. Likewise, you will begin to understand which sectors or sub-sectors are "structurally" challenged by the legislation, either because of the complexity of the task at hand, the nature of their activity/research,

or the commercial necessity of carrying on with an activity which is likely to be non-compliant. Do the regulations codify existing best practice or are they going to demand a complete shift in approach?

Whilst it is tempting to assume that large and well-resourced companies will be able to develop expertise that supports compliance and small companies will not have either the time or experience to enable them to comply, the picture can be more nuanced. Quite often we find that because a small company is so much more focussed in terms of the scope of its activities, and has better, closer or more longstanding relationships with suppliers, they are actually well placed to meet their obligations. Likewise, larger companies can be challenged simply by the scale of their activities and the temptation to create a systematic business-wide approach to compliance, which can lead to a lack of flexibility and disconnect between the individuals undertaking the work and those making decisions around compliance.

With limited resources available to the regulator, it is important to reflect upon what outcomes you are seeking to achieve and how best to deliver these. It is rare for any company to be fully compliant and whilst there is always a spectrum of compliance levels, there are potential benefits associated with engaging at both ends. Dealing robustly with serious, persistent or deliberate non-compliance does allow for your activity as a regulator to be highlighted and can act as a deterrent to other companies. That said, if a regulator is perceived as being too focussed on identifying and prosecuting non-compliance, you can find that companies refrain from engaging and asking for advice, that they put their heads in the sand and hope that you do not come knocking. This can have a negative impact upon overall compliance levels. Our experience is that most companies will comply if they are clear on what their obligations are – and so being seen as a progressive and approachable regulator is important.

In terms of intervention choices, it is possible to have a bigger overall impact by improving compliance slightly at a very large company than by driving big improvements at several small companies. There is no magic formula in terms of what the appropriate mix is, but it is important to be mindful of the impact of our activities and the market penetration of the organisations that you choose to visit.

A vital part of being as well informed as possible is for each member state enforcement authority to share information, best practice and ideas with its European counterparts. If a particular sector is found to be very non-compliant in one member state, this is likely to be repeated elsewhere, and the inverse is also true. Sharing experiences, coordination on interpretation of the legislation and approaches to enforcement drives consistency of implementation – which is good for us and for industry.

It is important to maintain channels through which specific information and intelligence can be transmitted – either from NGOs, individual businesses or provider countries. Our experience with timber is that the more open and positive you can be with NGOs, the more likely they will support your efforts. Where there is a lack of information or a lack of relationship, they are likely to create difficulties or challenge what you are doing. Depending on the volume of information and intelligence received, it may be necessary to develop a procedure for scrutinising information received and deciding on appropriate next steps.

We generally undertake enforcement on the basis of projects, looking at a particular sector, product type or country of supply. This allows officers to research and specialise in a particular area and then be better equipped to assess compliance in a credible manner.

Discussion

In the discussion, the idea of using company specific indicators to assess risk was raised. Such indicators would include e.g. the size of the company, the presence of accreditation, use of ISO, the presence of corporate social responsibility (CSR) strategies etc. The assumption might be made that well-run companies which have good resources and quality management processes in place are more likely to comply with the EU ABS Regulation. However, it was also argued that some caution needs to be taken when making such assumptions. Experience has shown that having such processes, standards etc. in place does not mean that they are effectively implemented and that outward appearance may be somewhat deceiving. It was acknowledged that the details of the relevant documentation need to be carefully checked to ensure that these users have actually complied with their obligations.

First Steps towards a Risk-based Approach in Denmark

Eva Juul Jensen

Agency for Water and Nature Management, Denmark

Denmark presented its initial steps towards the design of a risk-based approach. It was highlighted that the identification of users is crucial.

In that regard, it was pointed out that the EU ABS Regulation operates with different groups of users. For general awareness-raising, Article 13 of the ABS Regulation was underlined. For compliance checks, Article 7.1. and Article 7.2. were underlined.

Concerning general awareness-raising, Denmark has a stakeholder group that has existed since the beginning of 1990s when the ABS regime was negotiated. Over time, the stakeholder group has extended and the role has changed as the regulations have evolved. Now, the stakeholder group is used as a forum for updating the users from the private sector, collections and the universities about the EU ABS Regulation. It also functions as a forum for exchanging views and experiences with regard to ABS matters. In addition to that, Denmark also has an official ABS website at www.mst.dk.

Regarding the preparatory work for inspections based on a risk-based approach, it is considered to be crucial to do a survey of the users. The first user survey was conducted in 2013, before the EU ABS Regulation was adopted. For the upcoming survey of users, Denmark will identify the users of genetic resources and traditional knowledge associated with genetic resources within the different sectors identified in the EU draft sectorial Guidance Documents. Secondly, inspired by consultations with colleagues dealing with the EU Timber Regulation Denmark will give a lot of attention to continuously up-dating the register of users using other already existing registers.

The preliminary considerations about designing the risk-based approach are inspired by the EU Timber Regulation as well. In general, a risk-based approach deals with identifying the users most likely not to be complying, taking into account the impacts of not being in compliance. Denmark presented initial criteria to measure this within each of the sectors. Based on the findings, an estimation of the risk of not being in compliance was quantified. Concerning inspection plans, it is considered to build on a stepwise approach. The inspections will most likely be based on checking a few but important issues about ABS knowledge and compliance measures such as the knowledge about the ABS Regulation and establishment of internal procedures for compliance checks.

Discussion

In the discussion, it was noted that Denmark has included speed and continuity of flow of genetic resources as criteria for risk-based assessment and the question was raised about how to obtain the relevant data for this. It was suggested that this type of information can be obtained directly from stakeholders or alternatively from existing control mechanisms.

The need to check compliance within the biotechnology sector was again raised due to the potential impact of the sector.

Finally, the need for further discussion by the CNAs on potential criteria and sources of data was highlighted.

The Risk-based Approach in the Netherlands

Linda Wassink-de Ligt

Netherlands Food and Consumer Safety Authority, The Netherlands

The Netherlands: Institutional Organisation

- CNA: Ministry of Economic Affairs
- Monitoring agency: Netherlands Food and Consumer Product Safety Authority (which is part of Ministry of Economic Affairs)
- National Focal Point (NFP): Centre for Genetic Resources (which is part of the Wageningen University & Research Centre) www.absfocalpoint.nl/en/absfocalpoint.htm

Risks

To identify risks of non-compliance in the Netherlands, we considered the following criteria:

- Level of knowledge and awareness regarding the Nagoya Protocol
- The amount of genetic resources used (number of accessions)
- Origin of the genetic resources used (was the provider country a party to the Nagoya Protocol and were PIC and MAT needed?)
- Level of structure in an organisation (protocols, responsibilities, administration – the less structured organisations may present a higher risk of non-compliance)

Effects of Non-compliance

The effects of non-compliance at national level are:

- Political: Keeping in mind colonial history and past cases of biopiracy.
- Potential harm to trade interests: The Netherlands aims to be a reliable trade partner.
- Problems with access to genetic resources: The Netherlands aims to have open borders and therefore there is no access legislation.
- Potentially attracting negative campaigns from NGOs (which also affects the items mentioned above)

Risk Effect Matrix

A conceptual Risk Effect Matrix has been developed in order to prioritise inspections. The matrix helps to highlight and differentiate between the need for different activities, such as inspections with the highest priority, inspections with lower priority, inspections based on substantiated concern and awareness-raising activities. It is noted that monitoring takes place in all cases and awareness-raising is always the starting point before inspections are conducted.

How to Continue

- Setting up awareness campaigns where needed together with the NFP
- Setting up a monitoring system which provides an overview of compliance and risk factors in each sector
- Gathering more knowledge about the sectors to be inspected (specific risks, which methods are suitable for achieving compliance?)
- Consulting with other member states and working towards a uniform approach

Discussion

During the discussion, more information was provided about the capacity of the Netherlands to conduct controls. A number of inspectors have been trained so far but ABS compliance checks only form one part of the duties of these inspectors.

The issue of risk within different sectors was raised. It was suggested that provider countries are likely to see different types of sectors and users as presenting different types of risks. As such, it is likely that users will have to meet different standards in the provider countries.

Students were provided as an example of presenting a potentially high risk of non-compliance, if universities do not monitor or guide their activities. However, it was suggested that students would generally have a low impact. This assumption about impact was then questioned because the impact would depend on the student's activities and the type of project. A theoretical example was provided in which a student sequences a genetic resource and publishes the results. In that case, it was proposed that the provider country would lose control over the resource and the impact could potentially be high. A further question was raised about how students who use genetic resources without PIC or MAT and who fail to lodge a due diligence declaration at the relevant checkpoint would be dealt with. It was suggested at this stage that it is not really clear what type of measures would be taken but administrative steps would be taken first before other sanctions are imposed.

A question was raised about the Netherland's external focal point. It was noted that the external focal point brings additional expertise to ABS issues and that this arrangement functions very well.

The discussion then moved on to collections. The issue was raised that collections, which may not use resources in the sense of the regulation as they simply collect, store and redistribute the genetic resources, will nevertheless need to provide subsequent users of the genetic resources with all of the relevant documentation, even though the collection may not have any due diligence obligations. It was also pointed out that many collections are also potentially users and as a potential user, collections may also be checked for compliance.

Finally, the issue raised was about the difficulty for CNAs in terms of proving that genetic material is within the temporal scope of the Regulation.

5. Control Approaches and Processes, First Inspections

Implementation of the Regulation (EU) No 511/2014 in Slovakia

Peter Maňka

Ministry of Environment of the Slovak Republic

Basic Information

Act No. 263/2015 Col. on jurisdiction in the area of access to genetic resources and sharing of benefits arising from their utilization (hereafter "Act No. 263/2015 Col.") was enacted by the National Council of the Slovak Republic (Slovak Parliament) and entered into force on the 1st of December 2015. It implements Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (hereafter "EU Regulation"). Act No. 263/2015 Col. designates the competent national authorities and inspection authority as well as establishes the rules and sanctions applicable for violations of user obligations under the EU Regulation. It did not establish access rules.

The Preparatory Phase of our National Legislation

Prior to drafting Act No. 263/2014 Col., we analyzed the characteristics of Slovak stakeholders, the types of genetic resources they use and existing bodies and tools under other national legislation that could potentially be used for implementation purposes. A questionnaire was sent to stakeholders, who we found through various websites. Discussions were also held with representatives of other sectors. Together, this was used as a source of information to assist with preparation of the draft implementing Act.

Based on analysis of the information obtained through the questionnaire, we found out that the typical user of genetic resources in Slovakia is a legal person from the public sector that is involved in taxonomic or other fundamental research and uses genetic resources from Slovakia or from existing collections of genetic resources that are held in Slovakia or other EU member states. We did not identify any stakeholders that use genetic resources accessed from non-EU countries. We only received minimal information about the research and development (R&D) activities of stakeholders from the discussions with our partners from other sectors. There could be two reasons for this. Our partners may not have followed the activities of these stakeholders or alternatively, there was only little R&D. The Industrial Property Office of the Slovak Republic (Slovak Patent Office) only receives 3 to 4 patent applications per year that can be associated with the use of genetic resources. On this basis, we concluded that R&D by companies in Slovakia is minimal. These companies often form part of international corporations, meaning that R&D by the company often takes place in other countries, with those parts of the company based in Slovakia mainly using existing patented genetic material for production purposes and not for research.

Based on the information provided by our partners and gained through the questionnaire, it is possible to say that users of genetic resources in Slovakia predominantly come from the public sector.

Problems Encountered during the Drafting of our National Legislation

The main problem that we identified was the issue relating to the inspection bodies. The first idea was to rely on inspectorates from various sectors to conduct inspections within their designated area. This approach would have had some deficiencies, e.g. sectoral inspectorates are very specialized, not all sectors have an inspection body and the competences of various inspectorates and the level of cooperation between them appeared to be complicated. This approach would also have required the training of many inspectors in many areas.

The second idea was that all users will be checked by the Slovak Environmental Inspectorate, which is the inspection body of Ministry of Environment of the Slovak republic. This approach had some potential deficiencies. Information exchange between the Slovak Environmental Inspectorate and authorities from other sectors was identified as being essential for the functioning of the checks, because the Slovak Environmental Inspectorate only had partial information about research and development activities in other sectors, for example, in the pharmaceutical or cosmetics sectors. However, we also identified an advantage of this approach. We could use same department of the Slovak Environmental Inspectorate that conducts checks under the Cartagena Protocol on Biosafety, meaning that the inspectors already had some experience in this area and they knew some of the stakeholders.

Finally, we decided to take the second model. We have also tried to solve the problems with information flow between the Slovak Environmental Inspectorate and the authorities from other sectors. Therefore, the new legislation introduced an obligation that the checkpoints have to share information about the R&D activities of their stakeholders, which they acquire during their general activities, with the Slovak Environmental Inspectorate. These checkpoints are often authorities from other sectors and therefore fulfil roles under other legislation. Previously, they did not have any obligations to collect information about R&D activities or to share this information. Based on the information from these checkpoints and other information, plans are regularly prepared for the checks conducted by the Slovak Environmental Inspectorate, especially plans for checks of private companies.

In Slovakia, we have designated 7 checkpoints within the meaning of the Nagoya Protocol. They were established in the following areas: plant breeding, animal breeding, human pharmacy, veterinary pharmacy, biocidal products, food supplements, feed and research funding. There are also two checkpoints with special status. The first of them, the Ministry of Environment of the Slovak Republic, accepts due diligence declarations and information under the article 7(1) and 7(2) of the EU Regulation, if the other designated bodies or legal persons are not competent to receive them under Act. No. 263/2015 Col. This covers special cases where new research and development on genetic resources arise in the future or activities are simply not covered by the other competent authorities. The second special type of competent authority, referred to as “Other authorities in the area of genetic resource use”, is not a single institution but a group of institutions. This group includes research funding agencies that accept declarations under article 7(1) of the EU Regulation.

Risk of Non-compliance

Based on the information we obtained from the questionnaire, we assume that the likelihood of non-compliance in the public sector is very low because these stakeholders mainly receive funding from the government and the violation of laws would be “unimaginable” as it could lead to a restriction on future funding. Furthermore, the results are often published and inspectors can compare information about published genetic resources and their own findings,

and the penalties are too high for stakeholders from public institutions (up to 100 000 EUR). There may be more risk of non-compliance in the private sector, although this risk is probably not that much higher because only a few companies conduct research and development on genetic resources in Slovakia. According to our first experiences, private companies that are often parts of multinational corporations and have more information on EU regulation than entities in the public sector.

Plan of Checks and the First Checks

The Slovak Environmental Inspectorate prepares its plan of work in December every year and this plan is then approved by the Ministry of Environment of the Slovak Republic. Based on this plan, the inspectorate also prepares a quarterly plan of checks. These checks are based on a preventative approach, i.e. they are made regularly, or based on information that was received from the institutions that form the checkpoints (especially in the case of private companies).

During 2016, 16 legal entities were checked – 12 from the public sector and 4 from the private sector. These checks were conducted in the following areas: biotechnology (2), pharmacy (2), plant breeding (4), veterinary research (3) and fundamental research (5). No violation of the national law or the EU Regulation was recorded, mainly because the genetic resources used did not fall within the temporal scope of the regulation. The purpose of the first inspections was not only to conduct compliance checks but also to monitor the research activities of stakeholders, raise awareness and to monitor the use of genetic resources used for research and development (the stakeholders had to submit a list of genetic resources that they had used for research and development). Especially monitoring of genetic resources is essential for the next compliance checks. It can serve as tool for distinguishing those genetic resources which are within and outside the temporal scope of the regulation, i.e. to create a baseline for the next checks. It can be also an advantage for stakeholders to have official confirmation that they already had the checked genetic resources before 12 October 2014, i.e. it may provide legal certainty.

Discussion

During the discussion, some clarification was provided about the checkpoints in Slovakia. Slovakia has different institutes in different sectors which receive the due diligence declarations. Inspections, on the other hand, are carried out only by the inspectorates. It was noted that the increased cooperation with the actors in the various sectors and also the knowledge gained was a major advantage of involving these institutions as checkpoints.

The question was also raised as to why the first cycle of controls in Slovakia focused mostly on public institutions, even though the public sector was identified in the presentation as being lower risk. It was noted that conducting checks, even in low risk sectors, is useful way for establishing baselines, which could be more important at the initial stage of compliance regimes than discovering violations.

Processes for User Checks

Ellen Frederichs

Federal Agency for Nature Conservation, Germany

In order to find a reasonable balance between “proportionate, effective and dissuasive”, as stated in Article 9.2 of the Regulation (EU) No 511/2014 (hereafter referred to as the Regulation), user checks could be conducted in a stepwise process: From a written request for information at the beginning, to on-the-spot-checks if necessary, up to sanctions where infringements have been detected but could not be resolved. In this process, measures like the taking of samples, orders to stop utilization and confiscation of genetic resources might be necessary.

The written request for information, as the first step of the check, could contain a general section with the following information for the user: legal basis of the check, introduction of the agency responsible for the check, explanation of ABS and the scope of the Regulation as well as the due diligence obligations and declarations of the user. A specific section would pose questions about whether genetic resources have been used and if so, whether measures have been taken to exercise due diligence. A list of the genetic resources used with the dates they were accessed and the sources could be requested as well as the respective documentation. It is important to be aware that in many cases, not all of the utilized genetic resources can be checked, so it is important to get an overall view whether due diligence measures have been taken e.g. whether a responsible person has been appointed for ABS questions, whether an electronic system to document the genetic resources that enter and leave the institution exists, whether best practices are adhered to or whether there is cooperation with partners in other countries. The utilization of concrete genetic resources could then be checked at random.

