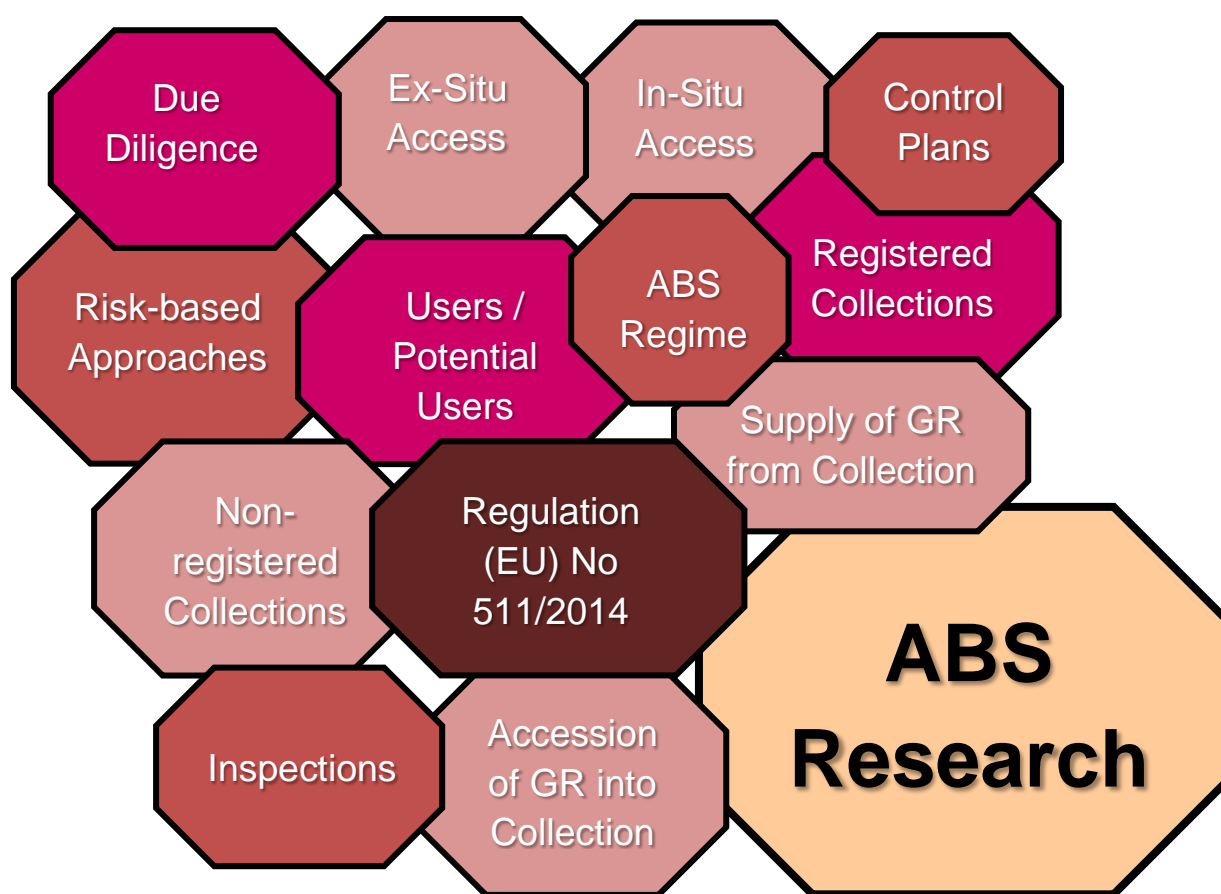


Ute Feit, Thomas Greiber and Elizabeth Karger (Eds.)

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

Final Report



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

**Final 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, 23 - 26 April 2018**

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Table of Contents

List of Abbreviations	5
1 Introduction to the Meeting	7
2 Implementation of Regulation (EU) No. 511/2014: Status Quo and Current Challenges	15
3 Risk-based Plans / Selection of Potential Users / Remote Inspections / Onsite Inspections	21
First Activities in Denmark.....	21
First Experiences in Selecting Users and Undertaking Remote Inspections in Germany	23
Evaluation of User Checks in 2017 in the Netherlands	31
Selection of Potential Users, Risk-based Plan and First Inspections in Poland.....	35
Situation in Sweden.....	39
4 Brief Update on Implementation Progress in other Member States	41
ABS Legislation and Implementation of the Regulation (EU) No 511/2014 in the Republic of Croatia.....	41
5 Practical Scenarios	43
Scenario 1: Breeding Companion Animals	43
Scenario 2: Use of Transgenic Mice	44
Scenario 3: Derivatives - The Product of Which Genetic Resources?	44
Scenario 4: Exercising Due Diligence – What to Do When the CNA in the Provider Country Does Not Respond	45
6 Round of “Stupid” Questions	47
7 First Registered Collection in the EU	53
8 Strict Liability for “Registered Collections”? Assessing Regulation (EU) No 511/2014	57
9 Application for Acknowledgement of Best Practice under Article 8 of Regulation (EU) No 511/2014: The CETAF Code of Conduct & Best Practice	71
10 Awareness Raising and Capacity Building: Measures to Inform/Involve User Sectors in Member States	79
Results of an Online Survey of (Potential) Users in Germany.....	79
Awareness Raising and Capacity Building – A German Project to Inform Collection Holders and Involve them in the Implementation of ABS.....	83
Awareness Raising and Capacity Building Measures to Inform/Involve Users in Poland.....	85
11 Way Forward and End of Meeting	87
12 List of Participants	89
13 Program	91

List of Abbreviations

ABS	Access and Benefit Sharing
ABSCH	ABS Clearing-House
API	Advanced Programmer Interface
BfN	Bundesamt für Naturschutz (German Federal Agency for Nature Conservation)
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities
CNA	Competent National Authority
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CISG	Convention on Contracts for the International Sale of Goods
DSMZ	German Collection of Microorganisms and Cell Cultures
EC	European Commission
EU	European Union
EU ABS Regulation	Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
EU Guidance Document	Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union
FAQs	Frequently asked questions
FLEGT	Forest Law Enforcement, Governance and Trade
IRCC	Internationally Recognized Certificate of Compliance
IT	Information Technology
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement

NFP	National Focal Point
NGO	Non-Governmental Organisation
Nagoya Protocol	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization
PIC	Prior Informed Consent
R&D	Research and Development
SNSB	Staatliche Naturwissenschaftliche Sammlungen Bayerns (Bavarian Natural History Collections)
SOP	Standard Operating Procedures
TÜV	Technischer Überwachungsverein (Technical Inspection Association)

1 Introduction to the Meeting

Ute Feit, Ellen Frederichs, Thomas Greiber

German Federal Agency for Nature Conservation

After the entry into force of the Nagoya Protocol and the corresponding Regulation (EU) No. 511/2014 (EU ABS Regulation), the Member States of the European Union (EU) are now obligated to take steps towards the operationalization of these legal instruments. Their implementation requires a multi-faceted approach, including *inter alia* the following activities: user identification and awareness raising, cooperation and exchange of information between the EU Member States as well as between EU Member States and provider States, interaction between EU Member States and the European Commission (EC), development and implementation of administrative procedures (including compliance checks), training of staff, data management etc.

Now that many of the EU Member States have enacted national implementing legislation and established their competent national authorities (CNA), 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 EU Member States.

Against this background and following a successful first meeting of European CNAs last year in Germany, the German CNA – a designated unit at the Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) – organized another informal meeting of the EU CNAs implementing the Nagoya Protocol and the EU ABS Regulation from 23 to 26 April 2018 at BfN's International Academy for Nature Conservation, located on the Isle of Vilm, Germany.

Purpose of the Meeting

The Vilm meeting complemented the half-day meetings of the EU CNAs, which occasionally take place before the EU Access and Benefit Sharing (ABS) Expert Group meetings in Brussels. It provided an ideal opportunity to identify, present and discuss challenges as well as possible solutions on all relevant topics related to the implementation of the Nagoya Protocol and the EU ABS Regulation, in particular on the application process for the first registration of a collection under the Regulation, experiences with user controls, information on best practice for exercising due diligence and awareness raising and capacity-building activities.

Beyond that, this second meeting of the EU CNAs was another important step towards fulfilling the obligation of the Member States under Article 12 of the EU ABS Regulation in terms of cooperation. It should also send 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 United Nation's Sustainable Development Goals, in particular Goal 2.5.

Participants and Workshop Format

ABS experts from 12 EU Member States (Sweden, Belgium, Croatia, Denmark, Spain, Poland, Finland, Austria, Czech Republic, Hungary, The Netherlands and Germany) and the EC joined this second meeting to discuss legal and practical issues arising from the establishment of the CNAs and the implementation of the EU ABS Regulation. The workshop was primarily addressed to representatives of the CNAs of the EU Member States. Additionally, experts from a university and two collections were present to provide technical input.

The meeting was treated as an informal workshop, the aim of which was to exchange ideas and not to reach (political) consensus on individual issues. The participants of the meeting benefited from a lively exchange of information, with even small implementation steps or advances by one CNA being very helpful for others. The informal setting of the meeting was seen as a major advantage as it gave participants the opportunity to speak freely.

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.

The meeting resulted in this report. Its objective is to highlight the challenges faced by CNAs with on-the-ground ABS implementation and the progress that has already been made in terms of operationalizing the Nagoya Protocol and the EU ABS Regulation. These workshop proceedings, including the collected views on different issues, are published for the benefit of both CNAs and other ABS stakeholders. 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.

Key Issues and some Outcomes

The following summary provides a brief overview of the key topics discussed during 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 section are based on the notes of the person who recorded the minutes (Ms. Elizabeth Karger) and therefore may not fully reflect the opinions or concerns of the participants.

The selection of topics and the meeting contributions from several States confirmed once again at this second meeting that the EU Member States are facing similar challenges and problems on their way to implementing the Nagoya Protocol and the EU ABS Regulation and that such a reciprocal exchange of information is mutually supportive.

Before the first session, a representative of the EC presented an overview of the status quo of the implementation of the EU ABS Regulation in the Member States based on the national reports that were submitted to the EC and other information obtained through meetings between the EC and national CNAs in Brussels. The current and future challenges for implementation were also identified.

The meeting then focused on an exchange of CNA-experiences on the so-called "risk-based" controls and inspections including the selection of users. After the controls section, the afternoon of the first day was reserved for any implementation progress and specific implementation problems by the EU Member States. The discussions were based on four practical scenarios and a question round (the so-called "Round of Stupid Questions", in which all questions were thematically possible).

On the second day, the first successful application by a collection for registration in the EU was presented as well as the potential legal liability of registered collections through registration. The other main topics were the application for recognition of best practice by the Consortium of European Taxonomic Facilities (CETAF) and the need for awareness raising and capacity building measures to inform/involve user sectors.

▪ **Risk-based Plans/ Selection of Potential Users/ Remote Inspections/ Onsite Inspections**

A major focus of the first day of the meeting was on institutional structures and procedures for user compliance checks (Article 9 of the EU ABS Regulation), including the development of risk-based plans, the selection of potential users, and remote and onsite inspections. One year after the first Vilm meeting of the CNAs in 2017, it was clear that significant progress had been made.

Several Member States shared their progress for the benefit of the other CNAs:

- The Danish inspection plan for 2018-2019 was presented as well as the current process of identifying potential users of genetic resources in Denmark from 8 different sectors. Potential users were identified by consulting the Danish central business register, resulting in the identification of 50,000 potential users. The Danish CNA explained how this number was reduced to 644 potential users, who will be contacted and requested to complete a questionnaire on their use of genetic resources. The Danish CNA indicated that some inspections may also be conducted in 2018 if time and resources allow for it.
- The German CNA also contributed on its compliance checks under Article 9 of the EU ABS Regulation, which started at the beginning of 2018. It is planned to conduct checks of 10 institutions from 8 different user sectors this year plus 2 institutions that will be checked on the basis of substantiated concerns. The compliance checks will mainly be conducted remotely, i.e. through written communication. However, at least 8 on-the-spot checks (one institution per sector) will be carried out. The contribution in this report outlines the approach taken by the German CNA to identify and select those institutions to be checked and the first experiences gained through a remote check in the cosmetics sector.
- The starting point for checks in The Netherlands was the entry into force of the Nagoya Protocol Implementation Act in April 2016. In 2017, twenty checks on compliance with the Nagoya Protocol and EU ABS Regulation were carried out. Whereas the focus in the first round of checks was on plant breeding, the focus in the second round of checks was on flower farming. The inspections were conducted by two people, including inspectors responsible for phytosanitary inspections and inspectors from the

nature conservation department. The contribution in this report provides further information on the criteria for selecting the companies as well as on some results from the inspections.