A checklist could function as a guidance tool and help to both structure the check and directly record the results. In the development of the checklist, the CNA should be well aware of the questions that need to be posed to the user in order to allow a complete check of the due diligence obligations.

If, based on the information provided in response to the written request, it appears probable that non-compliance with the Regulation has occurred an inspection should be conducted on-the-spot. Article 9.5 of the Regulation states that users are obliged to support the checks. This must particularly apply for the on-site inspections. The German national law has therefore further elaborated this obligation to support the checks by requiring users to provide information and submit the necessary documents and samples of genetic resources, to allow the inspectors to make copies of the inspected documents and to allow them to enter property and business premises during operating hours.

The person conducting an on-site inspection should be provided with a manual, similar to the general section in the written request, with information about the legal basis of the inspection, about the rights of the inspector, the scope of the Regulation, the subject and content of the check as well as the duties and rights of the users (such as the right to refuse to provide information which would subject them to the risk of prosecution).

In addition to this manual, the inspector will also need the above-mentioned checklist or at least some kind of protocol in which he / she can directly enter the information he / she receives.

With regard to the content of the check, the inspector might find that information and / or documentation about genetic resources, which are utilized, are missing. The user might give two reasons for this. One reason may be that the user claims to be outside the scope of the Regulation. The other reason may be that he / she states to have exercised due diligence but could not get the required information.

The user does not have a duty to prove that he / she is outside the scope of the Regulation. Nevertheless, the more indications there are that the utilization is within scope or the more uncertainties there are about the legality of access and utilization, the more the user will have to do in order to show that this is not the case. Where the user claims to have exercised due diligence, but does not have the necessary documentation, he / she will have to demonstrate his / her efforts to gather the information and the reasons why the information was not available and therefore could not be obtained. If there are continued uncertainties about the legality of access and utilization, the user will have to get the necessary access permit or its equivalent and establish MAT. If not, the user will have to stop utilization of the genetic resource according to Article 4.5 of the Regulation.

During the checks, it might be necessary to impose remedial actions or to take immediate interim measures (Article 9.6 of the Regulation). This could be, for instance, the seizure of certain genetic resources or the issuance of an order to stop utilization until such time as the necessary documents can be provided.

After the check has been conducted, records of the check need to be kept for at least five years (Article 10 of the Regulation) and the outcomes of the checks will form part of the reports which are to be submitted to the Commission.

Discussion

During the discussion, the issue of due diligence in cases where the user does not know where the resource comes from was raised. It was noted that users may choose to use these genetic resources and their due diligence obligations would be fulfilled if they take all possible steps to find out where the resource comes from and if PIC and MAT are required. It was noted that users must decide whether they want to undertake this type of risk because if the user obtains more information at a later stage about the source of the genetic resource, he / she may have to discontinue use until such time as PIC and MAT are obtained.

It was noted that CNAs would be able to check whether the genetic resource being used is that which is stated in the PIC. However, it was acknowledged that a high level of expertise is needed in order to collect samples of genetic resources during on the spot checks and to verify if they are the correct ones.

The question was again raised about whether the ABS Regulation requires the CNAs to check whether MAT has been complied with. The point was raised that CNAs are not in a position to enforce MAT as they are not a party to these contracts. It was argued that if there is no PIC or MAT, CNAs are able to take further steps against the user and impose sanctions. However, the question remained open as to whether the CNAs notify the provider countries if it becomes apparent that a breach of MAT has occurred.

The issue of confidentiality of contracts was also raised and whether it is possible for CNAs to view MAT e.g. if sub-contractors are involved and the relevant contracts are confidential. The example of tax auditors was raised and it was noted that in those circumstances, even confidential contracts have to be provided to authorities so that compliance can be verified. It

was suggested that the CNAs could probably view such contracts.

The issue of potential flow of information back to provider countries about breaches was further discussed. It was suggested that Article 18 of the Nagoya Protocol might also cover this. The argument was made that if the CNA notifies the provider country of the breach, the provider country can then initiate proceedings for enforcement of contract.

First Inspections: The Experience of the Netherlands

Linda Wassink-de Ligt

Netherlands Food and Consumer Product Safety Authority, The Netherlands

Preparation of the Compliance Checks:

2014: Inventory of the target group (CGN) was created

2015: Informative visits to stakeholders were conducted

2016: Law implementing the Nagoya Protocol came into effect

Enforcement strategy was prepared

Inspectors were trained

Why Was the Plant Breeding Sector Checked First?

The plant breeding sector was chosen because:

- It is an important sector in the Netherlands.
- There is a high level of knowledge and awareness within the sector.
- There is a high level of organisation in the sector (e.g. the organisation Plantum is very active).
- Tracking and tracing is inherent to plant breeding.
- It was possible to establish good practice for inspectors without too many risks.
- The first inspections were a possibility to gain knowledge and experience, like with the EU Timber Regulation.

How Did We Select Addresses?

Plant breeders were selected using:

- Open sources (UPOV register, websites, sector organisations etc.)
- Information about whether research and development was taking place in the Netherlands
- Information about varieties other than those covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

The goal was to:

- Measure the level of compliance
- Provide assistance with compliance
- Identify difficulties and risks

Inspections were conducted by two inspectors who prepared the inspection together. They did research on the companies and found out if the company had registered varieties and when these varieties were registered. The company website was checked to find out if research and development was taking place and to find any other information about the com-

pany that could be of use, e.g. did they import plant material from Nagoya Protocol countries?

The company was first called to make an appointment. It was important to make sure that the responsible person was actually present during the visit. The inspectors asked if the company was aware of the Nagoya Protocol. If not, the company was provided with information and a further visit was planned for a future point in time so that the company had an opportunity to prepare.

Sometimes, the language spoken at the company was English so it was important to ensure that the visiting inspectors were in a position to conduct the inspection in English.

What Did We Look at?

- The first step was to determine whether there was “use” or not.
- If there was no use, then we asked if the company was prepared in case use takes place in the future (if relevant and if they are willing to collaborate).
- If use was taking place, then we found out what resources were used, how the company could demonstrate due diligence and whether a due diligence declaration had been provided where necessary.
- Questions from the sector were gathered and a Q&A for the National Focal Point was prepared.

What Did We Find?

- The sector is very motivated to comply.
- The sector is mostly well prepared with good tracking and tracing systems in place.
- Use usually involved “old” material.
- The sector has many questions about interpretation, particularly with regard to commercial varieties.
- It is difficult to get new material.

If you have any questions about the inspections or want advice, please contact me:

L.Wassink@nvwa.nl

Discussion

During the discussion, more details about the first inspections were provided. Only a very small number of the people and institutes checked during these inspections were actual users within the meaning of the EU Regulation, mainly because they fell outside the temporal scope. Despite this, many companies were willing to show the inspectors their records and internal systems. Experience from the first inspection indicates that some companies have adopted a very cautious approach to compliance, treating all material as being Nagoya relevant and therefore ensuring that all of the relevant documentation is in place e.g. even in the case of non-Nagoya provider countries.

The discussion then moved to the issue of the “cut-off point” for new genetic resources. It

became apparent that this is an open question and that there are conflicting views about this issue. Experience from inspections indicates that new varieties are treated as new genetic resources by actors in the plant breeding sector. However, it was also noted during the discussion that there is no cut-off point identified by the EU ABS Regulation, meaning that these new varieties could potentially be treated as being within scope.

6. Lessons Learned from a German Expert Study: Typologies and Mandates of Collections

Typology and Mandate of Collections

Dunja Martin

ABS Compliance & Consulting, Germany

The term “collection” seems unambiguous and refers mainly to a repository for items of a particular kind. Collections, however, can be differentiated in various ways, e.g. based on the kind of items collected, the time period of their existence, their financial sources and overall mandate. These factors determine the basic typology of collections as shown in Figure 1:

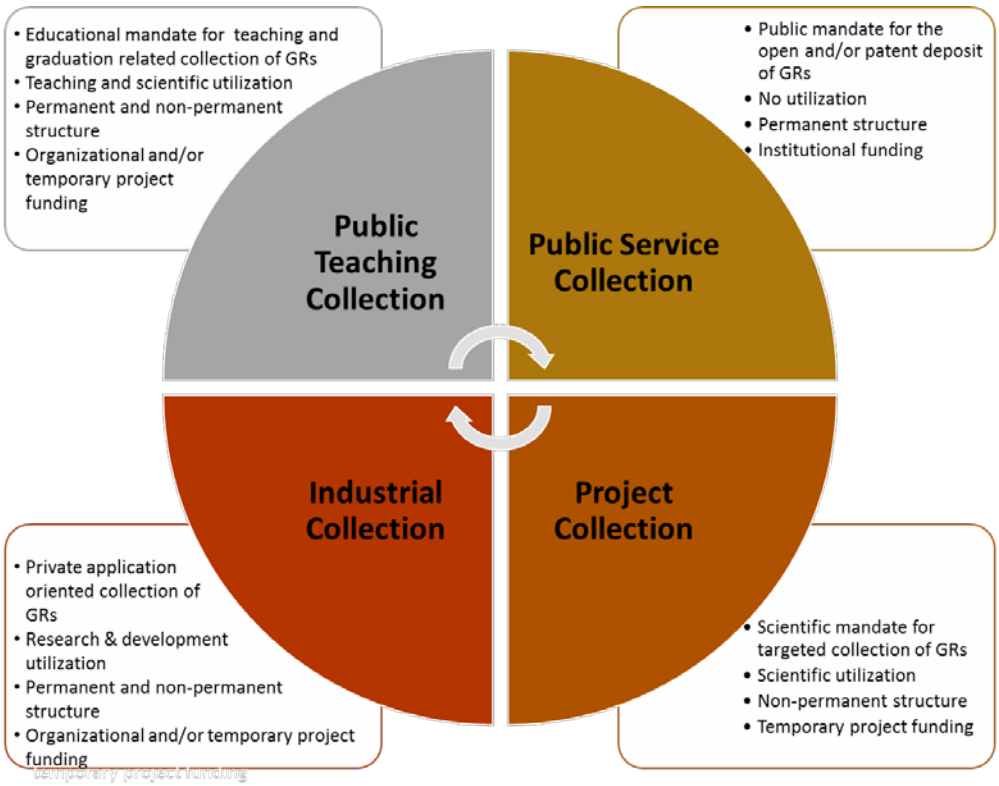

Figure 1: Typology of Collections

A more detailed description of the four different collection types is given in the *German Technical Analysis of Implementation Options for Collections and their Users - Research for the Implementation of the Nagoya Protocol and the Regulation (EU) No 511/2014.*

It was assessed that there is a smooth transition from one type of collection to another. Additionally, a collection, as an organisation, might include different types of collections. A project collection might be incorporated into a public service collection, although it remains organizationally und financially independent. A university might host a public service collection, a public teaching collection and a project collection under one institutional roof, but these collections may be independent of one another and financed from different sources.

As such, the relevance of ABS to collections and the measures taken by the different collections should be analysed. Whilst public service collections are highly visible in the ABS discussions, have high levels of ABS awareness and have put various measures in place, industrial collections are nearly invisible in the ABS context and do not make their ABS measures transparent to the public. However, these collections do have a high level of ABS awareness. Of the four types of collections, public service collections and public teaching collections are more likely to be not within the scope of the EU ABS Regulation, because normally their activities do not include utilisation. While single scopes (such as temporal or geographic scope) will in most cases apply, the cumulative applicability of the EU scopes and thus the falling under the EU ABS Regulation will most likely not occur. Project collections and industrial collections most likely fall within the scope of the EU ABS Regulation and thus will have to fulfil Due Diligence Obligations. However, public service collections are the most likely candidates for registration.

Collection Type	ABS Visibility	ABS Awareness	ABS Measures	Falling under EU ABS Regulation	Due Diligence Declaration	Registration Candidate
Service Collection	High	High	High	Less likely	No	Yes
Project Collection	Moderate / Low	Moderate / Low / None	Moderate / Low / None	More likely	Yes	? (non permanent structure)
Commercial Collection	Low / None	High	Unknown	More likely	Yes	? (strategic and economic decision)
Teaching Collection	Low	Low / None	Low / None	Less likely	No	? (do not feel being addressed)

Figure 2: ABS Relevance and Measures in Collections

The obligations of collections with regard to ABS will depend on the mandate and role of the collection. Thus, the perception of collections by providers and regulatory bodies should consider their differences to assess their obligations corresponding to their mandate. In addition, scientists within collections will have to learn that they need to fulfil their role in the ABS scheme and evaluate their specific activity in consideration of ABS requirements and obligations whenever they intend to work with genetic resources. The same scientist in the same organisation may be a non-user or a user, depending on the scope of their individual work within the collection.

Although collections operate differently, they share the same course of action with regard to the main aspects of accessing and providing genetic resources. Special attention has to be given to the “Entry Point” and “Exit Point” of genetic resources into and out of the collection to protect the collection and subsequent users from operating with legally unconfirmed genetic resources. The "Entry Point” offers the opportunity to clarify the legal conditions (e.g. PIC, MAT) associated with the genetic resources and to provide this information during all procedures within the collection. A clear and rigid accession regime and governance of the “Entry Point” by collections is the most influential part of a sustainable documentation of legal aspects for a genetic resource (see Figure 3). This information can be used for the collection and shall be part of the procedure at the “Exit Points”, even if the handling of the genetic resource happens within the same institution (e.g. transfer of a genetic resource of the Public Service Collection into an in-house Project Collection). A clear and consistent supply regime will put collections in a position where they can serve their role within the ABS scheme of the Nagoya Protocol.

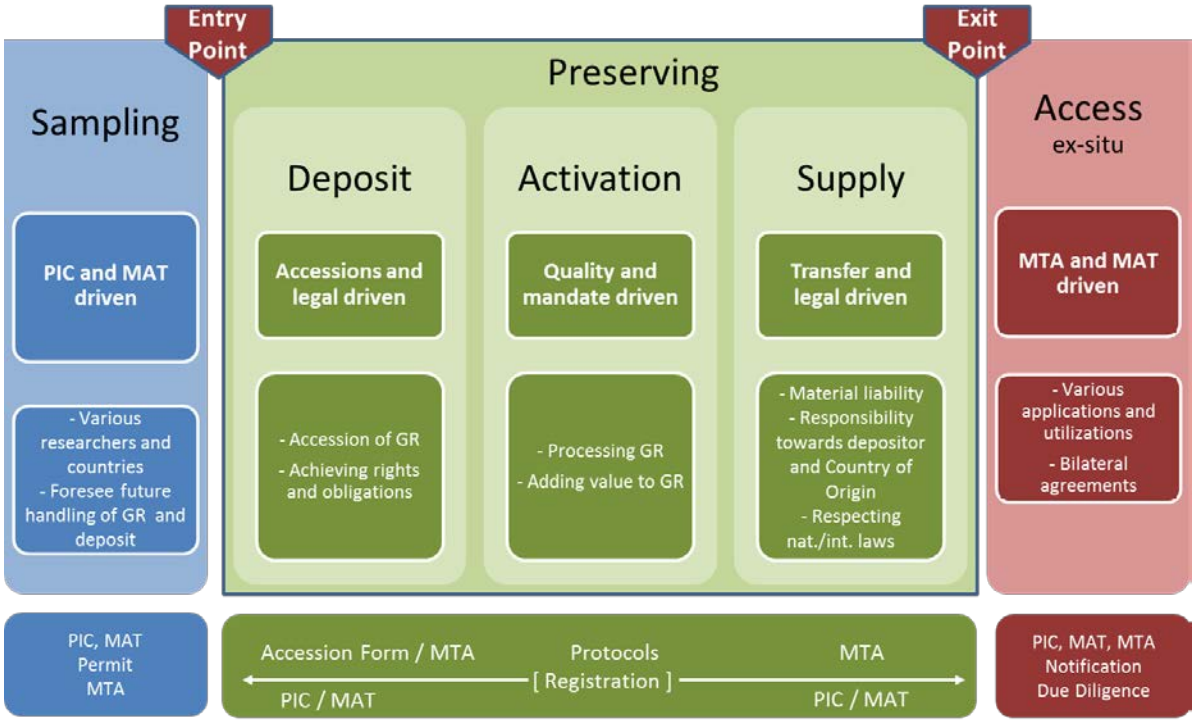

Figure 3: Safeguarding the Entry and Exit Points of Genetic Resources in Collections

Case Example: Microbial Service Collections

Dr. Dagmar Fritze

ABS Compliance & Consulting, Germany

One of the collection types, defined in the preceding contribution, is presented here in more depth, because this type of collection may be one of the most likely candidates to become a registered collection: the microbial service collection. To provide insights for the responsible CNAs, the typical focus of the work done by these collections and the mandates for their work is described. Further, an ABS relevant result of service collection work, namely the multiple, simultaneous existence of subcultures of one and the same microbial strain in various laboratories and countries is elucidated.

University collections and industrial collections of microbial genetic resources are typically in-house collections, focussing on their own particular subjects of work. Universities normally aim to use collections for teaching or research, with the results of the latter being published. Industries, however, normally aim at research that supports the development of products and results are not published. These collections serve their own goals and normally do not supply their samples to third parties. Only in the case of established cooperation would materials be given to third parties. Often, these in-house collections receive the microbial genetic resources they require from service collections and resources are only occasionally collected in-situ.

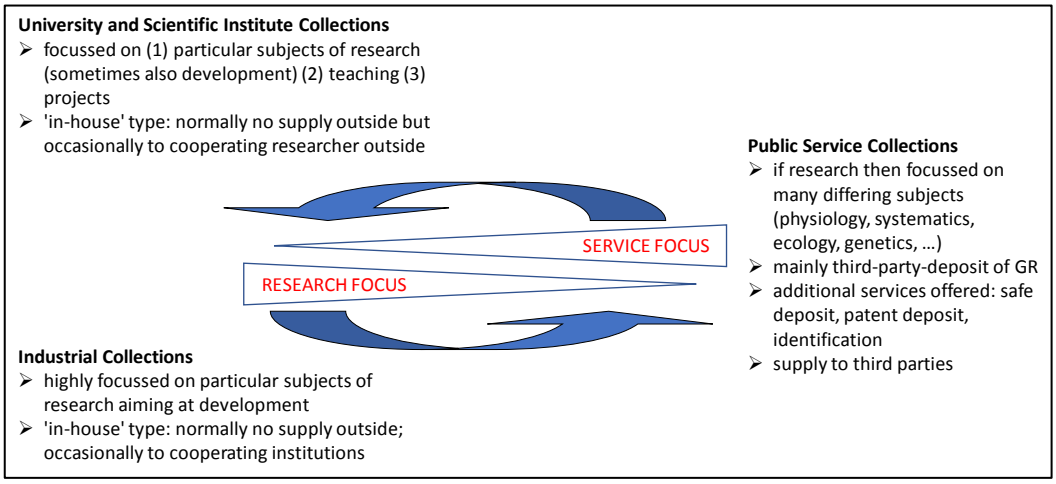

Figure 4: Types of Microbial Collections

In contrast, a public service collection needs to focus on the various interests of a multitude of different researchers outside the collection. If a collection carries out its own research, this is usually done in support of its core duties and covers areas such as physiology, systematics, ecology, genetics, maintenance, etc. New genetic material is added to the collection mainly through third party deposits from researchers all over the world, with only a small proportion being deposited as a result of direct sampling in the field, i.e. collecting in-situ. Exchange of material between collections is a traditional and customary operation. The genetic resources are maintained for the use of all researchers and the information on these holdings is published in open catalogues. In addition to the deposit of genetic material, service collections normally offer other types of deposits such as safe deposit or patent deposit (which will be described in the next chapter), where access to the material is not open but strictly regulated. In all cases, the supply of the deposited genetic resources to third parties is a main

task of service collections.

A special service, which is often offered by service collections, is the identification of genetic material. In such a case, the material is sent by a customer to the collection where the material is processed and identified. Afterwards, the results are communicated to the customer and the material is usually destroyed and therefore not incorporated into the collection.

Whereas in-house collections decide which materials they hold based on their own interests, service collections receive a mandate that shapes their work. This mandate may be determined by government, triggered by recommendations from national scientific societies or, for example, in response to biotechnology needs. In any case, the decision about which material is accepted and added to the collection and subsequently worked with also depends on the technical capacity of the laboratory and the skills of the staff. Additionally, restrictions may be imposed by law as many microorganisms can potentially pose a hazard to humans, animals or plants. Microorganisms are allocated to risk groups according to the risk they represent (RG 1, RG 2, RG 3, RG 4, with the risk increasing from level 1 to level 4). For biosafety reasons, there are rules that regulate the work with these organisms.

Typically, the voluntary mandate of in-house collections results in holdings that are comprised of a large number of strains belonging to a few species or genera, while the imposed mandate of service collections often results in holdings that cover a few strains of many different species, genera and families, thus having broader diversity. However, specialized collections with a public mandate may only hold a narrow range of microorganisms. The general service collections supporting basic research or biotechnology usually hold a large proportion of type-strains, i.e. designated reference strain of a species, other reference strains and recognized test strains.

Besides the basic tasks of accepting various types of deposits, providing access to genetic resources and participating in national and international research cooperation, most of the larger service collections also cooperate with different national and international regulative bodies. This work concerns, for example, normative work with the Comité Européen de Normalisation (CEN) or one of the national standardisation organisations, World Health Organization (WHO) or Organisation for Economic Co-operation and Development (OECD) or scientific and technical cooperation in committees and the boards of biodiversity programmes. Consultancy, expert advice and individual training and courses are often offered on all collection related matters. Collection staff may act as journal editors or reviewers and may be involved in university teaching and supervising university graduates and post-graduates.

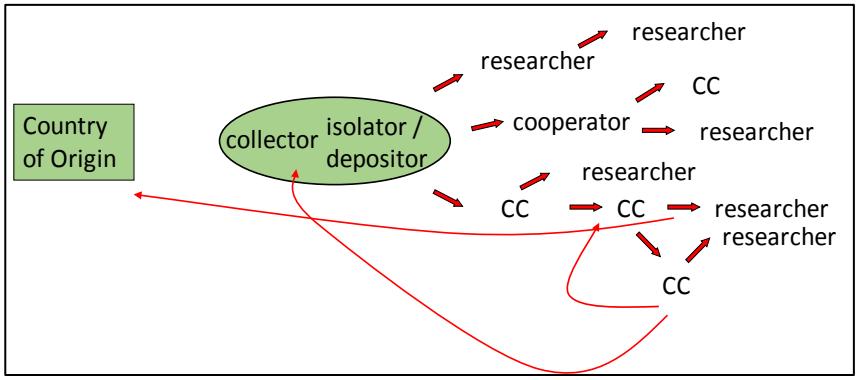

Figure 5: Typical Transfers and Simultaneous Existence and Handling of Subcultures of One and the Same Microbial Strain

Subcultures of a given microorganism may be held simultaneously in many hands in many places. In addition to the original site where the organism was first sampled and may persist, it may exist in many different collections and research laboratories around the world for various purposes. The advantage of this traditional approach is obvious. It offers easy and immediate access to microbes for all researchers worldwide, not only in the country of origin. Another aspect is that if the strain is lost in one place or there are doubts about its authenticity, it can be easily and quickly replaced from another collection. An example for the tradition of cooperation among microbial collections is the type strain of the species *Bacillus subtilis*, the so called “Marburg strain”. Since its description in 1936, it has been donated and passed on to more than 30 microbial service collections around the world from where it is still available today.

With regard to the term “user” as defined in the EU ABS Regulation, microbial collections take the view that their core activities as collections do not qualify as use. They understand themselves to be brokers between providers (who could be countries or individual researchers, describers of microbes and depositors of microbial diversity) and users or potential users - (who could again be countries or individual researchers as recipients of microbial diversity). However, it is the responsibility of collections to clearly differentiate between their core activities on one hand and the potential research activities of staff members. The latter activities could, of course, fall under the “user” provisions of the EU ABS Regulation.

Compliance Frame of Microbial Service Collections

Dr. Dagmar Fritze

ABS Compliance & Consulting, Germany

Work with genetic resources in microbial service collections is regulated by a complex series of laws and regulations that frame and structure their daily processes. ABS regulations are only one aspect of legal compliance. To be able to comprehend the situation of microbial service collection, it is necessary to first ask why researchers deposit their microbial strains with service collections and why are these collections needed.

Background

To be able to study microorganisms in depth, they need to first be isolated from their natural habitat. They are then typically enriched, purified and worked with as pure cultures in the laboratory. To make these pure strains available for future comparative or new studies, they are usually deposited and conserved in culture collections. As such, they form the living archival basis of our knowledge on microbial diversity.

Microorganisms are not geographically confined. Similar habitats around the world may harbour the same microorganisms. Microorganisms are easily transported across borders by wind and water. In the case of storms, large dust clouds can carry a myriad of microorganisms across continents and oceans. Animals and humans carry them on their skin, and in the case of humans, microorganisms are also carried on shoes and clothes.

Microorganisms can be isolated from any environmental sample, such as a piece of soil or dung, a spoonful of sand, a few millilitres of water etc. The sample may contain millions of microbial cells of possibly thousands of species, most of which are still unknown. Typically, during research studies, only a few of these microorganisms will be isolated from the sample matrix and propagated as pure cultures. This also depends on the methods applied and the intents, abilities, skills and knowledge of the researcher.

Reasons for Depositing Microbial Genetic Resources

There are several main reasons why researchers deposit microbial genetic resources with a collection, some of which are mandatory and others of which are voluntary.

- Mandatory Deposits

  (a) Deposit of Type Strains

The requirement to deposit the type strain of a species follows the concept of valid publication of species and validation of names as described in the International Code of Nomenclature of Prokaryotes (Parker, Tindall & Garrity (2015); http://dx.doi.org/10.1099/ijsem.0.000778). This code lays down the rules for the description of a bacterial species. In particular, it is required to designate and deposit the type strain of the species and to publish the new name in the International Journal of Systematic and Evolutionary Microbiology (IJSEM), previously the International Journal of Systematic Bacteriology (IJSB) or in its Validation Lists. In this context, Rule 30 of the code is the most relevant, demanding that "... a viable culture of the type strain of a given species must be deposited with two public service culture collections, located in two different countries, from which subcultures would be readily available." This international scientific

agreement can be understood as a kind of benefit-sharing system to foster research. It allows scientists from all around the world to access the system, to benefit from it and to contribute to the system. Yearly, about 1000 new species are described in bacteriology and their type strains are deposited for open access.

(b) Deposit of Strains for Patent Purposes According to the Budapest Treaty

Patent protection is often sought for biotechnological inventions that are based on living microbial material. In such cases, patent laws might require this biological material to be deposited in a recognized International Depositary Authority (IDA). This material becomes available to authorized third parties and therefore, the invention can be repeated by third parties.

The obligations and rights of patent offices, patent holders, depositaries and third parties with respect to the microbiological material and related data are regulated in detail by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. The idea is that the biological material is made available by a confidential place, independent from the influence of the patent owner.

Most of the larger microbial service collections have acquired the status of IDA from the World Intellectual Property Organization (WIPO).

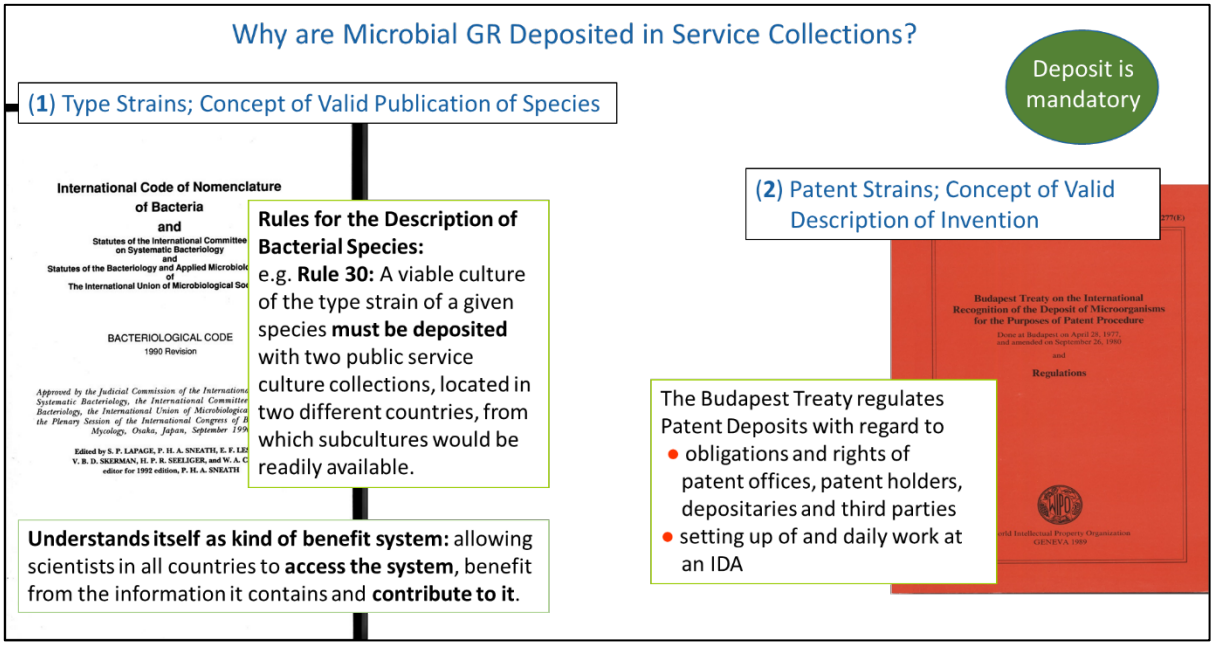

Figure 6: Mandatory Reasons for the Deposit of Microbial Genetic Resources

- Voluntary Deposits of Scientifically and / or Biotechnologically Interesting Microorganisms

When results are published from studies on scientifically interesting features of microorganisms, e.g. on metabolic pathways, life in extreme environments, ecosystems, degradation abilities, etc. it is usually not mandatory to deposit the microbial strains with which the results have been obtained. The same is true for research where new features of microorganisms for biotechnological or biomedical applications are published, such as enzymes for degrading, converting and synthesising substances, or the production of other compounds such as dextrans or glycosides. If these strains are deposited, then this decision is made freely by the researchers, who deposit the microorganisms out of their own interest or the interest of their institution in fostering research in the life sciences. However, scientific journals are increas-

ingly encouraging authors to deposit studied biological materials in service culture collections in order to safeguard continuity and scientific progress. This is based on the understanding that whoever performs research and publishes results is using previously published information and know-how. Therefore, researchers should accept the responsibility of sharing their findings and thus functioning as a link in the knowledge chain.

- Safe Deposits – Voluntary and / or Demanded

A further type of deposit is typically requested by industries. This is the so-called Safe Deposit, which is made with a trustworthy service collection on a voluntary basis. It serves as a back-up to safeguard microbial resources e.g. valuable production strains. This deposit is different from the ones described above in that this is done on a bilateral contract basis. Only the depositor has access to the deposited material, or the depositor may authorise the collection to release samples to third parties on a case-by-case basis.

This type of deposit may in principle also be chosen to serve the requirements of EU regulations, namely when a product containing microorganisms is put onto the EU market. In this case, a clause is added to the bilateral contract that the responsible EU authorities can additionally access the material.

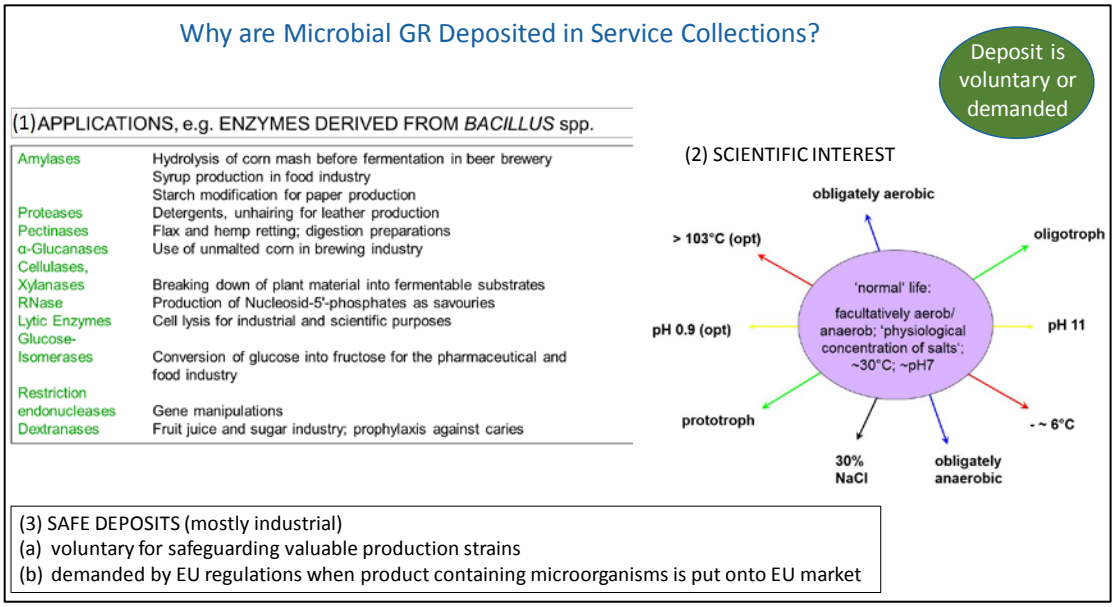

Figure 7: Voluntary and Demanded Reasons for the Deposit of Microbial Genetic Resources

All of these deposits are made for one reason, i.e. published data can only be verified if the biological material they pertain to is available for comparison and further study. Research can only be furthered if new studies can build upon existing results and the related tools, namely trustworthy data and authentic biological material. Without the supportive services of ex-situ collections, scientists would have to conduct the highly skilled and expensive process of isolation, characterization and identification of organisms constantly when beginning each new study.