- In Poland, the implementing Regulation on the detailed scope of user controls (Article 4 and 7 of the EU ABS Regulation) entered into force on 1 February 2018. In 2018, inspections will be carried out at 80 institutions/companies in Poland. Companies selected for the user checks come from three universities and research institutes financed from public funds, the pharmaceuticals sector and the cosmetics sector. The contribution provides more information on the way potential users in Poland were selected and the outcome of the first inspections at two universities.
- The Swedish-CNA is currently working on identifying potential users and is setting up a register. With respect to commercial users, the register is almost complete, but it was noted that it is not easy to identify these users because it is difficult to get the necessary information. Sweden will send out a questionnaire to potential users to determine which ones are actually users within the scope of EU ABS Regulation. Regarding non-commercial users in Sweden, work is in progress but before it can be continued, it needs to be established who is legally responsible for due diligence obligations at these higher education institutions.

The discussions in this session showed that many CNAs are still finding it challenging to develop appropriate and practical measures for the identification of users of genetic resources that fall under the EU ABS Regulation and at the same time to raise awareness amongst different user sectors. The session also highlighted some of the technical complexities of successfully implementing compliance checks given the limited resources (small budgets and few staff) 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 inspections by several Member States. During the discussions, there was also some focus on universities, the need to determine who are the responsible people within those institutions, and their role in creating top down initiatives such as policies, internal procedures, codes of conduct, training etc. so that university researchers can meet their obligations under the EU ABS Regulation.

▪ **Country Updates**

In this session, short updates on implementation were provided by Austria, Belgium, Croatia, the Czech Republic, Finland, Hungary, and Spain.

A contribution to this report has been provided by Croatia which outlines the existing national ABS legislation and the division of administrative responsibilities.

▪ **Practical Scenarios**

During the session “Practical Scenarios” four short cases were presented by individual participants and subsequently discussed. The aim of the discussion was less concerned with find-

ing a comprehensive solution to the respective scenario but rather the identification of implementation issues and the identification of points that need further clarification.

The cases covered the following topics:

- The first case specifically focused on the breeding of domestic animals using newly introduced genetic resources. A number of issues were highlighted, such as unclear terms and how to reach private actors who are not highly regulated or normally recorded in official registers. Also, the relative importance of this group within the whole spectrum of actors was questioned and how much effort should be invested into user checks in this sector by the CNAs.
- The second scenario was about the use of transgenic mice for R&D purposes and specifically to research brain disorders and signalling molecules that are the same in all animals.
- The next practical scenario related to the interaction of two genetic resources, namely a virus and a rabbit. The virus was used to stimulate a reaction in the rabbit's cells, namely the formation of antibodies, which were then used to identify the virus. The discussion focused on which genetic resource the antibodies (derivatives) could be attributed to, i.e. the rabbit or the virus.
- The last scenario dealt with the question of what to do if access requirements are unclear and the CNA in the provider country does not respond to requests for information etc. There were quite different views on how users can deal with this situation and the discussion was left open-ended.

▪ **Round of “Stupid” Questions**

In the final session of the first day, eight questions and/or discussion items identified by the meeting participants to help with their CNA work were briefly discussed. The aim of this session was not to find concrete answers to these questions but rather to identify implementation issues and points that require clarification.

The questions covered the following topics:

- unintentional access to bacteria brought into the EU by humans, e.g. on a dead body which has been repatriated,
- the scope of the term “research and development”,
- whether dairies and breweries can be regarded as users of genetic resources when they develop new products based on bacteria received from the food and feed industry,
- whether the EC has considered creating incentives for collections to become registered,
- what to do about resources from disputed areas, e.g. Taiwan,
- whether CNAs should be checking Mutually Agreed Terms (MAT),

- whether CNAs should provide official confirmation that there is no access legislation in their country, and
- the implications for user checks if a person's activities are actually outside the scope of the EU ABS Regulation.

The questions and a summary of the related discussions can be found in the corresponding part of this report. Again, it should be noted that also these informal discussions were conducted with the aim to exchange ideas and not to reach (political) consensus on individual issues.

▪ **Registration of Collections under Article 5 of Regulation (EU) No. 511/2014 – First Application**

A major focus of the second day of the meeting was on the successful application process for registration of a collection under Article 5 of the EU ABS Regulation.

The Leibniz Institute DSMZ GmbH (German Collection of Microorganisms and Cell Cultures, DSMZ) submitted an application to the BfN in November 2017. The 14-page application (as well as 11 supporting documents) was officially approved by the BfN on 18 March 2018 and has now been registered by the EC as the first official entry in the EU Register of Collections. The application took around four months to prepare by a two-person science-legal team. The DSMZ was asked to describe the process and the challenges in becoming the first registered collection in the EU. For more details, see the related contribution in this report.

In the discussion, it was noted by participants that there has been little interest from collections in becoming registered, but the registration of collections was an important part of the EU's vision when developing the EU ABS Regulation as these collections are intended to help users to obtain genetic material that has been obtained in accordance with the Nagoya Protocol. Registered collections are an important intermediary and one way of increasing transparency in the value chain. It was also noted that registered collection and best practices, although voluntary measures, support both CNAs and users as well as reducing the risk that illegal genetic material is used in the EU.

▪ **Potential Liability of Registered Collections – Legal Implications of Article 4.7 of Regulation (EU) No 511/2014**

The basis for the presentation on the potential liability of registered collections was a legal study, which was commissioned by the BfN and carried out by the University of Oldenburg in September 2017. This legal analysis explored the question if the liability of *ex situ* collections is increased by registration under Article 5 of the EU ABS Regulation.

The motivation for commissioning the study was the recognition that hardly any collections had made use of the possibility of applying for registration under Article 5. It was thought that the reluctance of collections to become registered could be due to the fear of increased liability, which is not specifically regulated by Article 5 of the Regulation. Without registered collections, a significant portion of the EU's Nagoya Protocol implementation approach is miss-

ing. Therefore, it was considered necessary to clarify whether Article 4.7 of the EU ABS Regulation actually creates an increased liability risk for registered collections

The presentation by the University of Oldenburg covered three distinct questions:

- Do Article 4.7 and Article 4.5 of the EU ABS Regulation impose strict liability on registered collections?
- What exactly is the standard of care required by registered collections?
- Can collections limit their liability via contractual clauses?

The related contribution in this report summarizes the results of the legal analysis, the full version of which is also available in German at: https://www.bfn.de/fileadmin/ABS/documents/ABS_Dokumente_ab_September_2015/20180618_Haftung_Registrierter_Sammlungen_gemaess_VO_EU_Nr.511_2014_.pdf.

In the discussion on the topic of liability, it was highlighted, among other things, that registered collections are not a checkpoint. Their main function is to secure information and to lower the risk that genetic resources have been obtained in contravention of ABS rules. It was stated that the way to lower this risk is to provide documentation, which is an improvement on the past, where there was little or no documentation accompanying genetic material.

▪ **Best Practices under Article 8 of Regulation (EU) No 511/2014 – Application for Recognition by CETAF**

The next presentation was about the application by CETAF for acknowledgement of the "CETAF Code of Conduct & Best Practice" as Best Practice under Article 8 of the EU ABS Regulation.

Best practices which have been recognized by the EC in accordance with the EU ABS Regulation play an important role in exercising due diligence. An application for recognition of Best Practice may be made to the EC by associations of users or other interested stakeholders.

CETAF is an association of 59 Natural History Collections and Botanic Gardens, which is represented in 21 European countries, including countries outside the EU. The CETAF Code of Conduct and Best Practice was designed to support CETAF members in developing compliance policies and processes at an institutional level. The official application for recognition under Article 8 was first submitted to the EC in January 2016.

In his presentation, the CETAF representative first outlined the content and benefits of the CETAF Code of Conduct and Best Practices for its members and the Nagoya implementation process. Afterwards he described the ongoing process of applying for recognition of CETAF's Code of Conduct and Best Practices by the EU Commission. The corresponding contribution in this report contains further detailed explanations of the entire process and its challenges.

In the discussion, the EC confirmed that it has circulated the current version of the Code of Conduct and Best Practice and is now waiting for comments from the Member States. Furthermore, it was emphasized - among other things – that when the CNAs do user checks, the presence of recognized best practices will be taken into account. It establishes a certain

amount of trust, shows that due diligence is taken seriously and can increase the credibility of collections and taxonomists in the EU, potentially shielding them from claims of biopiracy or being a loophole by provider countries or NGOs.

▪ **Awareness Raising and Capacity Building – Measures to Inform/ Involve User Sectors**

Awareness raising and capacity building measures are necessary for the successful implementation of the Nagoya Protocol. The final session of the CNA meeting contained three brief contributions on this subject.

- The German CNA presented the results of an online survey of (potential) users in Germany, which was conducted from August to October 2017. The main purpose of the survey was to determine the relevance of the Nagoya Protocol and the EU ABS Regulation to potential users and their level of awareness regarding their due diligence obligations. The survey was intended to raise awareness and it helped the German CNA to get an impression of users and how well-prepared they are to meet their obligations. Finally, it clearly showed that there is a need for further awareness raising measures.
- After that, the German CNA presented a second project which is currently running and was developed to tackle some of the awareness raising and capacity building processes that are needed. The project is aimed at holding a series of one-day seminars with various lectures and different training modules designed to inform and support collections in Germany with respect to the challenges they face with the implementation of the Nagoya Protocol and the EU ABS Regulation.
- The last contribution of the meeting came from Poland. The representative of the Ministry of Environment informed the participants that Poland has undertaken many actions to raise awareness of user obligations, including the organization of conferences, workshops, training sessions and bilateral meetings with various interested sectors and institutions, which has led to growing cooperation and understanding between authorities and the potential users of genetic resources.

2 Implementation of Regulation (EU) No 511/2014: Status Quo and Current Challenges

Mery Ciacci

European Commission

This presentation provided a first overview of the status of the implementation of the EU Regulation No 511/2014 (EU ABS Regulation) in the European Union (EU) Member States as well as of the current and future challenges for implementation that have been identified.

The presentation started with a brief introduction of the ABS concept, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the EU ABS Regulation. This introduction aimed to provide some conceptual insights on ABS under the Nagoya Protocol and a brief synthesis of the core provisions of the EU ABS Regulation. It addressed, in particular, those participants from Competent National Authorities (CNA) of the Member States who are mainly involved in the enforcement of the provisions of the EU ABS Regulation. The presentation then focused on the following aspects:

- institutional framework: which Member States have designated their CNAs, what tasks have been given to the designated CNAs and the current status of the designation process in other Member States;
- legislative measures: which kind of penalties Member States have adopted to sanction infringements of the due diligence obligation in order to implement Article 11 of the EU ABS Regulation;
- administrative measures: what measures Member State have taken to implement Article 7 on the monitoring of users' compliance; and whether Member States have adopted a risk-based plan for checks on users as required by Article 9 of the EU ABS Regulation;
- cooperation among Member States CNAs and cooperation between Member States' CNAs and the competent authorities in third States (Article 12) and the adoption of complementary measures to raise awareness (Article 13);
- figures concerning the enforcement of core provisions, such as the number of checks carried out in some Member States as well as collections' requests to become a registered collection under Article 5 of the EU ABS Regulation.