Core Types of Work with Genetic Resources

The nature of the microbial genetic resources (in contrast to herbaria, natural history museums, etc.) makes it necessary to perform true microbiological work with them in the laborato-

ries of a microbial collection. The agreed minimum requirements for checking new incoming cultures and re-cultivated batches of existing cultures are viability, purity and authenticity. With regard to incoming cultures, these standards prevent work from being done with the wrong cultures or cultures which are contaminated or dead. With existing cultures, these standards serve in-house quality control. Checking purity and authenticity is generally necessary to safeguard the institution and personnel from working with prohibited microorganisms. Checking purity, authenticity and viability is additionally necessary for a collection to be able to render scientifically acceptable services to researchers.

The basic authentication checks can be performed with isolates which are sent for deposit because these have already been characterized to a sufficient extent or have been identified to the taxon level using reproducible methods. This means that they can be identified using a few typical features and few standardized methods. Full identification is normally not performed on new incoming cultures. This is done, e.g., when new microbial isolates need to be screened and therefore compared to known taxa / species to find out whether they belong to one of these or whether they constitute a novel species. For this purpose, a highly standardised methodology is usually applied, the extent of which depends on the complexity of the culture in question. In-depth characterization of microbial isolates would be the next level of detail applied with those cultures which cannot be allocated to a known species and a new species has to be described taxonomically. For this purpose, extensive and varied methodologies are applied.

The requirement to authenticate, identify or characterise microbial cultures is a demanding challenge for service collections. In order to fulfil these functions, they need to be capable of using the necessary methodologies used by previous researcher-depositors to be able to repeat tests and techniques and to confirm results and findings. They need to keep abreast of scientific-technical developments over time in order to provide good up-to-date services. Today, most of these methodologies are based on genetic material. On all taxon levels, e.g. family, genus, species or strain level, morphological and physiological traits are important but do not offer enough power for differentiation.

All approaches described above concern the core activities of typical collection work and are considered as being outside of the scope of Regulation (EU) No 511/2014.

Compliance Frame Accompanying the Work with Microbial Genetic Resources

The activities of accepting microbial strains for deposit, working with them / processing them and supplying them to third parties are strongly influenced by numerous international, regional and national laws and regulations as well as agreed international, regional or national standards and codes of practice. These can be summarised under a number of topics as outlined below.

- Safety Considerations

These embrace biosafety aspects that have triggered import, export and transport / shipping regulations, e.g. with respect to genetically modified or infectious organisms, as well as regulations about who can work with this material. Biosecurity aspects concern e.g. international sanction lists, general working precautions and restricted access to certain material and data.

- Considerations of Open and Restrictive Access to Microbial Genetic Resources

Generally, the deposit of microbial genetic resources in a service collection implies open ac-

cess to this material for researchers. This is, e.g., required by the International Code of Nomenclature of Bacteria. For certain deposits, namely those made under the Budapest Treaty, clearly formulated access procedures have existed since it came into force. Today, the legitimacy of access to genetic resources (concerning deposits into collections as well as the supply of genetic resources from collections) need to be taken into account in light of the requirements of the CBD and the Nagoya Protocol.

- Corporate Quality Management Considerations

The concept of service collections demands the maintenance of high quality material and data. This concerns in particular, the comparability and traceability of material flow and data protection. In addition to societal expectations, service organisations also need to have solid financial arrangements and funding schemes. Modern service collections adhere to e.g. relevant ISO (International Organization for Standardization) Standards and OECD Best Practice Standards.

- Scientific Quality Considerations

The core duties of collections are to safeguard the stability, purity, authenticity and proper performance of the deposited microbial material, which includes maintenance of comparability of the material under scientific and systematic aspects. With this goal in mind, standards for the maintenance of these materials and good scientific practice need to be followed. These standards have been developed and laid down in association codes, like those of the World Federation for Culture Collections (WFCC) or the European Culture Collections' Organisation (ECCO). The larger service collections additionally undergo regular evaluations and participate in excellence schemes.

Microbial service culture collections try to reconcile scientific demands for open, unimpeded access to microbial genetic resources with the demands for legitimate and thus potentially restrictive access to that material. They have to work in a tight and ever more highly regulated framework, which puts increasing administrative burdens on them and entrusts them with extensive responsibilities, which could soon exceed their abilities.

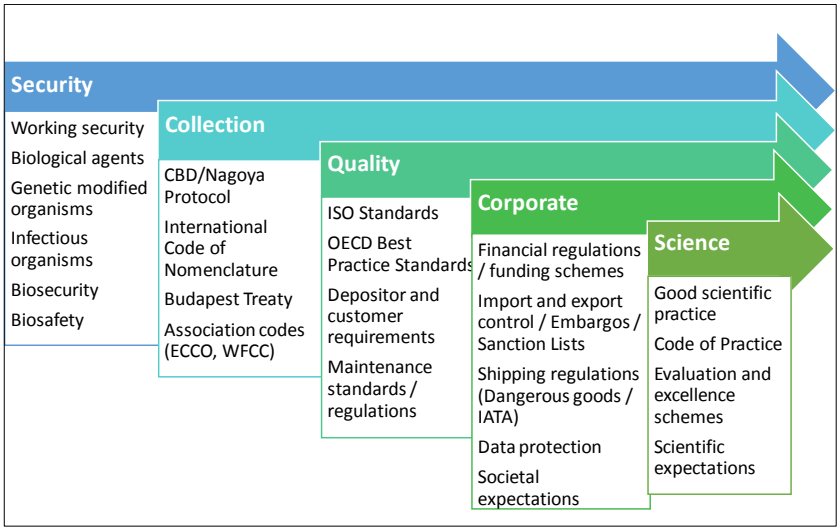

Figure 8: Compliance Frame of Microbial Service Collections

7. Discussions and National Perceptions

On the Way towards Registration

Dr. Amber Hartman Scholz, Ph.D.

German Collection of Microorganisms and Cell Cultures (DSMZ), Germany

The Leibniz Institute DSMZ (German Collection of Microorganisms and Cell Cultures) was asked to describe its early experience of working towards an application to become a registered collection as well to provide a general description of the institute and the role it plays in exchanging microbial genetic resources with worldwide partners.

The Leibniz Institute DSMZ is a research infrastructure, which is the modern-day result of a historical merger of 7 microbiological collections and 4 newly established ones. It consists of 200 employees and has a 13 million Euro annual budget, a third of which is generated by sales and service incomes and two-thirds which is provided from federal and state funding. It plays a central scientific role with around 140 publications per year, 11,000 citations of its resources (two-thirds outside systematics), and a sequencing centre that has sequenced 352 genomes in the past year. DSMZ receives around 2,000 deposits per year and has total holdings of 57,000 publicly available biological resources. It has approximately 10,000 worldwide customers from 86 countries, with 65% of its orders sent out internationally (outside of Germany) to recipients that are from both academic (60%) and industrial (40%) sectors. In sharp contrast to the 40,000 bioresources that are sent out per year for scientific use, DSMZ typically receives only a single commercial use request per year, suggesting that the commercial value of the biological resources for direct commercial use is unattractive (probably due to their public availability and limited patentability).

In the coming months, the Leibniz Institute DSMZ intends to submit an application for inclusion in the register of collections (Article 5(1) of the Regulation (EU) No 511/2014) to the German Competent National Authority (Bundesamt für Naturschutz). To this end, the DSMZ has begun an initial assessment of its compliance with the EU ABS Regulation. The DSMZ intends to register all publicly available, non-human biological resources (i.e. not patent and security deposit strains and not human cell lines). In terms of Article 5(3)(a) of the EU ABS Regulation, the existing ISO 9001:2008 Quality Management certification demonstrates the DSMZ's ability to "apply standardized procedures for exchanging samples of genetic resources". For Article 5(3)(c) to (e), the date and country of sampling have been requested with deposits since 1993 and have been required since September 2014. A unique identifier is assigned to every new deposit and an in-house workflow / tracking system records all pertinent details of usage and distribution. Furthermore, RFID tracking technology and, in the near future, robotic storage will enable highly precise records of resource distribution.

The current challenge facing the DSMZ is complying with Article 5(3)(b) of the EU ABS Regulation and properly assessing the depositor's "evidence that genetic resources were accessed in accordance with applicable access and benefit-sharing legislation". The challenge is both logistical and legal since DSMZ receives 2,000 deposits annually, half of which are from countries that are party to the Nagoya Protocol. Traditionally, scientific staff processed new deposits, but given that deposits have steadily increased in recent years, there is neither the capacity nor sufficient legal knowledge amongst the scientific staff to handle the demands imposed by the EU ABS Regulation completely, particularly in legally complicated

situations. To this end, the DSMZ has a two-pronged approach to surmount this hurdle: 1) take advantage of the ABS Clearing-House API in order to automate some of the process and 2) hire a lawyer to assess Nagoya-related documentation and standardize this process. In terms of the first solution, the DSMZ electronic accession form can now automatically determine whether a depositor needs to upload Nagoya-related documentation by using the sampling date and country information entered by the depositor. The DSMZ has also created an easy-to-understand infographic, which is available on its website, to inform depositors beforehand about the required documentation.

However, the challenge extends beyond IT solutions. It remains unclear the extent to which the DSMZ will be expected to legally verify the Nagoya-related documentation (PIC, MAT, MTA or combination thereof) provided by a depositor. Because of the large numbers of deposits received from a wide variety of countries, it is assumed that a “de minimis” check on behalf of the DSMZ is reasonable. Such a check might include the verification of the country issuing the documentation, the competent national authority, the dates of sampling, and perhaps the type of genetic resources that were allowed to be collected. The DSMZ has no authority to “police” depositor documentation and cannot check or ensure that the depositor is fulfilling any ABS conditions listed in their documentation. Similarly, on the user (purchaser) side, the DSMZ will make Nagoya-related documentation publicly available in its online catalog alongside the biological resource being offered. These biological resources will continue to remain available to all members of the public. The DSMZ MTA that will accompany all shipments will stipulate that the purchase of biological resources with Nagoya-related documentation legally obligates the purchaser to adhere to the terms laid out in the documents and to maintain the corresponding records for 20 years. The DSMZ has no authority to screen customers and hence cannot enforce the terms specified in the documentation, but instead, expects users to fulfill their due diligence by reading the documents, adhering to the terms listed there, and reporting on their activities as envisioned in Article 7(1) and (2) of the EU ABS Regulation.

Registration of French Collections

Florence Hervatin-Queney PhD

Ministry of Higher Education and Research, France

Competent Authority

Under the French Law on Recovering Biodiversity, Nature and Landscapes, the Ministry of Higher Education and Research is designated as the competent authority for processing requests from collections for entry into the European register of collections and for conducting the corresponding verification checks on registered collections.

Processing of Requests

- Expert Committee

An Expert Committee composed of 15 experts representing all of the life sciences disciplines as well as the public and private research sectors has been set up at the Ministry of Research. This Committee is responsible for assessing the requests, monitoring the management procedures at collections and analyzing whether good practices have been implemented.

The internal procedural rules of the Expert Committee are established by the Committee and are then approved by the Ministry of Research. These rules specify the procedures for assessing requests and verifying compliance of collections with their own management systems. They also set out the ethical rules applicable to the Committee members. The rules provide for the conditions under which members of the Committee must refrain from participating in the assessment of a request, e.g. in the event of a conflict of interest.

- IT Developments

Most of the activities of the experts are carried out virtually. We had previously developed a platform, which is connected to the European Commission, for handling requests to use animals for scientific purposes (ALURES). A platform for requests to become registered collections will be created in the same system. The system will contain the information about each collection required by Article 2 of the Implementing Regulation (EU) 2015/1866. This platform can also receive and retain all files which have been determined to be relevant by the Expert Committee. This secure platform will trace the receipt of the request and the exchanges between the experts, the applicant and the Ministry up to the point of notification of newly registered collection to the European Commission.

The national electronic database / registry, known as the National Directory of Research Structures (RNSR), which already has about 4000 research structures, will be used to register users. It will automatically be updated with information provided by the users.

The platform will automatically inform the legally responsible body when a request is made by a structure falling within its legal responsibility. The confidentiality of research projects between the laboratories will be maintained and a system of security keys will ensure the security of the information.

- Evaluation and Control of Requests

Each file will be examined by at least two experts from the Committee. A third expert may be

required in case of disagreement between the first two. When visits to the collections are necessary in order to assess the request, a report will be prepared and filed on the platform. The Ministry, i.e. the Competent Authority, will decide whether it is appropriate to include the collection in the European register.

The control procedures, including the visits to the collection in accordance with Article 4 of the Implementing Regulation, will have to be defined by the expert group.

- Reporting

An annual activity report will be prepared by the Chairman of the Expert Committee and forwarded to the Ministry. This report may refer to any documents which have been added to the platform (e.g. files and exchanges with applicants). It will concentrate on the procedure for assessing requests for inclusion of collections in the European register and also the definition and implementation of the procedures to check these collections in accordance with the EU regulations. This report and the documents on the platform will serve as the basis of the register of checks required by Article 10 of the EU ABS Regulation.

The Expert Committee will also have to provide advice on the implementation of the Nagoya Protocol and on the further development of the relevant legislative and regulatory provisions.

ABS Implementation and Collections in Hungary

Zsuzsanna Ujj

Ministry of Agriculture, Hungary

Introduction

In Hungary, the Ministry of Agriculture is responsible for nature conservation. The national focal point for the Nagoya Protocol is Mr. Levente Kőrösi, who is the Head of the Biodiversity and Gene Conservation Unit, Nature Conservation Department.

The CNA is the Pest County Government Office.

Two advisory bodies, responsible for animal and plant genetic resources respectively, have an advisory role with respect to gene conservation and the related government policies:

- Plant Genebanks Council: representation is organized by sectors (crops, vegetables, fruits, grape, herbs-spices-essential oils, microorganisms, forestry, horticulture), consists of 13 experts, and other delegates.
- Native Farm Animal Gene Conservation Council: representation is organized by species.

Meetings and both formal and informal relationships with the council members are important resources for ABS implementation.

Implementation Process

The Hungarian implementing regulation has been in place since January 2016. The implementation regulation assigns two checkpoints for commercial products (one for agriculture and one for pharmaceuticals and cosmetics) and two checkpoints for research. The penalty system is also in place.

We have started creating a control plan but it is at an early stage.

Hungary wants to have access legislation in the future, which is in an early drafting stage at the moment.

Collections

- Plants

The most important collection is at the Centre for Plant Diversity, which is the 13th largest agricultural gene bank in the world. It has more than 80,000 items and is the custodian of approximately 50% of the plant genetic resources for food and agriculture in Hungary. The Center has also established a project collection (Pannon Seed Bank) for the ex-situ preservation of the Hungarian vascular flora (currently stores about 800 species). Although it started as a project collection, it will be maintained in the long term.

Hungary also has four major fruit collections in Újfehértó, Cegléd, Érd and Fertőd.

Cereal Research Non-Profit Ltd. is a spin-off company of a Hungarian research institute; its collection is the byproduct of its research projects.

Major plant collections are aware of and comply with the EU ABS Regulation and have the relevant documentation traceability systems in place. They observe the FAO voluntary guide-

lines for gene banks (Genebank Standard).

Regarding the EU register of collections, it would be desirable to have the above mentioned 6 major plant gene banks included in the register.

- Microorganisms

The National Collection of Agricultural and Industrial Microorganisms operates as a unit of Szent István University. It is the biggest in terms of biodiversity with 3,200 strains. It is involved in species identification and selling cultures. It is also a deposit for patented strains and plays a very important role in the region. The collection expressed its interest in the results of the current workshop.

- Natural History Museum

It has several collections including plants and animals and a laboratory that is capable of isolating DNA from fossils. The Museum has expressed its interest in the registration process. However, it does not have standardized databases.

- Animals

This sector has established benefit-sharing systems but its involvement in ABS in the sense of the Nagoya Protocol is less strong than that of the plants sector. One of our most important in vivo and in vitro gene banks is the Research Centre for Farm Animal Conservation.

Conclusions

The national collections are generally enthusiastic about becoming registered collections. Organizations in the plants and microorganisms sector have their own standards and regulations with which they comply. These sectors believe that their already established systems ensure compliance with the Nagoya Protocol. However, in case of an inspection we might find gaps in the system. For example, usually the management has adequate knowledge of the subject, but this knowledge is not necessarily passed on to the staff, which might pose problems. Capacity-building is therefore the most important issue at the moment. Awareness-raising is ongoing with organizing our own workshops and also visiting sectorial events.

Collections of Genetic Resources in Poland

Bożena Haczek

Ministry of the Environment, Poland

The Polish collections of genetic resources have been analysed and can be divided into the following categories:

- Botanical gardens and arboretums

There are 41 officially registered entities, of which 19 have the status of National Collection. Most of them are run by universities, the Polish Academy of Science and scientific institutions. Some belong to the State Forest Holding, local governments and private entities.

- Zoological gardens

There are 26 officially registered zoos. In addition to their normal activities, they have collections of embryos, sperm, samples of blood and tissues, cell cultures and DNA.

- Polish Genebank

It is coordinated by the National Centre for Plant Genetic Resources – Plant Breeding and Acclimatization Institute (IHAR) in Radzików. It encompasses 40 collections of crop plants in several institutions, with the central seed bank located in Radzików.

- Kostrzyca Forest Gene Bank

It was created with the aim of preserving the gene pool of a selection of the most valuable specimens from State Forests which are used for commercial purposes, the oldest native forest stands and the so called individual conservation trees, which are protected endangered plants from natural stands.

- Collections of breeding animals' genetic resources

The National Bank of Farm Animals Biological Material in Balice is run by the National Research Institute of Animal Production. There are also several specific collections related to research projects, which are run by scientific institutions.

- Collections of microorganisms

There are nine Polish collections which are registered members of the World Federation of Culture Collections. Two of these collections have the right to receive deposits, including the Polish Collection of Microorganisms in Wroclaw, which has the status of an international deposit center.

- DNA collections

The National Bank of Plant, Fungi and Animal DNA was established in 2006 by five Polish scientific institutions that were using DNA barcoding for research as well as for many practical purposes.

In order to gather information about the collection holders' level of awareness about the Nagoya Protocol and Regulation (EU) No 511/2014, their interest in the EU register and the procedures used in the collections, a survey was conducted in 2015. Of the 119 collections that were identified, 40 collections answered the survey.

According to the survey results, 75% of the respondents were aware of the provisions of the Nagoya Protocol. At the same time, as much as 40% of collection holders had no knowledge of the EU ABS Regulation. This could have been a result of the very short period of time between the survey and the adoption of the EU ABS Regulation. 15% of the collections declared that they did not exchange samples with any other collections or users and hence have very limited engagement in the issue of ABS. On the other hand, ten collection holders declared their interest in the EU register and five collections had almost fulfilled the required criteria for registration.

8. Development of a Register of Collections and Expectations

Registered Collections: Developments and Expectations

Alicja Kozlowska

European Commission

This presentation provided preliminary feedback on the provisions of the EU ABS Regulation concerning registered collections, as well as some historical perspectives on the issue. It was also aimed at stimulating discussion about the development of these collections.

The concept of registered collections is provided for in Article 5 of the EU ABS Regulation (Regulation (EU) No 511/2014) and is one of the tools for facilitating compliance. The Commission Impact Assessment accompanying the proposal for the EU ABS Regulation identified a number of options for the implementation of the compliance pillar of the Nagoya Protocol, i.e. maintaining the status quo (option UC-1), general due diligence obligations on EU users (option UC-2), general due diligence obligation on EU users and system for formal recognition of collections as "trusted sources" of genetic resources (option UC-3), and prohibition of utilisation of illegally acquired genetic resources and "downstream" monitoring (option UC-4). Option UC-3 was selected in recognition of the fact that ex-situ collections play a fundamental role in the EU user chain, providing genetic resources both to commercial and non-commercial actors. Furthermore, it was apparent that the use of a system of trusted collections would significantly lower the risk that illegally acquired genetic resources enter the value chain in the EU and that it would be easier for EU users to comply with due their diligence obligations.

Under Article 5 of the EU ABS Regulation, the Commission needs to establish and maintain a register of collections that is internet based and easily accessible to users. The member states are, however, responsible for verifying whether a specific collection should be included in the register. Article 5(3) of the EU ABS Regulation provides criteria for becoming a registered collection, namely that the collection can

- demonstrate the capacity to apply standardised procedures when exchanging samples of genetic resources and the related information with other collections,
- supply genetic resources and related information to users together with the appropriate documentation (i.e. evidence that the resources were accessed in accordance with applicable laws),
- keep records of samples and related information,
- use unique identifiers, and
- use tracking and monitoring tools for the exchange of samples.

Article 5 also deals with the verification of registered collections to ensure that they continue to meet the requirements for registration. It also deals with situations where there is evidence that a collection no longer meets the relevant criteria and there is a need to identify remedial actions and measures.

The Implementing Regulation (Regulation (EU) 2015/1866) completes the legal landscape for registered collections in the EU. Article 2 of this Regulation identifies which information

needs to be entered into the register. Article 3 defines the rules concerning application for registration and provides guidance to member states on possible ways of verifying the eligibility of collections for inclusion in the register. Article 4 regulates the verification checks, i.e. whether registered collections still meet the relevant criteria. These verification checks should be done based on a periodically reviewed plan that uses a risk-based approach. The plan needs to define the minimum level of checks and their frequency. Various options for verification of registered collections are also mentioned.

The way in which the Implementing Regulation is structured provides an important incentive for users of genetic resources to obtain genetic material from a registered source. According to Article 4(5) of the Implementing Regulation, a user obtaining a genetic resource from a collection included in the register shall be considered to have exercised due diligence as regards the seeking of information.

Indeed, the Implementing Regulation provides more of an incentive for the user to obtain material from a registered collection than for collections to become registered. Currently, there is very limited interest among collections in obtaining registered status. Many collections are busy carrying out a business analysis of the potential impacts of registration. Some collections are even willing to apply stricter rules concerning the temporal scope of genetic material, which makes applying to be a registered collection even more challenging. The decision to become registered will also have implications for human resource policies at collections, as certain procedures will need to be put in place. Thus, it is only natural that collections are taking some time to evaluate the situation. Often, collections are afraid of potential liability claims in situations where something goes wrong.

Given that under the EU ABS Regulation the competent national authorities are responsible for verifying whether a collection meets the criteria to become registered and whether it continues to meet the criteria once registered, it is important that the Implementing Regulation is applied in a harmonised way in the EU. Meetings, where the CNAs have a chance to discuss the issues concerning implementation of Article 5, should be continued. Collections should be reassured about the harmonised application of the Implementing Regulation and the harmonised interpretation across the EU.

9. Towards a Registration Process: Use Cases, Approaches, Tools and Problems

EU Scopes and Definitions, Use Cases

Dunja Martin

ABS Compliance & Consulting, Germany

The EU ABS Regulation defines the kinds of activities involving genetic resources that are captured by this Regulation. The Guidance Document Commission Notice 2016/C 313/01 provides additional details as to the scope of the EU ABS Regulation**.** These guidelines and definitions should be consulted first when checking whether work with genetic resources falls within the scope of the EU ABS legislation.

A set of four elements has been defined, addressing the origin of genetic resources, the time of the applicability of the EU ABS Regulation, the range of affected genetic resources and the users.

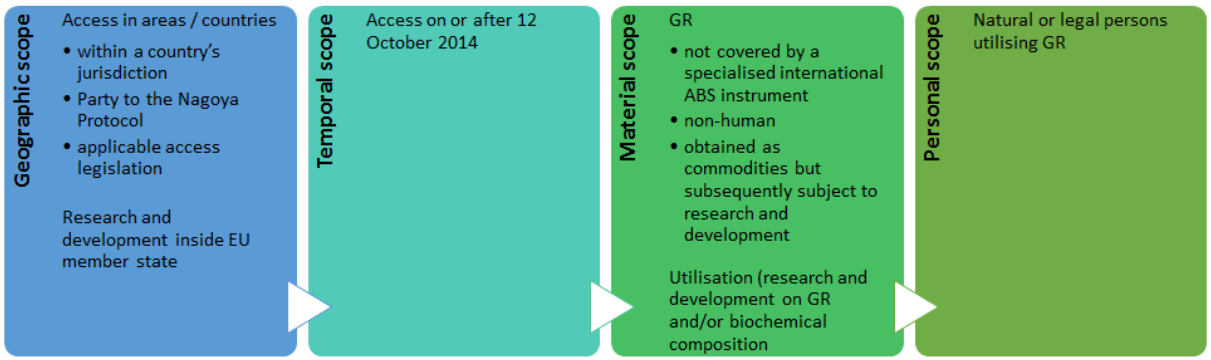

Figure 9: Scope of the EU ABS Regulation

It is emphasized that the EU ABS Regulation only applies if all of these conditions are met. As indicated in the Guidance Document Commission Notice 2016/C 313/01 "it is important to note from the outset that the conditions described below concerning the applicability of the Regulation are cumulative: Where the document indicates that "the Regulation applies" if a certain condition is met, this always presupposes that all the other conditions for being in the scope are also met."

However, it should be kept in mind that some Nagoya Protocol member states may introduce / may have introduced additional ABS-related measures that go beyond the due diligence requirements of the EU ABS Regulation. These laws may stipulate penalties that apply to breaches of their national laws. Thus, users should always be aware of national measures in order to avoid breaching national legislation, even though they may comply with the EU ABS Regulation.

The following scheme shows the cumulative application of the different elements of the scope of the EU ABS Regulation:

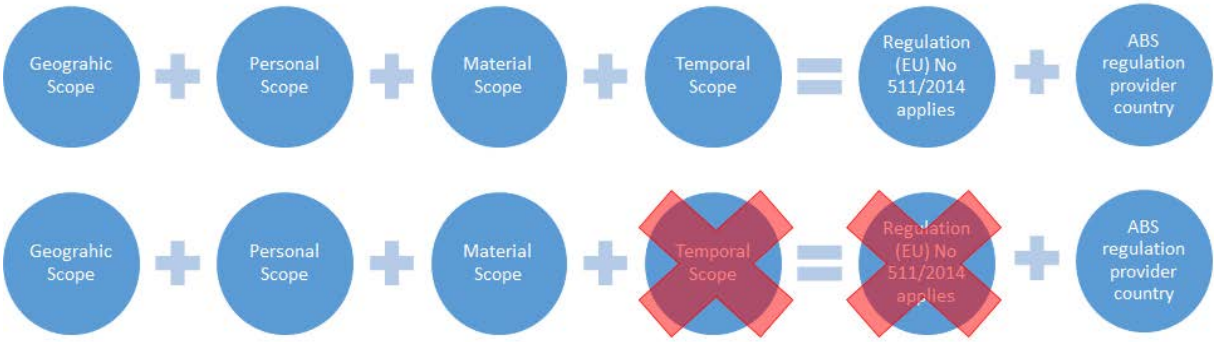

Figure 10: Applicability of the Scope of the EU ABS Regulation

Users should put emphasis on having a detailed procedure for checking the applicability of the EU ABS Regulation as well as any uncertainties in the information they have at hand. These uncertainties might, for example, arise from PIC and/or MAT in circumstances where the envisaged utilization is not covered by the legal documents. Whenever the information is insufficient or there are uncertainties, utilisation should not start or should be discontinued. The consequences of not stopping utilisation in cases of uncertainty or where the use does not comply with PIC or MAT will depend on whether the utilization is within the scope of the EU ABS Regulation and the applicability of the national provider country's laws. For those users who are within the scope of the EU ABS Regulation, a breach of their duty will lead to law enforcement measures set by the respective EU member state. Those users who are in breach of foreign national laws will have to take the responsibility according to those foreign laws.

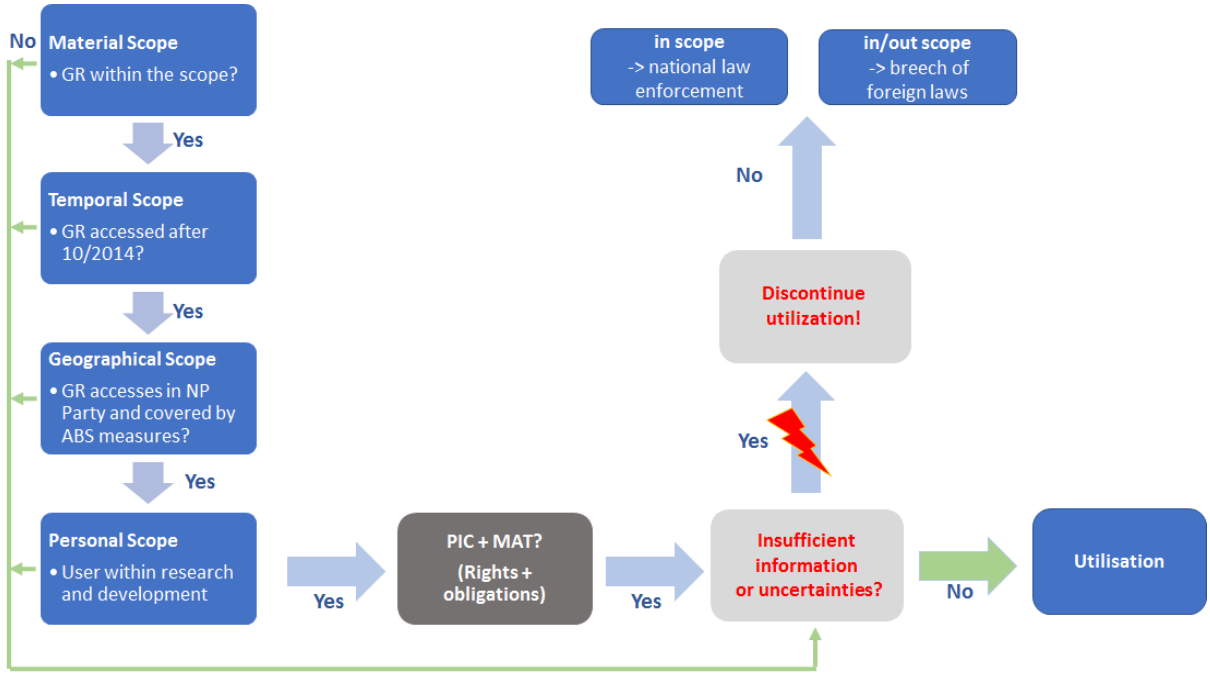

Figure 11: Workflow of the Decision Process Related to Scope

Seeking the information, which is needed in order to decide whether there are any obligations related to a genetic resource and whether the EU ABS Regulation applies, is a central aspect of accessing and utilizing genetic resources. Article 4(1) stipulates that the core obligation on users

is to “exercise due diligence to ascertain that the genetic resources […] which they utilize have been accessed in accordance with the applicable access and benefit-sharing legislation or regulatory requirements” of the provider countries of these genetic resources and “that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements”. A register of collections will be established by the European Commission as a voluntary tool to assist users in complying with their due diligence obligations. Collections applying for registration will have to comply with certain requirements and will receive approval through a formal process determined by their competent national authorities. Obtaining genetic resources from a registered collection will be an enormous relief for users, as they will be considered to have exercised due diligence regarding the seeking of information. There are different expectations from registered collections, which reflect the needs and interests of various stakeholders. These expectations and needs also have to be considered when the registration process is established so that the beneficial effects of this compliance tool can be achieved. The main expectations of the different stakeholders are:

Enforcement Authorities:

- sustainable law enforcement
- appropriate registration process
- staff, financial and operational resources
- establishment of internal and external assistance

Users:

- gain benefits
- impact on obligations, mainly due diligence
- increase legal certainty

Collections:

- required registration efforts
- staff, financial and operational resources
- appropriate course of action and measures
- potential assistance
- achieved benefits

Countries of Origin:

- safeguarding interests
- transparent exchange of material
- protection of assets

Legislators:

- sustainable implementation of legislation
- securing CBD / Nagoya Protocol targets

There is a wide spectrum of expectations towards collections, which will have to be addressed

through appropriate processes. Balancing the burden on collections by offering benefits or incentives for registration will not be an easy task and procedural efforts are needed on all sides.

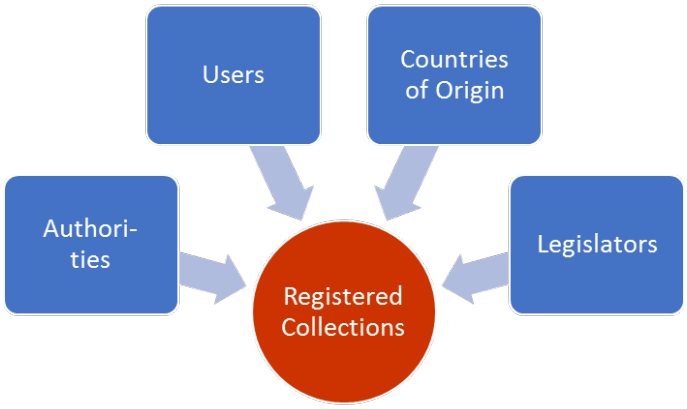

Figure 12: Stakeholder Expectations of Collections

Public service collections have a long tradition in the ABS regime. They demonstrate high levels of awareness, have a lot of knowledge and experience about ABS, have many contacts, have established tools and often even have guidelines to align their processes with legal requirements and stakeholder demands. Nevertheless, a review of existing measures is required to achieve consistency/compliance with the current EU ABS Regulation, to adapt guidelines, to enable a differentiated perception of their activities and to establish cooperation with legislators and authorities. Assuming that a register of collections is successfully established, these organizations will have to balance stakeholder needs and provide a stable basis for the legal exchange of genetic resources.