The presentation was based on the data contained in the national reports submitted to the European Commission (EC) by Member States in accordance with Article 16 of the EU ABS Regulation. At the time of the meeting in Vilm, 22 Member States¹ had submitted their national reports. In order to give a comprehensive picture, updates provided by Member States during the CNA meeting held in March 2018 in Brussels were also included in the presentation.

¹ AT, BE, BG, CZ, DE, DK, EE, ES, FI, HR, HU, IE, LT, LU, MT, NL, PL, PT, SE, SI, SK, UK

As far as it concerns the institutional framework, 19 Member States had formally designated their CNA by April 2018.² Different solutions have been identified, which vary according to national constitutional contexts: some Member States have identified one competent authority, while others have designated more than one institution. In some cases, additional agencies and authorities, which support the work of the competent authorities, have also been identified.

The CNAs identified deal with the following tasks:

- receiving due diligence declarations under Article 7.1 and 7.2;
- transmitting information to the ABS Clearing-House (ABSCH) under Article 7.3;
- carrying out checks on compliance in line with Article 9;
- recognition and verification of registered collections;
- cooperation with third countries under Article 7.3;
- implementation of complementary measures under Article 13 (awareness raising, training activities, guidance to users etc.).

Member States who have not designated their CNAs claim to be in the process of designating them. Most of them have identified the competent authorities, but they are still waiting for the adoption of the formal act of designation. Member States where competence on environmental issues is found within different administrations at different levels (such as the regional or local level) indicated that coordination among these different institutions is necessary and that it can entail a lengthy designation process. Other Member States signalled that it was difficult to identify the appropriate authority for the new tasks created by the EU ABS Regulation.

As far as it concerns the implementation of Article 11 of the EU ABS Regulation, 18 Member States had established penalties by April 2018. A variety of penalties can be observed, since Member States have opted for different solutions ranging from administrative fines³ to criminal sanctions.⁴ Some Member States foresee a combination of administrative fines for less severe offences and criminal sanctions for more severe offences.⁵ The range for these administrative fines is quite broad (from 510 euros to 2.000.000 euros) and criminal sanctions can also range from fines to imprisonment. One Member State also foresees the skimming of profits as an additional sanction.⁶ In order to establish whether an offence is of low, medium or high importance, Member States have often taken into account existing domestic legislation on environmental offences. In addition, the possibility of a remedial notice is foreseen by all of the 18 Member States (in line with Article 9.6 establishing that where, following the

² BG, DE, DK, EE, ES, FI, FR, HU, LT, LU, MT, NL, PL, PT, SE, SI, SK, RO, UK

³ BE, BG, DE, EE, ES, FI, HU, LT, LU, MT, NL, PL, PT, SE, SI, SK, UK

⁴ BE, DK, FI, LU, MT, NL, SE, UK

⁵ BE, FI, LU, MT, NL, SE, UK

⁶ DE

checks shortcomings have been detected, CNAs shall issue a notice of remedial action or measure to be taken by the user).

13 Member States have adopted administrative measures to request all recipients of research funding to file a due diligence declaration. This request, which implements the provision concerning the checkpoint at the stage of research funding (Article 7.1, the so called 1st checkpoint), is done via several means: through a website or enacted in the law or other legislative measures, or by direct request. A combination of these means is also foreseen as a possibility. Member States have not established additional checkpoints.

Implementation of Article 9 on checks on user compliance is still rather slow. Indeed, only 4 four Member States had adopted a risk-based plan for checks on users⁷ by April 2018. Other Member States reported that they are working towards the development of a risk-based plan for checks. Identifying the risk factors seems to be a common challenge faced during the preparation of these plans. However, most Member States are still in the process of identifying potential users.

Applications to become a registered collection under Article 5 of the EU ABS Regulation have been received by 2 Member States.⁸ Some Member States also reported having received a few requests for information about the Register of Collections, but collections' interest in this instrument remains rather low. Uncertainty regarding the exact standards to be fulfilled, the potential financial and/or administrative burdens to meet the registration requirements, the potential risks concerning the collection's liability and a lack of understanding of the added value of becoming a registered collection have been identified as reasons for such a low interest.

Cooperation among Member State CNAs is an ongoing process in 13 Member States, which are engaged in exchanging information and experiences, discussion on the interpretation and implementation of the provisions of the EU ABS Regulation as well as the organization of workshops, conferences and CNA meetings. In contrast, little cooperation is taking place among Member State CNAs and Nagoya Protocol CNAs in third States.

Activities to raise awareness are taking place in most Member States. They consist of the organization of seminars, conferences and workshops to introduce the ABS concept, the Nagoya Protocol and the EU ABS Regulation to both commercial and non-commercial users. Despite the increasing number of these activities, awareness raising is still needed in the EU Member States, in particular for non-commercial users, who are often reluctant to accept that ABS obligations may apply to them as well.

In terms of enforcement of the compliance measures of the EU ABS Regulation, some progress has been made but this remains at an early stage. So far, no due diligence declarations have been submitted and no checkpoint communiques have been transmitted to the ABSCH. Checks have been performed in 4 Member States in the form of on-site visits and inspections.⁹ No infringements were detected.

⁷ EE, NL, SK, UK

⁸ DE, MT

⁹ EE, NL, SK, UK

Overall, it can be observed that the implementation and the enforcement of the EU ABS Regulation are still at an early stage. Several challenges can be identified for the implementation of the EU ABS Regulation. First, the lack of designated CNAs is an obstacle to moving forward with the implementation of the other provisions of the EU ABS Regulation. Further, insufficient financial and human resources are an obstacle. Most Member States have to rely on a small number of specialized personnel. Due to limited financial resources, some Member States rely on existing personnel who are also working on other subjects.

Other challenges have also been identified at the policy level, such as the continuous need for awareness raising and the ongoing work on defining the boundaries of the scope of the EU ABS Regulation. On this last point, the presentation was concluded with a brief overview on the current status of discussions on some cross-cutting and sectoral issues which are still considered unresolved.

Discussion

In the discussion, there were a couple of questions about the process followed by the European Commission (EC) with respect to the national reports. One participant noted that it would be possible for CNAs to have different understandings of the requirements for the report format. The EC confirmed that it had simply analysed the reports provided by the Member States and created a document for the Parliament, but it had not posed any additional questions to the Member States. However, it was noted that if the EC needs clarification on any points, it is possible that it would request further information from the Member States.

During the discussion, the Czech CNA clarified that the Czech Republic does not intend to have access legislation.

The topic of unresolved issues was raised. It was acknowledged that these issues are complex and not easy to resolve, especially as various approaches would be possible. The importance of having consistency across the European Union (EU) and ensuring that CNAs do not deal with these issues in different ways was highlighted. One participant noted that the discussions on unresolved issues tend to go around in circles but cannot continue indefinitely. However, another participant added that these discussions have been very useful for gaining a sense of the actual practice by users of genetic resources. The EC suggested that there is a growing reluctance among the Member States to take a position or express their views on these unresolved issues, but the Commission needs the Member States' opinions on these issues. Another participant noted that there could be different possibilities for dealing with these issues, e.g. through voting or the EC could ascertain.

The discussion then focused specifically on the issue of large scale screening. One participant noted that discussions on this issue thus far have focused on the methodology but not on the results and how they are used. This participant suggested that if there was a focus on what is done with the results, it may be possible to find specific ways of dealing with the issue for different sectors. It is noted that large scale screening is not necessarily intended for "utilisation", e.g. in the case of monitoring in protected areas.

Although not mentioned in the presentation, the issue of the draft sectoral guidance documents was also raised. It was confirmed by the EC that there will not be seven separate sectoral guidance documents but that some guidance documents will be developed. It is not yet

clear how many documents there will be. It was noted that there was useful content in the existing draft documents and that some of this could possibly be reused but at this stage, it is not clear what form the final guidance documents will take, e.g. inclusion of criteria, cases and possible solutions etc. A couple of participants indicated that it would be a pity not to have specific guidance documents. One participant noted that despite the unresolved issues, the draft guidance documents provide a lot of answers to many questions and therefore have been very helpful for CNAs and users.

It was repeated during this discussion that the purpose of the Vilm meeting was to exchange information and improve common understandings but that no formal decisions would be reached.

3 Risk-based Plans/ Selection of Potential Users/ Remote Inspections/ Onsite Inspections

First Activities in Denmark

Eva Juul Jensen and Gry Errboe

Danish Environmental Protection Agency

The Danish inspection plan for 2018-2019 was presented as well as the current process of identifying potential users of genetic resources in Denmark from the following 8 sectors: bio-control and biostimulants, biotechnology, cosmetics, plant breeders, animal breeders, pharmaceutical industry, food and feed, and upstream users.

Potential users in these 8 sectors were identified by consulting the Danish central business register. From this register, more than 50,000 potential users were identified. By focusing only on the companies with 20 employees or more, the number of potential users was reduced to 1.096 companies/institutions. This group was analysed and companies that are certainly not conducting research and development (R&D), e.g. bakeries and manufacturers of agricultural machinery, were filtered out, which brought the number of potential users down to 644.

The Danish Competent National Authority (CNA) contacted these 644 potential users in writing and informed them about Access and Benefit Sharing (ABS) regulations and the relevant user obligations. These potential users were requested to respond to the letter and provide reasons as to why they are not users of genetic resources within the meaning of Regulation (EU) No 511/2014 (EU ABS Regulation). The letter is formulated in such a way that any recipients who do not respond to the letter will automatically be registered as a potential user of genetic resources, meaning that they could potentially be the subject of a user check by the Danish CNA.

The response rate to the first letter which was sent out to 644 potential users was 46%. The Danish CNA has received many inquiries in response to the letter and has helped potential users to clarify whether they are users of genetic resources within the meaning of the EU ABS Regulation or not. The potential users who have not responded to the letter and the ones who have not justified why they are not a user will be contacted in writing again before being registered as potential users.

Denmark also presented the next steps for the national ABS implementation in 2018-2019, which will involve more communication and awareness raising activities about the EU ABS Regulation and the commencement of the inspections.

Discussion

The Danish CNA confirmed that the purpose of the register is to have a list of potential users (registered by number) and that this list also includes academic institutions, namely two universities. These academic institutions received the same letter as other potential users, i.e.

companies etc. It was noted that it was not obligatory for these potential users to respond to the letter. According to the Danish CNA, there is some confusion at universities about how to deal with the questionnaire and how to spread the message about user obligations to their researchers. At this stage, it is not necessarily clear to these institutions who should deal with these issues, suggesting that there is a lot of awareness raising that needs to be done in the academic sector.

The Danish CNA indicated that they have started with the questionnaire and if there is time and sufficient resources, some inspections may also be conducted in 2018. A couple of CNA representatives also indicated that they have very small budgets and few staff, which limits the number of checks that can be done each year. A couple of participants indicated that they have received explicit directions to conduct inspections in such a way that it increases efficiency, e.g. by finding synergies and combining user checks under the EU ABS Regulation with other types of regulatory inspections.

One participant focused on the method used by the Danish CNA to limit the number of potential users. It was pointed out that filtering out potential users based on the number of employees, i.e. 20, may be a pragmatic way for the CNA to deal with the number of checks but it is also somewhat random. It was suggested that there are many biotechnology start-ups with just a few people that are more likely to be within the scope of the EU ABS Regulation than some bigger companies that simply use genetic resources as an ingredient for production but not for R&D. It was acknowledged that some strategy is needed to reduce the number of potential users to a manageable amount because CNAs cannot send out 50,000 letters or deal with all of the responses. The Danish CNA agreed that for practical reasons it is legitimate to narrow down the field in the beginning and that it can be enlarged again at a later stage.

Although the CNAs have identified many potential users, one participant suggested in the discussion that the actual number of users of genetic resources could be much higher and that a number of potential users could potentially have been missed.

The Danish CNA indicated that from their experience, it is very important for actors to know whether they fall within the scope of the EU ABS Regulation or not. Many actors are not concerned about the purpose of the legislation but are concerned mainly with regulatory compliance and managing their businesses. It was noted that it is not always easy to provide an answer about scope or to explain why actors have to comply with the EU ABS Regulation, especially as it is difficult to get information about actors and what they are doing, i.e. it is not easy to determine whether they are doing R&D. Another participant suggested that it is important that users of genetic resources understand the purpose of EU ABS Regulation and that it is useful and intended to protect them from challenges from provider countries. This participant suggested that the advantages of the regulation should also be highlighted to users.

It was also noted that in Denmark, there is an ABS stakeholder group which has existed since the 1990s. Although some stakeholders are more involved in this group than others, it was suggested that this group is a good platform for improving understanding of the different sectors. Awareness in various sectors is starting to increase and associations are taking a very active role in this respect, sending out information to members etc. The Danish CNA noted that some sectors are more active in this platform than others.

First Experiences in Selecting Users and Undertaking Remote Inspections in Germany

Sebastian Jank and Thomas Greiber

German Federal Agency for Nature Conservation

Since the beginning of 2018, the German Competent National Authority (CNA) has been undertaking its first compliance checks under Article 9 of Regulation (EU) No 511/2014 (EU ABS Regulation). Throughout the year, it is planned to conduct checks of 10 institutions from each of the following 8 sectors: cosmetics, pharmaceuticals, biotechnology, plant breeding, animal breeding, food and feed, biocontrol and basic research. Due to lack of experience with conducting checks and applying risk-based criteria, it was decided to do the same number of checks in each sector in this first round of compliance checks.

In addition to risk-based checks, compliance checks can also be undertaken on the basis of substantiated concerns. So far, it has been decided to only check 2 institutions on this basis. However, further compliance checks based on substantiated concerns could follow if required.

At least a total of 82 institutions will be checked by the end of the first cycle of user checks.

The compliance checks will mainly be conducted remotely, i.e. through written communication with the respective institutions. However, at least 8 on-the-spot checks (one institution per sector) will be carried out as well.

The following chapter will summarize the approach taken by the German CNA to select those institutions which will be checked. Furthermore, the first experiences gained through a remote check in the cosmetics sector will be shared.

Selection of Users

From a previously developed list of German institutions affiliated with the cosmetics sector, a total of 20 institutions were first randomly identified. In a second step, each of the identified institutions was analysed by an expert in order to estimate the probability of the institution falling within the scope of the EU ABS Regulation. The main focus of this analysis was to determine whether the respective institution is likely to undertake “utilization” in the sense of this regulation. It should be recognized that such an expert analysis requires an in-depth knowledge in natural sciences and at the same time an excellent understanding of the legal scope of the regulations.

Next, the 10 institutions with the highest chance of conducting utilization (and therefore arguably the greatest risk of violating the due diligence obligations under the EU ABS Regulation) were selected as potential users to be checked according to Article 9. As a back-up, it was envisaged that the process of random selection followed by expert analysis would be repeated if less than 10 institutions with a high chance of undertaking utilization had been selected in the first round. However, it is important to note that an extra selection round was not necessary for the first compliance checks in the cosmetics sector.

Based on our experiences with this process, we suggest that the following step-by-step approach could be taken for an expert analysis:

1. Collect information about the institution

There are at least three main sources of information that can be tapped into in order to get a better picture of an institution – the internet, patent databases and commercial registers.

2. Design a profile of the institution

In order to create a short profile of the institution, a search of its website, annual reports and the internet can reveal the following:

- institutional structure,
- location of the R&D department,
- annual budget or expenses dedicated to research and development (R&D),
- in-house vacancies (factory workers vs. biologists and chemists),
- products,
- innovation awards,
- publication of research results or
- future strategies.

3. Analyze the profile

As the main question of the expert analysis is whether an institution is doing R&D on genetic resources, the profile can be evaluated regarding certain indicators, such as:

- Given the structure of the institution, is it likely to conduct R&D?
- Is the R&D department located in the country where the compliance checks are planned?
- Is the R&D budget big enough to do the assumed research on genetic resources?
- Does the institution act for others (as a service provider) or in its own interest?
- Are new products actually being developed or just traded?
- If applicable, what is the relationship between the institution and other affiliated institutions (e.g. small association vs. parent company)?

4. Double-check the result

Finally, the result of the expert analysis can be double-checked by comparing it with the Google and Google patent scores. The Google score is determined using an Excel-based

program which searches the website of an institution for selected keywords (e.g. laboratory or research). The program will calculate an average amount of keywords found on the website leading to the google score. An institution with a high Google score can be interpreted as being highly likely to be a potential user. The advanced Google patent search provides a number of published patents related to the institution and thus, this search can support conclusions drawn from the calculated Google score.

It is important to note that both the Google and Google patent scores were only used as a test. Although both scores give a good hint as to whether an institution is a potential user or not, there are problems with these computer-based analyses. The Google score highly depends on the quality of the analysed website. If the website does not contain enough in-depth information about the institution and its activities, it will automatically get a low score. Furthermore, the keywords used in the program need to be adapted to the technical vocabulary used in different sectors, which is not a trivial process.

First Experiences from User Checks in the Cosmetics Sector

The cosmetics industry was chosen as the first sector to be checked using the selection process described above, starting with a remote compliance check. These remote checks take a “ping-pong” approach, i.e. it is envisaged from the beginning that there will be several rounds of exchange between the CNA and the selected institutions (if necessary).

First, an identical questionnaire was sent to the selected institutions (10 plus 2) via regular mail. The letter accompanying the questionnaire included a link where an electronic version of the questionnaire could be downloaded as well as a list of the relevant legal instruments (Convention on Biological Diversity (CBD), Nagoya Protocol, both of the European Union’s (EU) regulations, the German Implementing Act and EU Guidance Document on the scope of application and core obligations of the EU ABS Regulation). A one-month deadline was provided to respond.

The questionnaire included general questions regarding:

- due diligence measures being developed or already applied,
- steps taken to raise in-house awareness on matters relating to the Nagoya Protocol,
- designation of responsibilities for Nagoya Protocol matters within the institution,
- system(s) to track incoming and outgoing genetic material as well as Nagoya Protocol related documents,
- geographic origin of imported genetic material,
- presence of Internationally Recognized Certificates of Compliance (IRCC) or other permits,
- transfer of material to third parties,
- development of products and
- due diligence declarations already filed.

The objective of this first set of general questions was to get a better understanding regarding the institutions’:

- awareness of the Nagoya Protocol, and
- its preparedness to fulfil due diligence, but also to
- determine whether the institutions’ activities might fall within the scope of EU ABS Regulation or not.

In the following exchange with the institutions, individual follow-up questions were posed to get further clarification, confirm joint understandings or challenge certain responses or statements made by these institutions.

The preliminary results can be summarized as follows:

- In the first round, only 4 of the 12 institutions responded by the deadline, 4 requested an extension of the deadline (mainly due to holidays) and another 4 did not react until a reminder was sent by the CNA.
- A number of compliance checks were immediately concluded as it was determined that the institutions’ activities are not or not yet within scope of the EU ABS Regulation. In some cases, the exchange revealed that the institutions do not undertake utilization in the sense of the regulation, e.g. because they use genetic material but only as reference tools. In other cases, utilization was confirmed but only with material that is outside the geographic or temporal scope of the EU ABS Regulation.
- Some compliance checks are still ongoing and further information and/or explanation has been requested by the CNA.

Regardless of the final results of these compliance checks, the following observations could be made:

- The contacted institutions did not react in a negative way but showed a general willingness to fill out the questionnaire and thus cooperate.
- It was also important to see that the questions posed and the language used seem to be clear and understandable, which cannot necessarily be assumed in the context of the Nagoya Protocol.
- Furthermore, the deadline set for replies was feasible as it was met in several cases.
- The Guidance Document on the scope of application and core obligations of the Regulation (EU) No 511/2014 (EU Guidance Document) was cited by several institutions in order to explain why they consider themselves not to be users. This confirms the usefulness of that document not only to provide general guidance on the scope of the EU ABS Regulation but also to introduce (clear) language which facilitates communication and the exchange of arguments between CNAs and (potential) users.
- Several institutions have introduced “Nagoya Protocol statements” which they demand from their suppliers in order to clarify whether the material received is Nagoya-relevant or not. On the one hand, demanding these statements is an important component of the due diligence process and a critical step towards making supply chains more transparent. It also shows that suppliers of genetic resources, although they

might not necessarily be users in the sense of EU ABS Regulation, are coming under more pressure to look into ABS and Nagoya Protocol issues. On the other hand, it is also important to note that there were large differences in the sample statements provided by the institutions in terms of the level of information disclosed. Some of the statements, for example, simply confirmed that the material does not fall under the scope of the Nagoya Protocol. Such statements appear to be too simplistic and insufficient as they do not really provide the information that needs to be collected to determine the applicability of the EU ABS Regulation. This raises the question as to whether “standards” for such Nagoya Protocol statements should be set. Furthermore, the question also arises whether institutions will only use genetic material that is declared to be Nagoya-free.

- The institutions which were checked have very different levels of awareness about the Nagoya Protocol and are not equally prepared to fulfil the EU due diligence obligations. While some of them have already developed and clarified internal procedures as well as responsibilities (in most cases very recently), others have now been forced to wake up to their obligations.
- Even though a user check might lead to the conclusion that a particular institution is (still) out of scope of the EU ABS Regulation, this does not mean that the exercise was a waste of time. Depending on the information provided, the compliance check can lead to another institution (e.g. a supplier) which is within scope. In addition, depending on the location of collaboration partners and suppliers, opportunities for cooperation between European Unions’ CNAs may also arise.
- Last but not least, the results of the first compliance checks indicate that the process for selecting potential users seems to work as it did not lead to any “nonsense” selections.

Discussion

In the discussion, the importance of having a feasible number of potential users that can be dealt with was also highlighted. The German CNA noted that there was a large number of potential users in the cosmetics sector which had to be filtered through as first step. Determining which actors are potentially users requires looking at details and it was noted that it is a time-consuming process.

The German CNA also indicated that it was necessary to find ways to deal with certain situations whilst doing the first user checks because it was not known how the institutions that were contacted would respond, i.e. what type of information would be provided, or how the information provided could be evaluated, i.e. decisions had to be made about what was sufficient or not. It was also important to consider which questions had to be asked to find out about the actors’ activities. It was acknowledged that the lack of information about users makes it difficult to adopt a risk-based approach at this stage, but the experience gained so far has helped to improve the work flows for the user checks. It was also confirmed that it would be an administrative offence for the contacted institutions not to respond to the request for information and that this was stated in the first reminder sent out to those entities which did not respond to the first request for information.

It was noted that the German CNA is working on its database of potential users. The German CNA indicated that it refers to institutions but confirmed that this includes all entities, i.e. both universities and commercial entities. It was confirmed that it deals with universities at the institutional level and not at the level of the individual research unit or researcher. It was noted that staff turnover at universities would make it impossible to keep track of individuals. One of the first steps was to harmonize the data, e.g. in terms of how address is written. It was acknowledged that data management takes a lot of work and they are now considering how to update the database, e.g. using publicly available information in the business register. The question was raised as to whether actors who were contacted but are not users would be kept in the database or not. So far, these actors have not been deleted in order to avoid any possible duplication of work, i.e. so they are not added again and checked in future. Another CNA also indicated that they are taking the same approach.

One participant noted that publications are a good way of getting information about what potential users are doing but commercial companies do not publish their findings and many commercial entities are moving away from patents, meaning that less information about their R&D is publicly accessible. It was also noted that a company's annual report may show that there is a big budget for R&D but that does not necessarily mean that there is utilisation within the meaning of the Nagoya Protocol. Another participant also noted the difficulty associated with getting information and finding sources of information that the CNA is allowed to use. It was also noted that some sources, e.g. company websites, are of varying quality.

The Patent Office in Germany has to provide notification to the German CNA every 6 months about patents based on genetic resources, i.e. patent applicants have to disclose whether the patent is based on plant or animal genetic resources (it does not cover microorganisms). So far, no notifications have been given to the CNA.