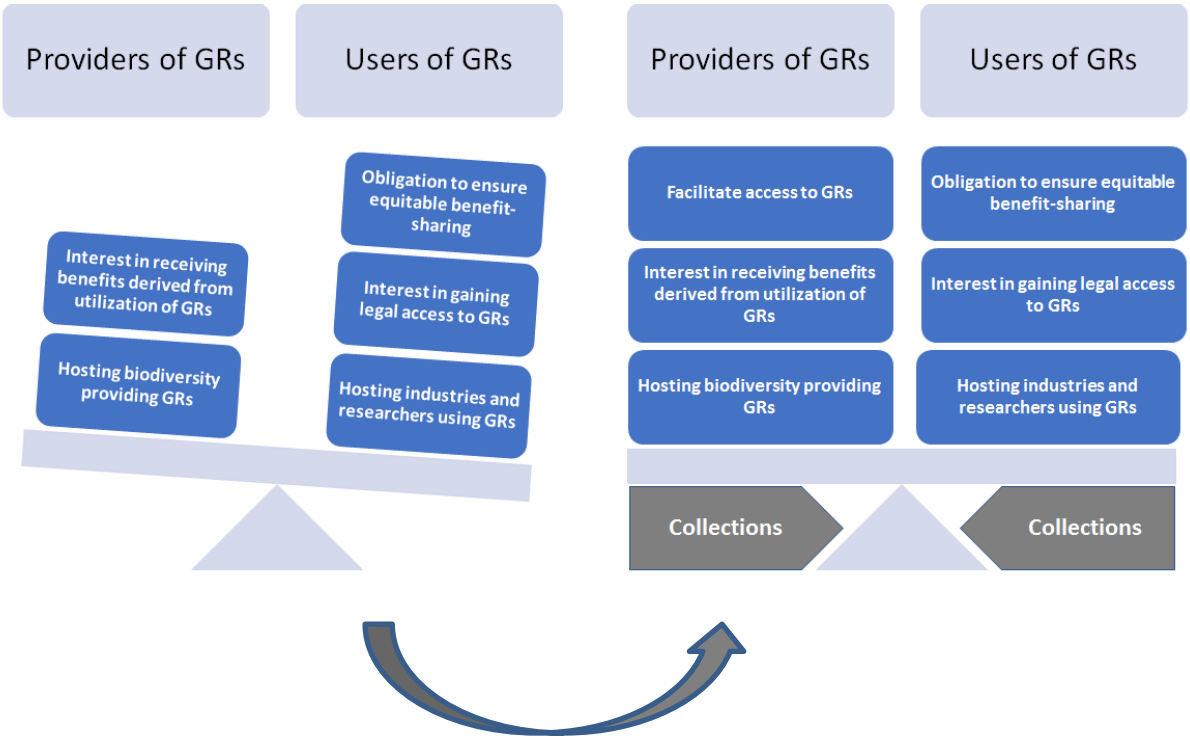

Figure 13: Balancing the Interests and Obligations of Stakeholders

Common and Domain Specific Approaches

Dr. Dagmar Fritze

ABS Compliance & Consulting, Germany

The complexity of the work done by collections and the highly regulated nature of access to, distribution of and use of living genetic resources demands cooperation and coordination among the institutions involved and the sharing of experiences. The design of standardised conditions for the acquisition, deposit, handling and supply of living microbial resources could form the basis of a confidence-building system for access and exchange of genetic resources.

In those sectors which focus on working with genetic resources, a series of sector and domain specific ABS models, guidelines and tools are in development or have already been developed. These models etc. are supported by international organisations, such as the ABS Capacity Development Initiative, which are active in provider countries. These organisations help provider countries to develop and design their own ABS approaches. Valuable documentation has been published, like the “Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing” from the International Union for Conservation of Nature (IUCN).

Documents have also been developed for academia, such as “Access and Benefit Sharing Good Practice for Academic Research on Genetic Resources” from the Swiss Academy of Sciences and the guideline for CBD relevant research projects from the German Science Foundation (DFG).

There are also sector specific documents, for example, the “Code of Conduct and Best Practice for Access and Benefit Sharing” from the Consortium of European Taxonomic Facilities (CETAF) or the CBD manual for botanic gardens from Botanic Gardens Conservation International (BGCI). Another very important sector is biotechnology. In Europe, the Biotechnology Industry Organization (BIO) has developed the “BIO Model MTA” for their members who engage in bioprospecting. The Japan Bioindustry Association (JBA) and the Japanese Ministry of Economy, Trade and Industry (METI) have also developed the “Japanese Guidelines on Access to and Benefit Sharing of Genetic Resources”.

Within sectors, specific model agreements can be developed which relate to the type of material used or the specific research area. Examples include the “MIRRI Best Practice Manual on Access and Benefit Sharing” in the microbial sector, the Mediterranean Science Commission's (CIESM) “Charter on ABS”, which is designed specifically for marine genetic resources, and the German “Micro B3 ABS Model Agreement”.

Microbial service culture collections have a long tradition of such cooperation. In 1960, the World Data Centre for Microorganisms (WDCM) was founded at the global level and this was complemented in 1974 by the WFCC. WFCC was then accepted as the umbrella organisation, underneath which regional associations were later formed. Examples include the ECCO, which was formed in 1981, and the Asian Consortium for the Conservation and Sustainable Use of Microbial Resources (ACM), which was established in 2004. Within Europe, like in other parts of the world, there are many national associations for ex-situ collections. Through these formal organisations, collections have developed cooperative platforms to tackle scientific and technical issues, issues relating to the quality of data and biological material or to tackle legal and regulatory issues.

The WFCC member collections have developed a corporate framework for the establishment and operation of microbial collections, which was designed long before the CBD came into effect but which nevertheless supports the spirit of the convention. E.g. WFCC members are registered through the WFCC's database system, WDCM, using a unique acronym and numerical identifier. Members are urged to catalogue all of their microbiological resources. In the "WFCC Guidelines", standard procedures are recommended for members, including:

- registration with WDCM,
- use of accession forms which request information on the country of origin and the related PIC and MAT,
- use of individual accession numbers for each deposited genetic resource,
- use of data entry for each genetic resource to show their complete history,
- publication of catalogues,
- recording the supply of material.

All of these procedures assist with tracking microbiological resources and serve to increase transparency and traceability, as today required by the EU ABS Regulation.

WFCC publications provide valuable background information on the issue of ABS in the context of microorganisms, for example, the paper from 1996 on "Access to ex-situ Microbial Genetic Resources within the Framework to the Convention on Biological Diversity" and the background paper to CBD COP9 (2008) titled "Access and benefit sharing, a main preoccupation of the World Federation of Culture Collections".

European collections have been particularly active as many projects have evolved through ECCO and many experts from ECCO member collections have cooperated in global projects.

The main aim of ECCO was to provide a forum to help in-house collections to develop into service collections. The increasing demand for readily available living microbiological material in the 1960s and 1970s triggered an increased interest in ex-situ collections. Today, over 70 members in 26 European countries hold archaea, bacteria, filamentous fungi, yeasts, bacterial viruses, plasmids, human and animal cells, plant cells, animal viruses, plant viruses, algae and protozoa. Corporate members are located in Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, Turkey and the UK.

A few of the more important projects with direct relevance to ABS shall be presented here. Some of the early activities addressed issues regarding the quality of data and biological material, such as the "Common Access to Biological Resources and Information" (CABRI) project. Others concerned CBD issues such as the "Micro-organism Sustainable Use and Access Regulation International Code of Conduct" (MOSAICC). The latter provided guidance on procedures and documents such as Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and monitoring transfers. The "ECCO Core Material Transfer Agreement (MTA) for the Supply of Cultures to the User" was developed directly from the MOSAIC project, leading to practical implementation of the project outcomes (www.eccosite.org/ecco-core-mta/). This MTA has been agreed to by ECCO collections and forms the minimum standard for governing the supply of genetic resources from service culture collections. It

takes into account the responsibilities imposed by legislation, while intending to facilitate exchange between the collections and not imposing restrictions on research. The main points covered in the MTA are the traceability of samples of biological material, fair and equitable benefit sharing, intellectual property rights, quality of microbiological material and safety and security.

In larger global and regional initiatives, the political impact of issues, including some of those mentioned above, were dealt with. The demonstration project for a Global Biological Resource Centres Network (GBRCN) made it clear that increased global exchange of living biological material would need increasingly coordinated and harmonised processes for all aspects of collection work (e.g. safety, security legitimacy, quality and comparability of material and data).

To this end, needs were made clear to overcome national differences in operational parameters of Biological Resource Centres (BRCs). The need for capacity-building programmes to address key challenges was also identified.

The European project “Microbial Resources Research Infrastructure” (MIRRI) took into consideration the previous activities of the culture collection community and aimed at bringing together the European microbial resource service collections with their stakeholders, i.e. users and policy makers. As a pan-European structure, it was envisioned that MIRRI would act as a coordinated service provider that would enable collaborative work between collections, thus inspiring excellence, facilitating collaboration across borders and disciplines, and stimulating interaction between academia, bio-industry and governing bodies. One of the important outcomes of this project is a policy document and a “Best Practice Manual on ABS for Biological Resource Centres”.

The above mentioned in-house agreements and processes resulting from WFCC and ECCO member collection cooperation projects together with the valuable work in the OECD-BRC initiative, widely match the requirements formulated for collections in the EU ABS Regulation on ABS implementation. Therefore, these agreements and processes should be viewed as the standard that countries of origin of genetic resources should expect from a microbial culture collection when considering the deposit of their microbial resources in an ex-situ collection. A microbial collection in the EU which has e.g. implemented the WFCC Guideline requirements and the ECCO Core MTA and has followed the OECD Best Practice Guidelines should be considered as both a trustworthy place to deposit genetic resources and a good candidate for becoming a registered collection.

Despite all efforts and the positive outcomes of cooperation, there are still challenges with ABS, even for very active collections. These collections still require support. ABS obligations will add to the extensive responsibilities of collections and their administrative work. Further assistance for collections could take the form of:

- awareness-raising which could be provided in cooperation with scientific and corporate societies,
- provision of information,
- central or in-house training seminars,
- provision of operational tools such as flow diagrams, check lists and tailor-made in-house procedures to support administrative processes,

- good contacts to national CNAs.

While service collections represent an experienced and willing community, a rather high number of invisible smaller collections exist, which have not had the chance to be involved in any awareness-raising projects.

In the interest of good international scientific and developmental cooperation, surveys which identify these so to speak hidden institutions are urgently needed so that these institutions can be provided with information concerning the EU ABS Regulations and the consequences for their collection and research work.

Requirements for and Impacts of Registration

Dunja Martin

ABS Compliance & Consulting, Germany

Implementing Regulation (EU) 2015/1866 and its Annex I lay down detailed rules for collections which make a request to be part of the register of collections referred to in Article 5 of the Regulation (EU) No 511/2014. Collections need to decide on how to implement these requirements and determine whether supporting tools are available to reduce the burden of implementing and maintaining the defined processes. Depending on the implementation efforts and the stage of development of the individual collection, the impact of a registration process will vary.

Each of the four central requirements for registration necessitates supporting tools and can be implemented by different options:

- The requirement for “collection category” demands adequate descriptions of the genetic resources in a catalogue, preferably using an electronic database as a tool. Technical and financial investment initially and ongoing for the maintenance of such a system as well as the need for validation/curation of data are main impacts on the collection.
- The requirement for “operational capacity” relates to the collection's ABS instruments and can be supported by a standardized management system, an organizational manual with operating procedures or by audits. Implementation of guidelines, standards, codes of conduct, manuals and/or procedures are essential to comply with this requirement. The impact can be characterized mainly by personnel and financial investment and time for implementation efforts.
- The requirement for “certification of the collection” can be implemented by a 3rd party certification or accreditation according to a recognized standard. For this requirement as well, the implementation of a formal management and process system will be supportive to the registration process. A permanent obligation to allocate financial and human recourses to maintain certificates will influence collections.
- The requirement for “participation in international collection networks” can be implemented by a membership in networks and associations or by a partnership in network projects. The impact appears mainly in the involvement of human resources in network activities.

The required course of action towards a registration in the EU register will have impacts mainly in the fields of technology, personnel, time and finance.

The conformity of accessions of genetic resources is of crucial importance to the registration process. A compliant accession procedure will entail access data, legal documents, knowledge of rights and obligations and documentation of subsequent users. There are implementation options and supporting tools which can be chosen by collections to support this. These are mainly:

- use of formalised accession forms,
- databases and open access library/catalogues,
- electronic accession procedures,

- document management systems,
- systemized distribution management,
- data tracing and tracking.

All of the above-mentioned options will depend upon the stage of development of the collection, the type of collection and the size of the holding(s) of genetic resources. In summary, the impacts of registration are manifold. These are illustrated in the following figures. Prior to a registration, each collection should evaluate the potential impacts. To accompany this process with individual and appropriate implementation options and tools, a strategy should then be developed. This strategy should seek to keep the impacts in balance with the overall interests of the organization and to potentially gain benefits and synergies within the organization by establishing new tools and procedures.

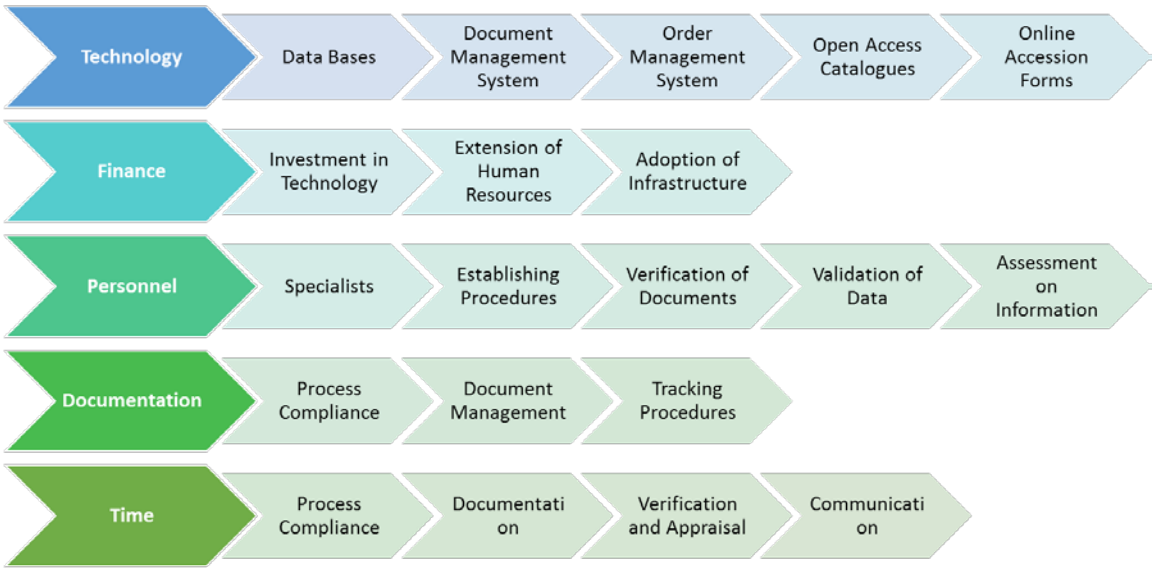

Figure 14: Overview of the Impacts on Collections from Registration

Registered collections are part of the due diligence system within the EU ABS Regulation. After registration, due diligence shifts from the users to the registered collection. Therefore, the duty to exercise due diligence in registered collections, especially for the accession of genetic resources, is a logical consequence as “the user is considered to have exercised due diligence as regards the seeking of information”, when “genetic resources are obtained from a collection registered” (Guidance Document Commission Notice 2016/C 313/01). This due diligence obligation is not imposed on non-registered collections as long as they do not act as a user.

It is expected that this shift of due diligence obligations will reduce the administrative burden and compliance requirements of users. For collections applying for registration, this will mean an increase in their administrative and compliance efforts as well as potential liability towards the recipients of genetic resources. A concept is needed to compensate this increased burden on collections. Appropriate benefits and incentives should be developed in order to avoid overload, which may result in underuse of registration as a tool for implementation of the EU

ABS Regulation.

When establishing the registration process, CNAs face similar issues. An alignment of the efforts on both sides will allow processes to be coordinated and harmonized. A deep insight into the processes of collections will support the CNAs in their decisions. Thus, a continuous, bilateral exchange of information and process models will foster a frictionless registration process. As collections mostly operate internationally, this exchange between collections and CNAs should not only occur at the member state level but at the European level. The following figure shows the identical approaches in the establishment of registration processes on both sides. Both CNAs and collections will have similar phases while establishing the registration process - including basic determinations, implementation and awareness-raising and execution of the registration. In these phases, funding need to be secured, consultancy and advice is needed on legal questions and operational or technical aspects. Additionally, an intensive communication strategy should be built up, approaching collections and users in academic and industrial sectors to inform and prepare them for their obligations arising from the EU ABS regime.

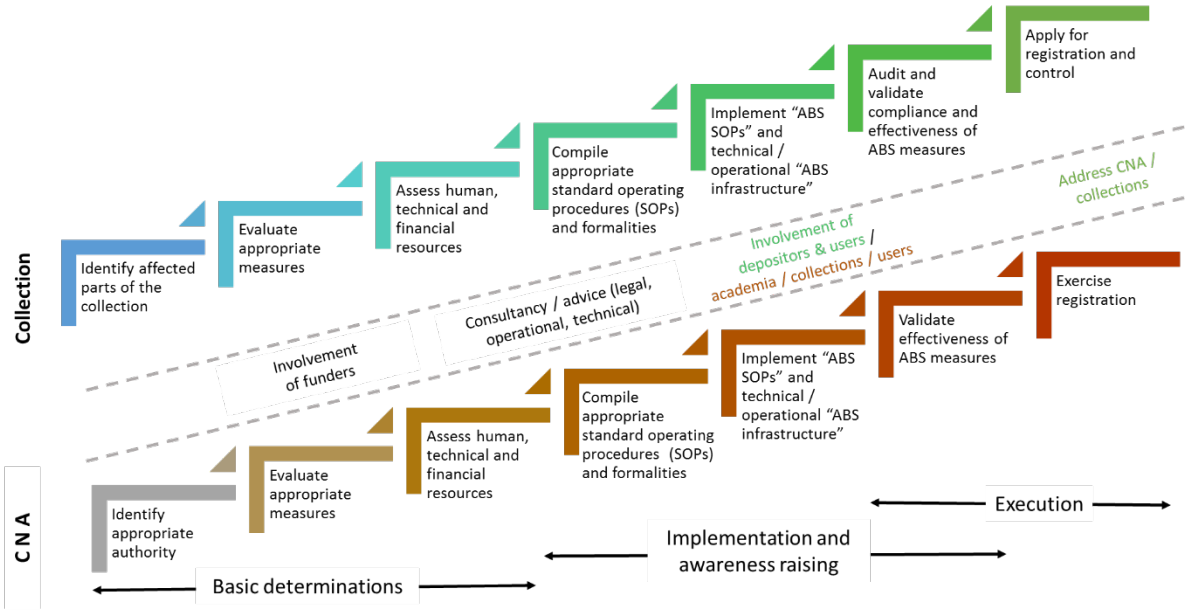

Figure 15: Approach towards the Registration Process

10. Summary of Discussions of Preceding Sessions and Working Group Results

An important part of the discussion in the preceding sessions and the following two working groups covered the issue of ABS compliance by collections. It was suggested that collections are generally nervous about non-compliance. Consequently, there is a high level of awareness about the Nagoya Protocol amongst collections with many collections already having internal systems and checks in place. However, there is very little data available about the level of compliance so that it is still possible that breaches of the EU ABS Regulation occur. On the other hand, it was noted that an assumption should not be made that genetic material is obtained illegally. Even though there could be possible instances of non-compliance, in future collections will most likely comply with the EU ABS Regulation.