A question was asked about whether awareness about ABS was growing in various sectors due to the fact that the German CNA was conducting user checks. It was noted that there are loosely built networks and word of mouth could allow a broader community to be reached but it is not clear whether the user checks are having an effect. The German CNA is also doing awareness raising activities and capacity building and it was suggested that awareness is growing in sectors, particularly among the relevant industry associations. It was also noted that the fact that companies can respond quickly to requests for information from the CNA and provide evidence of their user/non-user status indicates that a certain level of awareness exists. On the other hand, it was noted that there are some institutions that are completely unaware of their obligations. The need to do both awareness raising activities and capacity building in parallel with user checks was highlighted. It was noted that the CNA can learn from the user checks but can also show the various sectors that they are serious about compliance. The German CNA indicated that through its contact with various sectors, it has learned that many companies have stopped bioprospecting (or at least have claimed to have stopped). It was suggested that it is possible that these entities have contracts with academics and intermediaries or are focusing on genetic resources from areas with no Access and Benefit Sharing (ABS) obligations.

A participant noted that some suppliers want certification that there are no access obligations in the country of origin. The German CNA indicated that it would be possible to send an email saying there are no access obligations in Germany. However, other participants sug-

gested that this could represent a high administrative burden, which would contradict having unregulated access, which should reduce the administrative workload for national authorities.

Evaluation of User Checks in 2017 in the Netherlands

Abel van Winkoop

Food and Consumer Product Safety Authority, The Netherlands

Reason for the Checks

The starting point for these checks was the entry into force of the Nagoya Protocol Implementation Act in April 2016. It was decided to start with the plant breeding sector because this sector was expected to be best prepared owing to the extensive awareness raising efforts by the sector organization “Plantum”. It is also an important sector in the Netherlands, it has an important international reputation and it is heavily dependent on genetic resources from all over the world to improve crops for the global food supply. Both at a national and at international level, it is important that the sector has legally obtained material so that exchange of material is guaranteed in the future.

Criteria for Selecting the Companies

In order to be within the scope of Regulation (EU) No 511/2014 (EU ABS Regulation), a number of criteria must be met:

1. There must be use of genetic material, not including human genetic material. Use means research and development (R&D), for example, plant breeding or R&D in the biotechnology sector.
2. The material used must come from a country that is party to the Nagoya Protocol and which has legislation regulating access to the genetic resources of that country.
3. The genetic material must have been obtained from the country after 12 October 2014.
4. The genetic material must not be covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

We searched for companies that are engaged in plant breeding in the Netherlands. Subsequently, we checked whether the plant material used for R&D is included in Appendix I to the ITPGRFA. If the ITPGRFA applies to a specific genetic resource, the provisions of the Nagoya Protocol do not apply, as long as the purpose of the R&D is for food and agricultural research. The species listed in Appendix I are, therefore, assumed to be less relevant for our checks because there is a good chance that they will fall outside the scope of the Nagoya Protocol and EU ABS Regulation. To test this, a number of addresses were selected where crops from Annex I are used for R&D. These addresses were obtained from:

- the register for new varieties (vegetables, flowers),
- the Plantum membership list,
- information in professional journals,
- other public sources, and

- people who have tried to import plants or seeds into the Netherlands in their baggage without the required phytosanitary declaration.

The Process

The inspections were conducted by two people. Inspectors who are responsible for phytosanitary inspections were trained together with inspectors from the nature conservation department on the Nagoya Protocol. The phytosanitary inspectors were already familiar with the plant breeding sector, whereas the inspectors from nature conservation were not. This familiarity helped the inspectors with conducting more effective conversations with the company representatives.

Following the training, the companies were notified about the upcoming inspections. The companies were called and asked whether they were familiar with the Nagoya Protocol. If not or the company was not very familiar with it, the company was referred to the website of the National Focal Point (NFP) and was given time to prepare. An appointment was then scheduled with the person responsible for the use of the genetic resources.

The on-site inspection involved checking whether:

- the material used was subject to Nagoya Protocol obligations,
- the company has exercised due diligence through its internal business system (tracking and tracing, issuing due diligence statements), and
- the company obtained PIC and MAT.

In 2017, twenty checks on compliance with the Nagoya Protocol and the EU ABS Regulation were completed.

Whereas the focus in 2016 was on plant breeding, the focus in 2017 was on flower farming. Of the twenty companies initially identified, four were disregarded because there was no longer any question of utilization, i.e. plant breeding, in the Netherlands.

At fourteen of the companies, there was breeding of ornamental plants, including flower bulbs. At two companies, vegetables were being bred.

Findings

Use of material within the scope of the EU ABS Regulation:

- In four cases, there appeared to be no (more) breeding being conducted in the Netherlands. At all of the other companies, breeding was being conducted, i.e. R&D was taking place.
- Only two companies indicated that they had material that falls within the scope of the EU ABS Regulation. The majority of companies indicated that they only use their own material for breeding. Many companies deposited a list of the genetic resources in their own collections with a notary before 12 October 2014 in order to be able to show that the material was already in their possession and thus outside the scope of EU ABS Regulation.

Due diligence:

- Most companies were well informed about the Nagoya Protocol and had their administration in order. E-bridia is a system that is often used by plant breeders in the Netherlands and this system can also be used for tracking and tracing genetic resources. Sometimes, Nagoya relevant information was kept in separate systems and sometimes it was added to systems such as E-bridia.
- In six of the sixteen companies, advice on compliance was provided. Although there was no use of Nagoya-relevant material in these cases, advice was still given on organizing transparent administration procedures in order to be able to trace the flow of genetic resources. No situations of utilization based on Nagoya-obligatory material were found.

Short Look Ahead

Checks in other sectors are planned for 2018/19. This process involves:

1. Developing an online check list.
2. Sending a letter notifying the potential user that the check will take place. This contains information that the check is obligatory, the legal basis of the inspection (the relevant regulations), a statement that company information will be kept confidential, and the questions that will be asked. A statement is also included that an on-site inspection could also take place. A link to an online questionnaire is provided as well as the deadline for responding.
3. Potential users create a safe login account (also used for filing tax returns).
4. Selection of addresses within the target group.
5. Finding the right person to address the letter to. It has not yet been decided if the letter is to be sent via email or post.
6. The follow-up process if a timely reply is not provided. First, this will be done by email/telephone and then will be followed by an on-site inspection.

The response provided by the companies will be evaluated by an inspector. It is possible that there will be a need for follow-up, on-site inspections. The documents relating to the check will be archived once the check has been resolved to the satisfaction of the inspector.

The person providing the response to our questions must declare that he/she will answer fully and truthfully. The questions are about:

- whether genetic resources are used,
- whether this use is in scope,
- the kind of genetic resources used and the country of origin,
- what measures have been taken to implement the Nagoya Protocol internally,
- how the company tracks and traces the use of genetic resources, and

- if due diligence declarations are needed, how these were submitted (by post or electronically).

There are also some extra questions about the company's experiences with the Nagoya Protocol and whether they have any examples of good practices or ways in which they have dealt with relevant problems.

Discussion

In the discussion, the Dutch CNA confirmed that before an on-site inspection is done by the two inspectors, inspectors check as far as possible whether the company is within scope of the EU ABS Regulation. Things that can be checked include whether R&D is conducted and whether the company's plants are within scope of the Nagoya Protocol etc. It was confirmed that information from the companies' websites is used, e.g. the seeds available for sale, together with information on new varieties registered to that company. However, it was also noted that based on the information obtained externally, inspectors can only assume that the companies are within scope and that certain things can only really be checked during an on-site inspection, e.g. when the use started and whether it really is "utilisation" within the meaning of the EU ABS Regulation. According to the Dutch CNA, this makes it important that the right people are present at the company during the on-site inspection so that the right information can be obtained by the inspectors. It was also noted that if a company is "suspicious" in some way, a spot check might be conducted like under the European Union's Timber Regulations, but typically inspections will be announced and organized with the company.

The Dutch CNA noted that the plant sector association in the Netherlands is very active in informing breeders about both plant breeders' rights and the Nagoya Protocol and that it has been a focal point for communication and information exchange with the CNA.

The discussion then turned to the material that is being used by plant breeders in the Netherlands. The Dutch CNA indicated that plant breeders are typically using their own seeds or material acquired before 2014. Another participant also pointed out that in their country, a lot of collecting was conducted before 2014 so that many companies would have enough material for R&D for the coming years which was not subject to due diligence obligations under the EU ABS Regulation.

A question was asked about what types of food companies will be checked in the Netherlands in the future. It was noted that there are some companies that do R&D on bacteria and yeast but at this point, the potential users who will be checked have not yet been selected. The Dutch CNA noted that there is still awareness raising which is being done in this sector, but this is made more difficult as the umbrella organization in that sector has been unresponsive so far.

Selection of Potential Users, Risk-based Plan and First Inspections in Poland

Magdalena Jankiewicz-Damska

Chief Inspectorate for Environmental Protection

The Polish Regulatory Framework

The Polish legislation on ABS contains the followings acts and regulations:

1. The Convention on Biological Diversity.
2. The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation, which entered into force on 12 October 2014.
3. Regulation (EU) No 511/2014 (EU ABS Regulation) and Implementing Regulation (EU) 2015/1866.
4. The national law, which is the Act of 16 July 2016 on access to the genetic resources and benefit sharing from their utilization. The Act contains provisions about conducting checks of users of genetic resources:
 - Competent authority: Ministry of the Environment.
 - Authority for compliance checks: Inspectorate for Environmental Protection.
 - The Chief Inspector for Environmental Protection prepares a control plan using a risk-based approach. A new plan is prepared for each year.
 - The Ministry of the Environment approves the plan.
 - Voivodeship (provincial) Inspectors for Environmental Protection carry out the checks to verify whether users have complied with their obligations under Article 4 of the EU ABS Regulation.
5. Implementing Regulation on the detailed scope of user controls (entered into force on 1 February 2018) (Article 4 and 7 of the EU ABS Regulation).

Selection of Potential Users

The process for selecting potential users consisted of three steps:

- Step No. 1: a list of the most “suspicious” sectors operating in Poland (universities, research institutes financed from public funds, animal and plant breeding, pharmacy, cosmetics, biotechnology, food processing, production of fuels and plastics, others);
- Step No. 2: a list (draft database) of potential users from selected sectors was created which included about 500 companies/institutions;
- Step No. 3: searching for information about companies operating within the selected sectors (associations of companies in Poland), which was a source of information on the scope of their activities. The identification process included searching for information on the internet, the analysis of these companies’ websites, and the analysis of other databases managed by Inspection Unit for Environmental Protection.

Risk-based Plan for 2018

In 2018, inspections will be carried out at 80 institutions/companies in Poland.

Entities selected for user checks come from three different sectors: universities and research institutes financed from public funds, pharmacy and cosmetics.

The inspections are planned for the second quarter of 2018, i.e. from May to June 2018. The Implementing Regulation on the detailed scope of user controls entered into force on 1 February 2018.

Poland is divided into 16 “voivodeships” or provinces – Voivodeship Inspector for Environmental Protection. The control plan provides for five inspections in each “voivodship”.

The first check in each province will start with universities and research institutes financed from public funds. Most of the entities included in the plan come from this sector. What is the reasoning for this?

- This is an important or top sector in Poland,
- it is typically open to new ideas and is eager to learn,
- it has a high level of knowledge and awareness,
- it is highly organised,
- it is accustomed to frequent changes in the regulations, and
- it is friendly.

First “Inspections” = Informative On-site Visits

So far, two “checks” have been carried out. These were more informative visits at the University of Wrocław (Faculty of Biological Sciences) and at the Wrocław University of Environmental and Life Sciences (the Natural and Technological Faculty).

The agenda of these checks was:

1. a meeting between the inspector and the dean of the faculty, and
2. a meeting with the research workers from the faculty, who filled in a questionnaire with sixteen questions, including:
 - whether they conduct research and development (R&D) on genetic resources;
 - the origin of the resources and the date of acquisition;
 - measures undertaken to meet the due diligence obligation of users;
 - the person responsible for Access and Benefit Sharing (ABS)/Nagoya Protocol;
 - copies of Internationally Recognized Certificates of Compliance (IRCC) or any other relevant documentation;
 - evidence of using best practices;
3. analysis of the completed questionnaires.

First Inspections – What Did We Find?

Based on the responses to the completed questionnaires and the meetings with university representatives, we found:

- There is a strong motivation to comply.
- Generally, actors in this sector use “old” material, i.e. material obtained before 12 October 2014.
- There is material from countries that are parties to the Nagoya Protocol that was obtained after the 12 October 2014 but it is primarily a part of collections and no R&D is conducted on this material.
- These actors have many questions about the interpretation of the EU ABS Regulation. E.g. the inspector carried out several meetings with the representatives with each meeting lasting over 8 hours.

Discussion

In the discussion, it was confirmed that Poland does not regulate access to its genetic resources.

The Polish representative explained that the Inspectorate has its own rules of procedure, which also have to be followed for the inspections under the EU ABS Regulation. This is the reason why the plan for the checks is prepared by the Inspectorate and adopted by the Ministry. It is also the reason why the plan is prepared annually.

The Polish representatives noted that there are no large companies in Poland which are doing R&D on genetic resources and therefore, it is more likely to find R&D being conducted in scientific institutions. A question was raised about the possibility of SMEs doing R&D. The Polish CNA noted that many meetings have been conducted with actors from various sectors and these actors provided information indicating that they are outside scope of the EU ABS Regulation, e.g. they do not conduct R&D but use ingredients from genetic resources provided by foreign companies, which is not R&D within the meaning of the Nagoya Protocol. Although these companies claim to be out of scope, this does not mean they will be excluded from user checks but based on the information provided, the Polish CNA decided to start user checks in other sectors. It was acknowledged that SMEs could also do R&D and checks of these potential users might be considered in future but have not been included in the current annual plan. The planned inspections will be conducted over a period of a few months and later this year, a new plan will be prepared for 2019.

The fact that very long meetings were conducted with the two universities was raised. It was noted that this time was used for the university to answer the inspectors' questions but also for the inspectors to answer questions from the university. The meetings started more generally with the dean and then involved the individual researchers during which the legal basis of the checks was explained etc. It was noted that these meetings were very good in terms of awareness raising and the questions from the universities also helped the inspectors to bet-

ter understand the potential users, their way of thinking and the issues that are unclear for them.

Participants noted that universities are very heterogeneous actors and that every institution is different. Participants recognised that universities can often be a combination of users, collections and institutes that provide material to other actors. One participant noted that universities may have their own collections of genetic material or there may be small collections within research groups that potentially get “stranded” at the end of research projects.

Situation in Sweden

Louise Bednarz

Swedish Environmental Protection Agency

Sweden is still working on identifying potential users and setting up a register.

Regarding non-commercial users, work is in progress but before the CNA can move on, it needs to be established who is legally responsible at higher education institutions for due diligence obligations under Regulation (EU) No 511/2014 (EU ABS Regulation).

With respect to commercial users, the register is almost complete. However, it has not been easy to find users in the commercial sectors because other government agencies and sector organizations are not willing to share information about these potential users. Due to the lack of response from commercial users so far, a questionnaire will be sent out which will hopefully determine which users are within the scope of the EU ABS Regulation. The answers to these questionnaires will not be anonymous and the information gathered will be used for risk classification.

Discussion

In the discussion, it was confirmed that the intention of the questionnaire is to find out which companies are within the scope of the EU ABS Regulation. A few hundred questionnaires will be sent out via email, but it will not be mandatory for potential users to answer the questionnaire as the legal basis is unclear. Reminders will be sent out, but the Swedish CNA does not expect that there will be a high level of response.

A question was posed about the rationale for dividing the register into commercial and non-commercial users. The Swedish CNA indicated that it would be good to combine the registers into one, but it is not possible at this stage because of the uncertainty about who is legally responsible at the institutions focused on non-commercial research.

Much of the discussion subsequently focused on legal responsibility at universities and research institutes. It was commented that it can be difficult to establish who really has the legal authority in a given situation, e.g. to sign off on a deposit at a collection or to enter into PIC and MAT. It was suggested that there are different levels of authority within the university system and depending on the nature of the documents, different people will be responsible.

The discussion then turned to the question of due diligence obligations. One participant suggested that it is the individual researcher who is responsible. At the same time, it was suggested that ultimately the university, as the employer, also has some responsibility because researchers are employed by the university and are bound by their processes and policies. The question was raised as to whether the fact that funding flows to the university would also make a difference in terms of due diligence obligations. One participant emphasised that universities should be showing top down initiative to create policies, internal procedures, codes of conduct etc. and conducting training so that university employees can deal with Access and Benefit Sharing (ABS) and their due diligence obligations under the EU ABS

Regulation. It was suggested that this has not been seen so far and that there is scope for further awareness raising activities by CNAs at universities.

4 Brief Update on Implementation Progress in other Member States

ABS Legislation and Implementation of the Regulation (EU) No 511/2014 in the Republic of Croatia

Dubravka Stepić

Ministry of Environment and Energy, Croatia

The Republic of Croatia became a Party to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) on 1 December 2015.

The current national Access and Benefit Sharing (ABS) legislation relevant to the implementation of the Nagoya Protocol, Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU ABS Regulation) and Regulation (EU) 2015/1866 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices includes:

- the Act on Ratification of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Official Gazette – International Agreements No 5/15),
- the Act on Implementation of the Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (Official Gazette No 20/18), and
- the Nature Protection Act (Official Gazette No 80/13 and 15/18).

The Competent National Authority (CNA) responsible for implementation of the Nagoya Protocol is the Ministry of Environment and Energy and CNAs responsible for implementation of the EU ABS Regulation are the Ministry of Agriculture and the Ministry of Environment and Energy. The Ministry of Environment and Energy is responsible for the genetic resources of wild plants, animals, fungi, algae and microorganisms, and pathogenic genetic resources not falling under the jurisdiction of the Ministry of Agriculture. The Ministry of Agriculture is responsible for plant genetic resources for food and agriculture, genetic resources from farmed animal breeds, genetic resources from fungi and microorganisms used in the food industry and genetic resources from animal and plant pathogens.

Access to genetic resources from wild native species is regulated under the Nature Protection Act. Accordingly, the permit issued by the Ministry of Environment and Energy is obligatory in cases where samples are taken of strictly protected species, in cases where genetic resources from wild native species are accessed and used for commercial purposes, or where collecting and sampling takes place in protected areas.

There are different categories of protected areas at the national level. In the case of strict nature reserves, national parks, special reserves or nature parks, the permit for access to genetic resources is issued by the Ministry, but if collecting is planned in locally protected areas, such as regional parks, nature monuments, significant landscapes, park forests and park architectural monuments, potential users need to request a permit from the local nature protection authority.

Discussion

In the discussion, it was noted that the Croatian legislation entered into force in 2013 and that this legislation was enacted because it was not clear what was happening at the EU level. It was confirmed that the legislation is not ABS legislation per se but is mainly intended to protect certain species. It was noted that the application procedure for a permit is not very complicated. A request must be made to the Ministry and it takes a maximum of 60 days to process.

It was confirmed that an official English translation of the Croatian national legislation is available on the ABS Clearing-House (ABSCH).

5 Practical Scenarios

Scenario 1: Breeding Companion Animals

The Finnish CNA presented a case from the draft guidance document on animal breeding, which relates specifically to the breeding of companion animals using newly introduced genetic resources. In the text of the draft guidance document, the concepts of “fresh genetic resources” and “newly introduced” are used. It was pointed out that these terms would need some clarification. Some figures were also presented on the non-commercial movement of dogs in the European Union (EU) and the import of dogs to Finland from countries outside the EU.

The audience was asked for advice on how to reach the actors (companion animal breeders), who are typically not covered by any official registers. The Finnish CNA also wanted to discuss the importance of this relatively marginal group within the whole spectrum of actors and how much effort should be invested investigating this group, keeping in mind the principle of proportionality.

The question was also posed if any of the countries that regulate genetic resources had given any thought to companion animals and whether they have been excluded or possibly unintentionally regulated.

It was noted that the Finnish CNA has been tentatively in contact with the National Kennel Club but there has been no agreement or further action so far.

Discussion

In the discussion, the question was raised as to how many cases would really come up with respect to companion animals. Some of the difficulties associated with this sector were also raised, e.g. that it does not have the same regulatory system as for plant breeding, making it somewhat difficult to identify actors etc.

One participant suggested that animal breeding is more relevant for livestock, but another participant pointed out that the Nagoya Protocol does not distinguish between the type of product, meaning that commercial or non-commercial breeding of companion animals is relevant if the genetic resources are within the scope of the Nagoya Protocol. Different examples were suggested by participants, e.g. lizards or turtles, which could be collected in the wild in Nagoya Protocol countries. The commercial breeding of rabbits in Poland as companion animals was also raised as an example. As such, a couple of participants indicated that this sector cannot be ignored. It was suggested that whether animals are bred in captivity or whether they are sourced from the wild could also be a relevant factor. The Spanish CNA, for example, confirmed that Spain does not regulate any domestic breeds and that access permits are only needed for wild species.

The discussion then focused on the example of dogs. The question was raised as to whether a dog, e.g. from Argentina, is considered a genetic resource or not. Reference was also made to rescue dogs but it was pointed out that these animals are typically sterilized before they are imported, meaning that no subsequent breeding is possible. The Hungarian CNA

informed the participants that they have been in contact with relevant actors in relation to the nine Hungarian dog breeds.

It was also pointed out in the discussion that there is a difference between importing an animal and what is subsequently done with it. The relevant question is whether the animal is then used as companion animal or a breeding animal, noting that the term “breeding” is also difficult because it is not clear whether it refers to selecting or breeding them.

Also, the question of thresholds arose during the discussion and the point at which obligations would no longer apply. It was suggested that although it may not be an appropriate framework, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) may provide some guidance on this point, e.g. there are no further CITES obligations if no animals covered by CITES were present in the previous four generations, meaning that the 5th generation is obligation free.

Scenario 2: Use of Transgenic Mice

This practical scenario was about the use of transgenic laboratory mice for research on signalling molecules associated with human brain disorders. These signalling molecules are the same in all animals. In this scenario, the research is conducted on laboratory mice that have been modified with a human gene so that the brain disorder more closely resembles the relevant human disease.

Discussion

Firstly, participants clarified that human genetic resources are not within the scope of the Nagoya Protocol and Regulation (EU) No 511/2014 (EU ABS Regulation). Secondly, the issue of the mice was addressed. One participant noted that these laboratory mice have been developed in laboratories over many years and are available from commercial providers. These mice are highly inbred, have almost standardised genomes and have been in use in research for around 50 years. They are regarded as being free of Nagoya Protocol obligations and not within the scope of the EU ABS Regulation. It was also noted that in this scenario, the mice serve only as a tool for research process, i.e. the purpose was not to research the genetic and/or biochemical composition of the mouse but to provide an animal model as a tool for investigating a (human) disease.

Scenario 3: Derivatives - The Product of Which Genetic Resources?

This practical scenario related to the interaction of two genetic resources, namely a virus and a rabbit. The virus is used to stimulate a reaction in the rabbit’s cells, namely the formation of antibodies, which are then used to identify the virus. The question was to which genetic resource the antibodies created by the rabbits’ cells would be attributed.

Discussion

In this case, the virus, which is a genetic resource, was used as a physical stimulus. The rabbit, which is a laboratory animal, is also regarded as a genetic resource. The question was whether the antibodies, which would be regarded as derivatives, could be attributed to the virus or the rabbit, bearing in mind that the mammalian cells produced the antibodies. In the end, the antibody was considered to be a derivative from the rabbit and although it might be regarded utilisation, the rabbit itself would not fall within the scope of the Nagoya Protocol as it is a laboratory animal.