The discussions also touched upon the specific role of collections and the fact that many collections do not use resources for research and development but simply collect and store them. Collections which adopt this business model are outside the scope of the EU ABS Regulation in terms of use. They are also not likely to be concerned with the subsequent activities of users and therefore it is questionable as to what measures should be taken where no utilization takes place.

While collections claim that obtaining all of the relevant documentation on the behalf of subsequent users of genetic resources would place an additional burden on them, the point was raised that the ABS concept has been in place since the Convention on Biological Diversity came into force in 1993 and therefore is not really new. In this context it was further noted that many collections do obtain some information about resources anyway, especially about when and where they were collected. This lead to the question whether the scope of the EU ABS Regulation is really the critical point for consideration.

Ultimately, it was agreed that people and institutions accessing genetic resources in provider countries have to comply with the national legislation of that country, irrespective of whether that legislation came into force before or after the Nagoya Protocol. It was pointed out that compliance, e.g. in terms of obtaining PIC and MAT, is more challenging for smaller collections. Furthermore, the real changes arising from the EU ABS Regulation are the due diligence obligations and the fact that CNAs can conduct checks on users. On this basis, the point was made that collections cannot assume that there are no PIC and MAT obligations for genetic material accessed prior to October 2014.

It was further suggested that these issues are not simply a matter of legality but also critical for the reputation of collections. It was noted that users place a lot of trust in collections, particularly public funded ones. The difference between public and private collections was noted. Whereas public collections receive, store and transfer genetic resources, private collections are less likely to provide resources to other users. As such, it might be expected that large public collections will become registered at some stage.

The discussions also covered the expectations of registered collections and how competent national authorities can guide them through the process of registration. It became apparent that collections are still not very clear about how far their obligations extend and exactly what documentation is required to meet the registration requirements. In particular, the question was asked whether the EU ABS Regulation requires registered collections to check the legal documents provided with genetic materials coming into their collections and whether these have been complied with. It was pointed out that this would be a particularly difficult task for

collections, especially for small collections with few resources.

Some specific examples were provided about what a registered collection should check when accepting genetic resources, i.e.

- if the documentation provided with the resource is correct,
- whether the permit was issued by the right institution and
- whether the permit matches the sample.

Repeatedly, concerns were raised about the extent to which a registered collection would be expected to check whether a user who obtains a genetic resource from the collection respects the contractual agreements under which the collection obtained the genetic resource. It was suggested that this would pose an excessive administrative burden on collections, if they are expected to do this. The language barrier was also raised in terms of provider country legislation but it was suggested that this would not be an acceptable excuse for non-compliance. It was concluded that if CNAs carry out checks of users who obtained genetic resources from a registered collection, according to the EU ABS Regulation, they should be able to assume that all conditions of Article 4(3) of this Regulation about seeking information were met, including the requirement to have a valid contractual agreement.

The discussions highlighted that legal certainty is needed for both collections and users. It was suggested that registration by collections may ultimately be a minor concern when one considers that PIC and MAT would be required from provider countries, even if due diligence obligations in the EU do not apply. It was also suggested that all collections should be prepared for compliance checks, either as a registered collection or as a potential user.

Further deliberations were made whether a partial registration in contrast to a full registration would relieve the collection from parts of the expected burden. However, it was estimated that the administrative measures would be equally high as general ABS processes would have to be established and implemented anyway. Additionally, a differing handling of genetic resources in a collection could bear conflicts and would complicate daily workflows Advantages of having non-registered parts in a collection could not immediately be seen.

This led to the question how to create incentives for collections to become registered. It was discussed what could be done to make registration more attractive for collections, although no concrete suggestions were made.

Finally, different issues of temporal and geographical scope were raised. Regarding the temporal scope it was noted that it is important for collections to take into account not only what happens after October 2014 but also the date when the provider country implemented its access and benefit sharing legislation, as there may have been PIC and MAT obligations in the provider country before the EU ABS Regulation took effect. In this context, the difficulty with establishing whether material was accessed before or after the Nagoya Protocol was raised and it was noted that experts would be needed to establish where genetic material came from and when it was collected etc. It was further noted that when a genetic resource is accessed from an ex-situ collection located in a Nagoya Protocol Party with access legislation and this country is the country of origin of the genetic resources, the time when the genetic resource was collected in-situ does not play a role for the temporal scope of the EU ABS Regulation.

Regarding the geographical scope it was suggested that when a genetic resource originally comes from a country without access legislation but an ex-situ collection holding this resource is located in a provider state with ABS access legislation, the provider country and not the country of origin might extend its rights to the genetic resources as the genetic material was acquired in accordance with the CBD.

Furthermore, it was concluded that if a new genetic resource has been developed, then the country of origin cannot extend its rights to this new resource.

A checklist was considered as a useful tool to help collections determine whether genetic material is within or outside of the scope of the EU ABS Regulation. In this context, the two working groups were provided with two case studies with several different variations, a matrix for assessing the applicability of the EU ABS Regulation to these case studies and a series of questions for discussion. The purpose of the exercise was to consider whether the matrix provided would be an appropriate tool for determining whether the EU ABS Regulation applied in a given situation or not and to identify any other relevant issues.

However, it became apparent that a lot of information is needed in order to determine whether an activity falls within the scope of the EU ABS Regulation or not. Participants indicated that they needed much more additional information than was provided e.g. about the researcher, the concrete activities, whether there is applicable access legislation in the provider country, the type of genetic resource etc.

11. Presentation of a German Technical Analysis on Implementation Options for Collections and their Users

Introduction to the MIRRI Research Project and History

Dunja Martin

ABS Compliance & Consulting, Germany

Launched in 2012, the pan-European Microbial Resource Research Infrastructure (MIRRI) is part of the BioMedical Science Research Infrastructure (BMS RI) of the ESFRI landscape. More than 40 public collections and research institutes from 19 European countries collaborated to establish MIRRI as a European Research Infrastructure Consortium (ERIC) under EU law. The transition phase of MIRRI started in November 2015 and it should become fully operational in 2017.

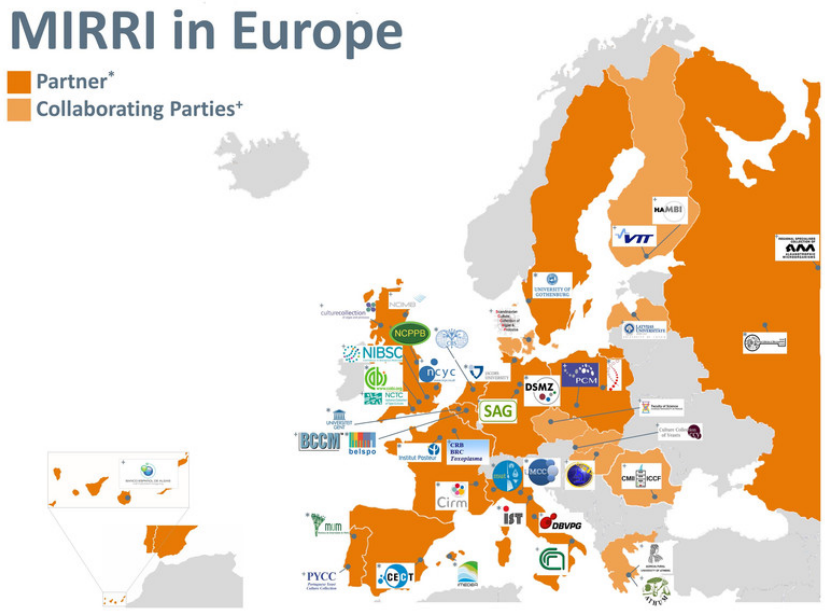

Figure 16: MIRRI Membership and Cooperation in Europe (© www.mirri.org/home.html)

By providing high quality microorganisms, the associated data and the broad expertise of the consortium partners, MIRRI aims to support research and development in the field of biotechnology. This will be achieved by adding value to known and still unknown microbial biodiversity and by providing novel sources and knowledge for the bioeconomy and bioscience. In its operations, MIRRI helps to translate innovative ideas into added value in order to address societal challenges in bio-science and bio-industry. It provides more than 350,000 microbial resources and comprehensive data, ensuring their legal compliance (regarding e.g. the Nagoya Protocol and ABS) and offering international experts as well as training opportunities.

MIRRI's vision is based on the development of strong trust in the legally compliant exchange of high quality genetic resources. An ABS policy statement and an ABS Best Practice Manual was developed for MIRRI member collections to commit themselves to the main objectives of the CBD and to comply with all applicable national and international laws or regulatory requirements for ABS. The MIRRI Best Practice Manual was agreed upon by all participating

service collections holding living microbial strains and their derivatives (e.g., DNA samples). As it had been developed in light of the (then) coming EU ABS Regulation, it was considered as offering the most extensive basis for the development of implementation options for collections and their users.

Concept of and Reasoning for the Technical Analysis

Dr. Dagmar Fritze and Dunja Martin

ABS Compliance & Consulting, Germany

Approach

A first analysis of the MIRRI ABS Manual showed that in order to establish implementation options, it would be necessary to adapt the structure, logic and contents of the Manual thoroughly so that it would be applicable in the broadest way. This meant, in particular:

- transposing applicability to all kinds of collections and genetic resources,
- adapting to the actual legal situation,
- being applicable on the national level and
- potentially having a model character for the needs of other EU member states.

The goal of the technical study was to analyse implementation options for collections and their users, which would support the objectives of the Nagoya Protocol and implementation of Regulation (EU) No 511/2014. Analysis of gaps as well as strengths and weaknesses of the consensus based MIRRI ABS Manual resulted in a concept that can serve as recommendations to support collections, their users as well as competent national authorities.

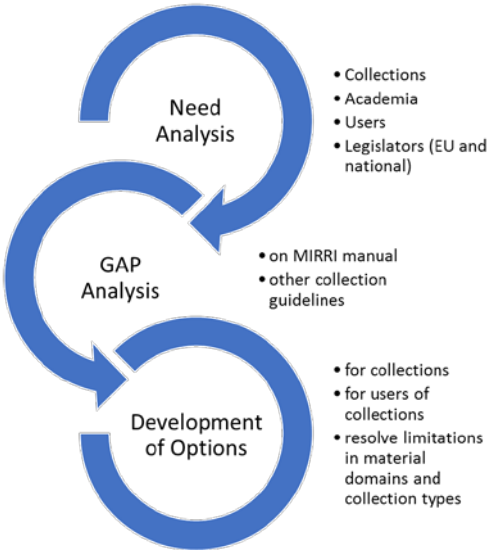

Figure 17: Need and Gap Analysis for the Development of Implementation Options

The emphasis of the technical analysis is thus on helping collections to fulfil their ABS duties and to help them to inform their users about their duties. At the same time, emphasis is also placed on providing detailed information for CNAs to support them in their enforcement duties. In this way, the document forms a basis for mutual cooperation. The final goal is to make the applicability of this technical analysis as broad as possible. Additionally, the intention is to have a document with a manual characteristic, which provides handling advice for daily practice in a collection.

For now, to give it a meaningful content, and to enable judgement on its future application, the focus is still strongly on microbial genetic resources. However, the document is structured in such a way that it can be opened up to embrace collections from other domains and with other types of genetic resources. In some places, the text already contains overarching passages that apply to other domains and material types. Nevertheless, further specifications may be desirable for other domains (e.g. adaptations of the text passages, additional new paragraphs and/or additional domain specific technical annexes).

Two approaches could be taken to arrive at an inclusive document providing recommendations for all types of collections. One approach, to our mind, would not be advisable, i.e. to break down the present contents to a minimum common understanding for all collections. While this could be done in a relatively short time, it would run the risk of being a meaningless document.

We, instead, would recommend another more practical and sensible approach that takes into account the diversity of collections and their mandates, i.e. to design an agreed general overarching “umbrella document” that would include common ABS aspects which are relevant to all types and kinds of collections. Within this, individual domain specific chapters should be added as needed. These would be adapted to the particular needs of the various domains e.g. zoological, botanical, microbial, algal, and other collections, resulting in a comprehensive, useful and presentable guidance document.

Structure

The overall structure of the draft technical analysis is briefly outlined below:

First, the different typologies and mandates of collections are described as well as the types of users and potential users of collections. This does not only help to understand the potential relevance of ABS to the work of collections but also provides the diverse collections with information to position themselves within the overall picture of ABS responsibilities.

In the following chapter, an overview and synopsis of the scope of Regulation (EU) No 511/2014 is given, including the cumulative applicability of the different elements of the scope. At the same time, it is made clear that while the EU ABS Regulation may not apply, the ABS related laws and regulations of the country of origin of a genetic resource in question may continue to apply.

The main body of the text includes detailed descriptions of situations and activities in the daily practice of a collection that may be relevant for ABS together with explanations as to their performance under ABS considerations. These include accepting genetic resources into the collection, processing the genetic resources for various purposes and supplying the genetic resources to third parties.

Special cases regarding the deposit of genetic resources by third parties in service collections are described as well as deposits resulting from in-situ sampling conducted by collection staff. The situation where genetic resources are temporarily held for reasons of analysis is explained as well as the differentiation between performing genuine collection work and performing collection based research work. The subjects of transparent and traceable documentation and proper data processing, which are of enormous relevance to ABS, are thoroughly addressed.

All described situations and activities are accompanied by detailed handling advice and instructions on how to design administrative and laboratory processes so that the Nagoya Protocol and the due diligence obligations under the EU ABS Regulation can be met.

To provide help for collections in determining whether their activities are within the scope of Regulation (EU) No 511/2014, excerpts from this Regulation and from the Guidance Document Commission Notice 2016/C 313/01, which are relevant for collection work, have been compiled in an additional chapter.

Based on the experience of the daily work in collections and other institutions holding genetic resources, typical use cases involving work with genetic resources have been integrated in the analysis.

Finally, a series of annexes with detailed flow diagrams are provided. These flow diagrams visualise the complete life cycle of a genetic resource, the necessary steps involved to comply with ABS requirements and documentation which needs to accompany a genetic resource from in-situ sampling/collection through to receipt of the genetic resource by a user.

Annex 1 is designed for users in general and for users as potential depositors of genetic resources. It provides recommendations for collecting material in-situ in a country that is Party to the Nagoya Protocol.

Annex 2 is designed for users who act as depositors of genetic resources and for collections that receive genetic resources. It provides recommendations for the deposit of genetic resources in a collection.

Annex 3 and **Annex 4** are directed towards collections and provide recommendations for accepting material from external providers for analysis and for the content of accession forms.

Annex 5 is designed for collections and their users as recipients of genetic resources. It provides recommendations for access to and supply of ex-situ genetic resources.

Annex 6 is designed solely for users as recipients of genetic resources. It provides recommendations for the utilization of genetic resources by users.

Importance of Collections in the Genetic Resources Value Chain

An important reason for the technical analysis was the position and functions of collections in the value chain of genetic resources. According to Article 1 of the CBD, the objectives of the Convention are to strive for the “conservation of biodiversity”, “sustainable use” of biodiversity and “access” to genetic resources as well as the fair and equitable “sharing of benefits” derived from their utilisation. By facilitating the legitimate exchange of genetic resources, collections play an essential role in the conservation of biodiversity as well as the sustainable use of genetic resources. PIC and MAT underpin this value chain and create an environment of trust and legal certainty.

The following figure shows the lifecycle of a genetic resource from its source to access, preparation for its sustainable use, utilization and potential commercialization. The green boxes show the cornerstones of the legal relationship between the country of origin of the genetic resource, access by researchers and utilization by users. This relational triangle is governed by PIC and MAT. Collections have a dual role, being located within the areas of analysis and preservation (blue boxes).