Scenario 4: Exercising Due Diligence – What to Do When the CNA in the Provider Country Does Not Respond

An issue regarding communication with a particular CNA in a third State was raised. Various actors have attempted to contact this CNA regarding access arrangements but without success. The CNA has not responded to any requests or emails from researchers and collections in Germany. Attempts by the German CNA to contact this CNA have also been unsuccessful. Attempts have also been made to make contact through diplomatic channels, i.e. through the Ministry, but these have also been unsuccessful. An official from the country in question had been invited to a workshop in the European Union (EU) to provide information on access arrangements in their country but that person cancelled their attendance at short notice. The national interim report from the country in question states that it is in the process of developing a specialized Access and Benefit Sharing (ABS) law/s and that ABS rules are currently incorporated into various sectoral laws etc. Users in the EU need information about these access arrangements but cannot get this information or the required permits despite their best efforts. The question was what users and collections in the EU can do in this situation and what steps would be necessary for users to satisfy their due diligence obligations.

Discussion

In the discussion, it was noted that although there are no specialized ABS rules in a country, ABS provisions may be incorporated into other instruments and there may also other laws, e.g. private laws (property) etc. that are relevant. It was pointed out that the time of access is the key date and if no national laws were in place at time of access, there are no due diligence obligations.

A couple of participants indicated that CNAs should recommend to users to very carefully consider the consequences of proceeding with R&D in cases where they are uncertain about the actual ABS requirements, e.g. the potential to have to stop utilization in the future, fines etc.

The participants noted that users and collections are in an extremely difficult position if the CNAs in provider countries are not responsive to their requests for information etc. The discussion then turned to what users can do in order to fulfil their due diligence obligations in this situation. One participant suggested that users could make a journal of all attempts to communicate with the CNA in question and if there is no reaction, they could carry on with their work with the full knowledge that there may be claim against them in the future. However,

er, there were diverging opinions on whether this way of dealing with the issue is advisable. Other participants questioned whether simply documenting attempts to contact a CNA in a provider country would be sufficient evidence, e.g. if the matter was to come before a judge. It was noted that this situation raises many questions, such as how long should users continue trying to communicate with the relevant CNA? It was noted by one participant, for example, that some people expect to get Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) straight away, which is also not a realistic expectation. Several participants also suggested that the period of time waited is not an adequate argument for not getting PIC and MAT. One participant suggested that if people are acting in good faith, there should be no problem. However, this approach was also questioned. It was argued by other participants that if a user knows that PIC/MAT is or could possibly be necessary but does not receive an answer from the relevant authority, this user knows that the documentation is or may be incomplete. Some participants expressed the opinion that in order to be considered to be acting bona fide, it would be necessary to wait until this uncertainty has been removed. However, it was also recognized by the participants that with that approach, users could end up waiting a long time or indefinitely. Nevertheless, it was noted that it is not possible to give foreign authorities a deadline for action.

One participant noted that deposits made into a collection which cannot be shared for scientific purposes are useless as a certificate has to be provided to journals stating that the deposited organism is freely available to the scientific community. According to this participant, the German Collection of Microorganisms and Cell Cultures (DSMZ) is not accepting any deposits of genetic material from one particular country as it is not clear whether that material is subject to ABS rules or not. However, it was noted that those strains, which were rejected by DSMZ, have been deposited elsewhere in the EU.

6 Round of “Stupid” Questions

If someone collects, breeds and conducts research on bacteria obtained from the skin/teeth/stomach of a (dead) human, is that in or out of scope of Regulation (EU) No. 511/2014?

This question was raised by one participant who wanted to discuss the implications if bacteria are found on the skin of a dead person whose body has been repatriated to the European Union (EU) from another country.

For all participants, it was clear that the human genetic resources are not within scope of the Nagoya Protocol and Regulation (EU) No 511/2014 (EU ABS Regulation). It was suggested that if an EU citizen dies abroad and the body is returned to the EU where the bacteria are subsequently isolated, this would be a case of unintentional access. However, it was also agreed that the virus or bacteria generally could be within scope if all of the other requirements are met, i.e. the bacteria are from a Nagoya Protocol country with access legislation etc. The importance of looking into things on a case-by-case basis was highlighted.

The question was then raised about whether it really makes a difference whether the person from whom the bacteria is collected is dead or not. It was also noted that there is also an open discussion on the scope of the Nagoya Protocol with respect to the human biome.

The difficulty with identifying the origin of genetic resources was then raised more broadly. It was suggested that many species do not observe strict geopolitical borders, meaning that many specimens cross borders, which can make origin problematic or complicated. It was noted that different arrangements may apply to the same specimen depending on where it is sampled. The example was given of a migratory bird which travels through the EU and whether access legislation would apply. Spain, for example, has access regulation for all wild animals and an access permit would be necessary. If the same bird is collected in Germany, there would be no access requirements.

Is there a common understanding throughout the European Union on what constitutes research and development?

This was a question about whether there is a common understanding of the term research and development (R&D) in the European Union (EU).

One participant indicated that the definition is very broad and general in Regulation (EU) No 511/2014 (EU ABS Regulation) and the EU Guidance Document is not very useful. It was suggested that there are still possibilities for improving how this term is applied in practice. It was noted that every sector is specific, meaning that there is a need to address things on a case by case basis. However, another participant referred to the need to try find common threads and general solutions across all sectors.

The unresolved issues with respect to the meaning of R&D, which are still open for discussion, were also raised. The issue of derivatives and the cut-off point was referred to specifically. It was noted that the industry position is to narrow down the use of these derivatives to their first use in their original form.

Are dairies and breweries regarded as users when they develop new products based on bacteria received from the food and feed industry if the bacteria are covered by Prior Informed Consent and Mutually Agreed Terms?

It was noted that there are restrictions in Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) which can be passed on to third parties. Participants indicated that whether the research is focused on the bacteria per se or whether the research is on the cheese or the beer and the bacteria are used as a tool or ingredient would be a relevant consideration. It was noted that it is necessary to look into the details of each case of use to determine whether utilisation is occurring. It was suggested that these actors could possibly be using the genetic resources and might be regarded as potential users.

Has the European Commission considered creating incentives for collections to become registered or how the registration process could be encouraged or simplified?

It was noted that registration is a voluntary measure and that there appears to be a lack of interest in registration, probably because collections do not see any benefits or advantages in becoming registered. Although there was some initial interest in registration, this interest seems to have waned.

The question was then raised as to what the benefits are for collections which become registered. One participant indicated that registration may simply mean more work for the collection and potential liability. It was also noted that compliance with Article 5 requires a coherent management scheme to be put in place, which would probably be easier for some types of collections than for others, e.g. collections focused on one type of organism. This participant indicated that large, diverse collections would find it very difficult to take a one-size-fits-all approach for managing all of their material, although registration of parts of these collections may be a possibility. It was also highlighted that there are a lot of personnel costs associated with registration and that not all collections can make this investment if no benefits flow back to the collection as a result of registration. Although some collections may have the possibility of regaining some of their investment, e.g. from selling strains, this would not be the case for many collections. Due to the lack of funding and the associated burden, it was suggested that registration for some collections is simply not an attractive alternative.

One participant suggested that it would be helpful for positive examples of registration to be published and made known in the broader community. This might support registration and have a snowball effect. It was noted that information will be made available at some stage about the registration process of the first registered collection, i.e. the German Collection of Microorganisms and Cell Cultures (DSMZ).

A couple of participants indicated that as registration is voluntary, there have to be incentives for collections to go ahead with registration. The European Commission (EC) noted that it is responsible for establishing the register of collections, but Member States have to decide whether and how to incentivise collections to become registered or not. The EC has not developed any programmes, although one participant suggested the possibility of the EC providing some funding for this purpose. At the same time, it was noted that different collections may be motivated by different incentives and that not all motivations will necessarily be

money driven. Motivations may be, for example, taking a leadership role in the research community, innovation or business, i.e. that collections are more attractive to commercial clients.

A final suggestion was made that some sort of label could be developed (Nagoya Protocol compliant material) along the lines of a quality label, which would be recognized.

What should Competent National Authorities do about resources from disputed areas, e.g. Taiwan? Can genetic resources from these areas be utilized in the European Union? Can some written guidance on this issue be provided?

This issue is not addressed by the EU Guidance Document. It was noted that the issue of disputed territories goes well beyond the scope of the Nagoya Protocol. This issue, however, makes it difficult for researchers because it is not clear for them which authorities should be contacted with respect to information, permits etc.

Participants indicated that an important issue for due diligence obligations is the level of effort made to get the relevant documentation. The best option for users in this situation is to engage in a dialogue with the relevant competent national authorities (CNA) and to document the entire process. Participants suggested that users should keep a journal of all activities and although it may not be considered a sufficient evidence or formal documentation, such records are regarded as useful.

The question was then raised as to the meaning of documentation. There was some disagreement among participants about what form of documentation could suffice. It was suggested that stamped official documents may be required in some circumstance. At the same time, others took the view that emails from the relevant authorities could also serve as evidence.

During inspections, do inspectors have to check that the user is carrying out his or her activities in accordance with the Mutually Agreed Terms?

This question was about whether the competent national authorities (CNA) can only enquire as to whether Mutually Agreed Terms (MAT) have been established or whether CNAs should also be able to look into the terms and conditions of MAT to determine whether it is being complied with.

It emerged that there are different legal opinions on this point. In one country, the legal opinion is that Art 4.2 requires use to be in accordance with MAT and that user checks should also cover MAT. Other participants indicated that it is necessary to check Prior Informed Consent (PIC) has been followed and that MAT have been established but the terms of the contract are not reviewed.

It was noted that MAT is very likely to be confidential but at the same time, it was acknowledged that without seeing the contract, it is impossible to know under what conditions or restrictions genetic resources can be used and whether users are complying with those terms. It was suggested that if users show MAT to the CNAs, they should look at it. It was noted that the enforcement of benefit sharing obligation is subject to contract and private law, which

ultimately cannot be enforced by the CNA but has to be done by the contract parties. However, it was noted that if the CNAs learn of a breach, there could be an obligation to inform the provider country. However, it was also pointed out that understanding MAT could be difficult as terminology etc. will have been chosen according to the laws of the provider country where the material was obtained and may have different meanings or implications.

One participant noted that if benefits are not shared, a sanction may be imposed on the offending user but at the same time, these fines do not flow back to the provider country but according to national legislation, are retained by the national government of the user country.

How should competent national authorities react to requests for official confirmation that there is no access legislation in their country?

One participant mentioned that it is not possible to go to the websites of the competent national authorities (CNA) to certify that there are no access arrangements because there is no time stamp. Another participant suggested that a screen shot of the website with the date may be sufficient or the CNAs could provide an email to people wanting confirmation that there is no access legislation in the relevant country so that they can fulfil their due diligence obligations.

The possibility of issuing an official letter was also suggested. However, the question was raised whether CNAs would want to issue individual letters for all samples exchanged, noting that this would be a lot of administrative work. One CNA representative suggested that a standard letter may be sufficient. However, there could also be difficulties with standardised letters as there may be different access requirements for different areas. The possibility of charging fees for documents confirming that there is no relevant access legislation was also raised.

What are the implications for user checks if the person's activities are actually outside the scope of the Regulation (EU) No 511/2014?

One participant noted that from a strictly legal perspective, inspectors in her country are only permitted to check users under their national law and any checks of potential users would require a change to the legislation. Another participant also indicated that their national law refers to checks of users but in practice the inspections also include potential users.

Some participants noted that it is impossible to know whether a person is really a user of genetic resources without doing a check. At the same time, it was recommended that CNAs reduce the group of potential users as much as possible to a "user" group.

Several participants indicated that it would be impossible to do user checks if potential users cannot be contacted and asked questions. In some cases, it was suggested that there may need to be some evidence why someone is not a user and that some users may not even know that they are users of genetic resources within the meaning of Regulation (EU) No 511/2014 (EU ABS Regulation). In terms of the process, it was suggested that in the first round of enquiries, CNAs can clarify user status and in a second step, enquiries can be made about due diligence obligations. However, one CNA indicated that in their experience,

combining these two steps was not problematic. The importance of having efficient and practical administrative processes was highlighted.