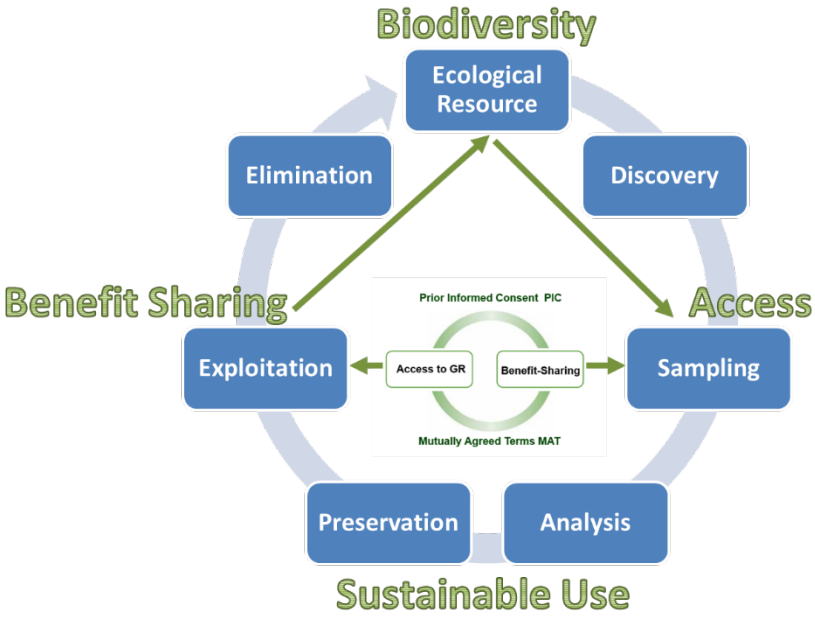

Figure 18: Lifecycle of Genetic Resources in Relation to the Nagoya Protocol

Preservation of pure cultures is a predominant characteristic in the lifecycle of genetic resources, as in-situ maintenance or conservation is not possible. Pure and authentic genetic resources which do not require re-isolation are needed for research and development. Appropriate preservation in a collection allows genetic resources to be maintained in the long term in an unaltered state, published data to be verified and genetic resources to be made available from neutral and competent places. In the microbial domain, reference strains, type strains, quality control strains and test strains must also be readily available for comparison and as archives for future studies. Overall, the deposit and preservation of genetic resources in collection plays an invaluable role in protecting biodiversity from being lost.

The lifecycle of genetic resources as outlined above illustrates the beneficiary role of research and collection work for researchers, users and countries of origin as the value of a genetic resource increases with each step within the lifecycle. A value chain can be generated, where the value of a genetic resource increases in particular in a public collection. The scientific and technical information gathered and provided by a public service collection together with legally relevant and legally required documentation brings the recipient of genetic resources the scientific and legal certainty for his envisaged activities.

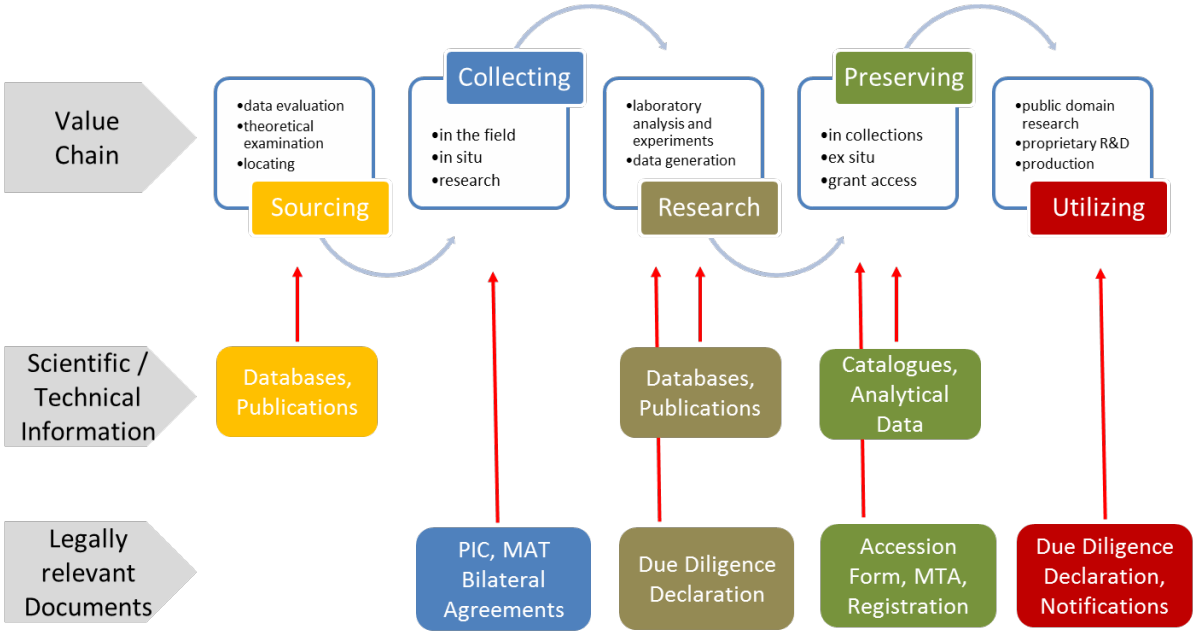

Figure 19: Generating a Value Chain for Genetic Resources

In this scheme, especially public service collections facilitate open and compliant access to genetic resources and data and thus serve as a gateway to utilization. In order to prove compliance with legal requirements, a collection will collect all of the necessary information at the time of deposit of genetic resources, as well as when handling them, preserving them and supplying them to others. This allows evidence of legal compliance to be tracked through all stages of the value chain. Information and documentation will be partly public (PIC, MAT, MTA) and partly confidential (laboratory and customer statistics). Disclosure will follow data protection regulations, but this information will be subject to review by national/legal authorities (due diligence, routine assessment, assessments by country of origin).

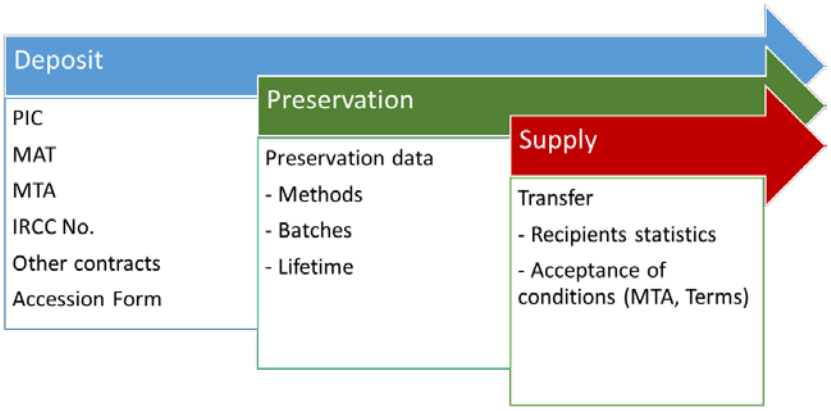

Figure 20: Evidence of the Legal Situation of Genetic Resources in a Public Collection

Relationship with EU Guidance Documents

The presented draft technical analysis needs to be positioned in the light of the Guidance Documents, which are being prepared by the EU Commission, as it will potentially lead towards recommendations for collections and their users. The Commission is presently work-

ing on individual Guidance Documents for various sectors, namely Food and Feed, Animal Breeding, Plant Breeding, Biotechnology, Biocontrol and Biostimulants, Cosmetics and Pharmaceuticals. Two further Guidance Documents are planned, namely for basic research and collections. All of these EU documents will focus on the utilisation of genetic resources in the sense of the Regulation (EU) No 511/2014. In contrast, the draft technical analysis presented here focusses on access to genetic resources before use. As such, there is no anticipated duplication of efforts.

List of Participants

First Meeting of the European Competent National Authorities Implementing the Nagoya-Protocol and the Corresponding EU ABS regulation

20 to 23 March 2017, INA Vilm, Germany

No.	Name	Institution / Address
1	Ahrlin, Pernilla	Environmental Protection Agency, Sweden
2	Dr. Becker, Anne	Robert Koch Institut, Germany
3	Beckett, Katie	Department for Business, Energy and Industrial Strategy, UK
4	Dr. Besenyei, Adrián	Government Office of Pest County, Hungary
5	Botlik, David	Government Office of Pest County, Hungary
6	Brandl, Klara	Environment Agency, Austria
7	Dadasiewicz, Pawel	Chief Inspectorate for Environmental Protection, Poland
8	von den Driesch, Marliese	Federal Office for Agriculture and Food, Germany
9	PhD Eek, Liina	Ministry of Environment, Estonia
10	Feit, Ute	Federal Agency for Nature Conservation, Germany
11	Frederichs, Ellen	Federal Agency for Nature Conservation, Germany
12	Fresta, Louis	Ministry for Sustainable Development, the Environment and Climate Change – Plant Health Directorate, Malta
13	Dr. Fritze, Dagmar	ABS Compliance & Consulting
14	Gardt, Sebastian	Global Nature Fund
15	Greiber, Thomas	Federal Agency for Nature Conservation, Germany
16	Haczek, Bozena	Ministry of the Environment, Poland
17	Hanke, Bettina	Robert Koch Institute, Germany
18	Heinsoo, Kris	Ministry of Environment, Estonia
19	Hervatin-Queney, Florence	Ministry of Higher Education and Research, France
20	Holsbeek, Ludo	Department of Environment, Nature and Energy, Flemish Government
21	Juul Jensen, Eva	Environmental Protection Agency, Denmark
22	Karger, Elizabeth	Federal Agency for Nature Conservation, Germany
23	Kearney, Michael	Department for Business, Energy and Industrial Strategy, UK
24	Kozlowska, Alicja	European Commission
25	Lohtander-Buckbee, Katileena	Finnish Environment Institute
26	Manka, Peter	Ministry of Environment, Slovak Republic
27	Martin, Dunja	ABS Compliance & Consulting
28	Rasmussen, Janne Schultz	Ministry of Industry, Labour, Trade and Energy, Greenland
29	Reinsalu, Piret	Environmental Inspectorate, Estonia
30	Rolfova, Eliska	Ministry of Environment, Czech Republic
31	Rusanen, Mari	Natural Resources Institute, Finland
32	Rutkowska, Boguslawa	Chief Inspectorate for Environmental Protection, Poland
33	Dr. Scholz, Amber	German Collection of Microorganisms and Cell Cultures (Leibniz Institute – DSMZ)
34	Stiegeler, Ramona	Federal Agency for Nature Conservation, Germany
35	Szuba, Gabriela	Ministry of Environment, Poland
36	Ujj, Zsuzsanna	Ministry of Agriculture, Hungary

No.	Name	Institution / Address
37	Wassink-de Ligt, Linda	Food and Consumer Product Safety Authority, The Netherlands
38	Yanakiev, Georgi	Ministry of Environment and Waters, Bulgaria
39	Dr. Zippel, Elke	Botanical Garden and Botanical Museum Berlin – Dahlem (University of Berlin)

Federal Agency for Nature Conservation

Insel Vilm
INTERNATIONAL ACADEMY FOR NATURE CONSERVATION

Program

Meeting of the European Competent National Authorities Implementing the Nagoya Protocol and the Corresponding EU Regulation

Isle of Vilm, Germany
March 20 - 23, 2017

After entry into force of the Nagoya Protocol and the corresponding Regulation (EU) No 511/2014 the EU member states are now obligated to take steps towards their operationalization. In several EU member states "competent national authorities" (CNA) are in the course of formation.

To foster this process and to be mutually supportive among the member states there is a great demand to exchange information on ongoing technical and structural processes as well as early implementation experiences. Therefore the Nagoya CNA–Unit of the German Federal Agency for Nature Conservation (BfN) provides a platform for a first informal meeting of the EU Competent National Authorities implementing the Nagoya Protocol and the corresponding EU Regulation.

This workshop will give an opportunity to identify, present and discuss implementation challenges as well as possible solutions, i.a. ideas for the development of plans using a risk-based approach to control users, potential best practices for collections seeking registration and reflecting fields of future collaboration between EU CNAs.

The output of the meeting will be a report containing abstracts of contributions of the experts as well as workshop proceedings including the collected views on different subjects to support the work of the CNAs in implementing the Nagoya Protocol and the corresponding Regulation (EU) No 511/2014.

Monday, 20.03.2017

Arrival of the participants at the Isle of Vilm

18.30 *Dinner*

20.30 **Welcome and brief introduction to the meeting**
UTE FEIT, Federal Agency for Nature Conservation

21.30 *Informal get-together*

Tuesday, 21.03.2017

08.00 *Breakfast*

I. State of play

09.00 **Results of COP-MOP2 related to the work of the CNAs**
ALICJA KOZLOWSKA, EUROPEAN COMMISSION

II. User controls – first country experiences

09.30 **Development of control plans (structure, content, etc.)**

- GERMANY: THOMAS GREIBER, FEDERAL AGENCY FOR NATURE CONSERVATION
- UK: KATIE BECKETT, DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY
- BELGIUM: LUDO HOLSBEEK, FLEMISH GOVERNMENT, DEPARTMENT OF ENVIRONMENT, NATURE AND ENERGY

10-min. contributions / integrated discussions

10.45 *Coffee / tea*

11.00 **Identification of users (data management, etc.)**

- UK: KATIE BECKETT, DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY
- GERMANY: DR. ELKE ZIPPEL, BOTANIC GARDEN AND BOTANICAL MUSEUM BERLIN DAHLEM (UNIVERSITY OF BERLIN), SEBASTIAN GARDT, GLOBAL NATURE FUND
- FINLAND: KATILEENA LOHTANDER-BUCKBEE, FINNISH ENVIRONMENT INSTITUTE

10-min. contributions / integrated discussions

12.30 *Lunch*

13.30 **Guided tour and walk through the nature reserve of the Island of Vilm**
DR. CHRISTIAN PUSCH, FEDERAL AGENCY FOR NATURE CONSERVATION

15.00 *Coffee / tea*

15.15 **"Risk-based" approaches and criteria**

- GERMANY: THOMAS GREIBER, FEDERAL AGENCY FOR NATURE CONSERVATION
- UK: MICHEL KEARNEY, DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY
- DENMARK: EVA JUUL JENSEN, AGENCY FOR WATER AND NATURE MANAGEMENT
- THE NETHERLANDS: LINDA WASSINK-DE LIGT, NETHERLANDS FOOD AND CONSUMER PRODUCT SAFETY AUTHORITY

10-min. contributions / integrated discussions

16.30 *Coffee/ tea*

16.45 **Control approaches and processes, first inspections**

- SLOVAKIA: PETER MANCA, MINISTRY OF ENVIRONMENT
- GERMANY: ELLEN FREDERICHS, FEDERAL AGENCY FOR NATURE CONSERVATION
- THE NETHERLANDS: LINDA WASSINK-DE LIGT, NETHERLANDS FOOD AND CONSUMER PRODUCT SAFETY AUTHORITY

10-min. contributions / integrated discussions

18.30 *Dinner*

20.00 *Informal get-together*

Wednesday, 22.03.2017

08.00 *Breakfast*

III. Registration of collections

09.00 **Lessons learned from a German expert study: Typologies and mandates of collections**

DR. DAGMAR FRITZE, DUNJA MARTIN, ABS COMPLIANCE & CONSULTING

09.45 **Discussion and national perceptions**

FIRST EXPERIENCES OF/WITH COLLECTIONS REGARDING ABS IMPLEMENTATION AND/OR REGISTRATION (CHALLENGES, PROBLEMS, APPROACHES, EXISTING TOOLS, ETC.)

- GERMANY: DR. AMBER HARTMAN SCHOLZ, GERMAN COLLECTION OF MICROORGANISMS AND CELL CULTURES (DSMZ)
- FRANCE: FLORENCE HERVATIN-QUENEY, MINISTRY OF HIGHER EDUCATION AND RESEARCH
- HUNGARY: ZSUZSANNA UJJ, MINISTRY OF AGRICULTURE
- POLAND: BOZENA HACZEK, MINISTRY OF ENVIRONMENT

10-min. contributions / integrated discussions

10.30 *Coffee / tea*

10.45 **Development of a register of collections and expectations**
ALICJA KOZLOWSKA, EUROPEAN COMMISSION

Discussion on diverse challenges

11.30 **Towards a registration process: use cases, approaches, tools and problems**
DUNJA MARTIN AND DR. DAGMAR FRITZE, ABS COMPLIANCE & CONSULTING

Background info and introduction to afternoon working groups

12.30 *Lunch*

13.30 **Break-out sessions**
DUNJA MARTIN AND DR. DAGMAR FRITZE, ABS COMPLIANCE & CONSULTING

14.45 *Coffee / tea*

15.00 **Presentation of working group results: recommendations for registration of collections (plenary)**

15.45 **Presentation of a German technical analysis of implementation options for collections and their users**
DUNJA MARTIN AND DR. DAGMAR FRITZE, ABS COMPLIANCE & CONSULTING

Discussion on diverse challenges, awareness raising and incentives

17.30 *Reception at the invitation of the German Federal Agency for Nature Conservation (BfN)*

IV. Way forward

20.00 **Reflection on further fields of CNAs cooperation**
ALL TOGETHER – (UTE FEIT, FEDERAL AGENCY FOR NATURE CONSERVATION)

21.00 *Informal gathering and farewell*

Thursday, 23.03.2017

06.45 – 09:00 *Breakfast*

The Isle of Vilm, 94 hectares in area, is a beautiful nature paradise, a Baltic Sea coast treasure. The island's natural beauty has long fascinated people. The first steps to protect its ancient forest from logging were taken back in 1812. In 1936, the Isle of Vilm was set aside as a nature reserve. Since 1990, it has been one of the core areas of the Southeast-Rügen Biosphere Reserve.