A couple of participants suggested that there was not really anything to stop potential users from being included in the risk-based control plans, i.e. that the concept of a potential user is included in the risk-based approach. It was noted that user checks include checks of various things including whether a management system is in place etc. and not only checking whether there is illegal behaviour. It was further argued that if CNAs take the approach that potential users do not have to reply to requests for information, only those people who respond to requests for information (and possibly have nothing to hide) could be checked, which would not make sense.

It was also suggested that the EU ABS Regulation may lend some support to the idea that potential users can be checked. It was noted that the term “user” refers to user of genetic resources and not users of genetic resources within scope of the regulation. The EU ABS Regulation also allows for best practices to be developed but this does not necessarily mean that all people following those best practices will be within scope. It was also suggested that one could look into general principles of public law and draw analogies to support requests of information from potential users, e.g. when the police asks questions to get information about a danger or risk.

7 First Registered Collection in the EU

Dr. Amber Hartman Scholz

Leibniz Institute DSMZ – German Collection of Microorganisms and Cell Cultures

The Leibniz Institute DSMZ GmbH (German Collection of Microorganisms and Cell Cultures, DSMZ) was asked to describe its experience in becoming the first registered collection in the EU.

The Leibniz Institute DSMZ, a member of the Leibniz Association, is a research infrastructure that is the result of a historical merger of 7 microbiological collections which were added to 4 newly established collections over the past decade. It has roughly 200 employees and an annual budget of 13 million Euros, a third of which is generated by sales and service income and two-thirds which comes 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) over the past 2 decades, and a sequencing center that sequences hundreds of genomes per year. DSMZ receives around 2,000 deposits per year and holds 57,000 publicly available biological resources. It has approximately 10,000 worldwide customers from 89 countries and 65% of its orders are sent out internationally (outside of Germany) to customers from both academia (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 these biological resources are unattractive for direct commercial use (probably due to their public availability and thus limited patentability).

The Leibniz Institute DSMZ submitted an application to become a registered collection to the German Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) in November 2017. The 14-page application (as well as 11 supporting documents), which was submitted in accordance with Article 5.2 of EU Regulation 511/2014, was officially approved by BfN on March 18, 2018 (in early May 2018, the Leibniz Institute DSMZ appeared on the EU Commission website as the first official entry in the Register of Collections). The application took around four months to prepare by a two-person science-legal team (Dr. Amber Scholz and Dr. Hilke Püschner) and was a high priority for the DSMZ Director, Prof. Jörg Overmann. Indeed, there were significant personnel investments from quality management, scientific and administrative staff. This is an important consideration for future applicants to consider as there are significant in-house investments that must be made to prepare an application for registration. Furthermore, the German competent national authority (CNA), i.e BfN, invested considerable time in the application process, including multiple reviews of the draft application, phone conferences and a site visit.

Beyond the significant financial investment to become registered, which was estimated at around €200,000 (legal staff, IT implementation), the most important changes for the DSMZ in order to become registered stemmed from the need to comply with Article 5.3 (a) to (c). Long-standing procedures were already in place to comply with Articles 5.3 (d) to (e). Standard Operating Procedures (SOPs) for handling new deposits of biological resources were modified and an internal Nagoya legal review process was established. There were also considerable IT adaptations needed for the online deposit form, the online catalogue, as well

as changes to DSMZ's terms and conditions and webshop acknowledgement thereof. To understand the meaning of these changes, it is helpful to consider the DSMZ from two angles, i.e. entry and exit.

Entry (new deposits): Before deposit, the DSMZ provides depositors with an overview of what will be required for a deposit. When a new bioresource is deposited at the DSMZ, the online accession form requires, among other scientific information, the depositor to detail where the strain was sampled (including GPS coordinates) and the date of sampling. Using this information, real-time information is obtained from the ABS Clearing-House (ABSCH) API (advanced programmer interface), which determines whether the deposit is within the geographic and temporal scope of the Nagoya Protocol. If so, the depositor is required to upload supporting documentation that is subsequently reviewed by the curator and legal team. If the bioresource is not within scope, no Nagoya relevant documentation is required. For countries that have proactively (by enacting legislation) granted free access to genetic resources, documentation is also not required. A list of those countries which have granted free access to their genetic resources was verified by the BfN and, in some cases, directly with the CNAs present at the Vilm Meeting in April 2017. The legal team verifies the submitted documents by cross-checking information listed in the ABSCH and by contacting the provider country CNA to verify the documentation. If these verifications are successful, the bioresource is accepted. The practical consequences of this procedure have led to a more than a 30% decrease in the number of deposits made over the past year. This is a significant negative impact for the DSMZ that we hope will, in the long-run, pay off as customers realize that we can certify that all our holdings were legally obtained.

A short side note demonstrates some of the challenges for practical implementation of the Nagoya Protocol. In late 2017, Dr. Püschner contacted the 198 Parties to the Convention on Biological Diversity (CBD) through the email addresses provided in the country profiles in the ABSCH asking, hypothetically, what documents, if any, would be required to accept a new bacterial isolate in the public collection and which authority would issue them. 15% of the CNAs contacted provided a useable answer to her enquiry and two-thirds did not respond at all.

Exit (purchases of bioresources): The online catalogue offers customers an overview of each bioresource's relevant scientific information and, since registration, the country of origin, sampling date and any associated documentation (although only 3 strains had any Nagoya relevant documentation at the time this presentation was held). It also will allow for individual warnings to be posted, e.g. "for taxonomic purposes only" for newly accessed Spanish strains together with a link to the relevant Spanish law. DSMZ uses a Material Transfer Agreement (MTA) (and accompanying terms and conditions) that explicitly require customers to use bioresources for non-commercial research purposes only, not to distribute strains to third parties, and to adhere to the terms listed in the "Nagoya Restrictions" section of the catalogue. Upon purchase of a strain, the customer must expressly agree to the conditions of purchase. The DSMZ cannot and does not ask customers what they will do with the strains, nor do we discriminate between researchers in commercial or academic settings. The terms and conditions attached to the strains are transparent and only the EU CNAs or other international CNAs are legally responsible for ensuring that users of these genetic resources are compliant with the EU Regulation 511/2014 (EU ABS Regulation) or other relevant national legislation.

During the course of the registration, several critical points became clear:

1. The DSMZ performs hundreds of (legally non-binding) “user compliance checks“ of depositors per year. We are on the front line of Nagoya Protocol implementation and, in many cases, probably have more practical experience with international Nagoya legislation and implementation than some CNAs. Very frequently, we realize that the provider country CNAs have no system in place for issuing Nagoya “permits” and have never heard the terms Prior Informed Consent (PIC)/Mutually Agreed Terms (MAT). We are often put in the position where we give practical suggestions to these CNAs, which places us in a challenging situation. A forum to exchange information with European and international CNAs would be very helpful.
2. We know from specific cases that if we reject a deposit, it will probably get accepted by another culture collection elsewhere in Europe or beyond and it could be distributed notwithstanding the legal uncertainty surrounding compliance with the Nagoya Protocol and EU Regulation. Downstream users of these collections are likely to be unaware of any problems with compliance.
3. We report strains that are not Nagoya-compliant to journal editors and invalidate the deposit certificates associated with these strains. However, if the journal does nothing (which often happens), the publication and strain stay in the public domain. We are unclear if and when we should notify (CNA in Germany? EU Commission? CNA where the depositor resides?) when such problems arise.
4. The registration process could be made more transparent or comprehensible if the CNAs or the European Commission (EC) offered standardized application templates or guidelines for collections.
5. If a registered collection has a difference of opinion with their CNA, what is the appropriate legal recourse that we should seek? A lawsuit is clearly undesirable, so it would be helpful to have a fair and transparent process or forum where broad-ranging matters that go beyond national borders could be addressed.

Discussion

In the discussion, the fact that there has been little interest from collections in becoming registered was raised again. The EC noted that the registration of collections was an important part of the European Union’s (EU) vision when developing the EU ABS Regulation, in which collections help users to have access to genetic material that has been obtained in accordance with the Nagoya Protocol. It was suggested that registered collections should be seen as an important intermediary and one way of increasing transparency in the value chain. It was also noted that registered collection and best practices, although voluntary measures, are important for supporting both CNAs and users as well as for reducing the risk that illegal genetic material is used in the EU. With respect to the register of collection, it was also emphasised that it is not only the job of the EC to register collections but also to ensure useful and harmonized processes among the Member States.

The discussion then turned to the role collections play. One participant suggested that registered collections need to engage in face to face dialogue with recipients of material. Howev-

er, this was countered by another participant, who argued that this is simply not possible due to the volume (thousands) of samples sent out annually. This participant suggested that if collections are to fulfil such a role, funding would need to be made available for this purpose.

It was emphasised by several participants that registered collections are not an extension of the CNAs but are intended to make due diligence easier for users and to reduce risk. It was noted that collections have no legal authority to check what people are doing with the material they receive and that ultimately, the fulfilment of due diligence obligations can only be checked by the CNAs. Several participants indicated that the role of registered collections is to support users by providing them with all information available.

Dr Hartmann-Scholz clarified that material that is subject to Access and Benefit Sharing (ABS) obligations is accepted by DSMZ as long as all of the relevant documentation is provided. However, it was also noted that type strains have to be provided to the scientific community freely and without restriction, meaning that if PIC and MAT restrict research and development (R&D) on that material, those strains cannot be deposited. It was also confirmed that for those countries that are not party to the Nagoya Protocol but have access laws, depositors are still required to provide the relevant documentation.

Dr Hartmann-Scholz confirmed that the DSMZ's accession system requires customers to comply with DSMZ's terms and conditions, in which it is stated that the customers can be fined etc. if they do not comply with obligations arising from any related PIC and MAT. The terms and conditions capture any change in intent, but it was noted that the responsibility is ultimately with the user to determine their obligations. It was also noted that if the DSMZ's terms and conditions are violated, the BfN could be notified.

Several participants pointed to the high level of innovation needed to go through the registration process. The German CNA collaborated with the DSMZ and supported the application process and it was noted that there was a high level of satisfaction with the process for all parties involved. However, Dr Hartmann-Scholz noted that writing the application was challenging for DSMZ and that the Annex to the Implementing Regulation only provided little guidance, meaning that a lot of solutions and answers had to be found during the registration process.

Despite the high level of collaboration and support between the DSMZ and the BfN, it was also noted that there could sometimes be differences in opinion on various issues. The question was raised as to what channels are available to actors when there is disagreement between them and their national CNA. One participant suggested that disagreements could be approached in collaborative way but noted that it may be possible to bring unresolved issues to other fora, e.g. the relevant ministry.

Finally, it was noted that further consideration needs to be given to the relevance of data protection laws. It was suggested that there is a need to better understand privacy laws and the relevant implications for user checks because information is not necessarily available to the CNAs for identifying potential users of genetic resources.

8 Strict Liability for “Registered Collections”? Assessing Regulation (EU) No 511/2014

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8.1 Content and Scope

This legal expertise, which was commissioned by the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) in September 2017,¹⁰ investigates the question if liability for *ex situ* collections is exacerbated by registration under Article 5 Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU ABS Regulation).¹¹ This question arose in the course of the international debate as some national jurisdictions privileged basic research by shifting the duty to declare utilization to registered collections.¹²

The analysis covers three distinct questions:

- Do Article 4.7 and Article 4.5 of the EU ABS Regulation impose a ‘strict liability’ on registered collections (*infra 2*)?
- What exactly is the standard of care required by registered collections (*infra 3*)?
- Can collections limit their liability via contractual clauses (*infra 4*)?

The analysis concludes with a birds-eye-view on the issue at hand (*infra 5*).

Three limitations restricted the scope of the study at the outset:

- We assumed that German law is the applicable law for claims of contractual and tortious liability: Since the EU ABS Regulation itself does not regulate liability, the rules applicable to the liability regime fall within the purview of national law. The aim was to focus the analysis exclusively on the effects of the norm triangle of Article 4.5, Article 4.7 and Article 5 of the EU ABS Regulation. However, as it is possible to choose the applicable law or contracts and (in a limited manner) for torts (delicts), this assumption is not necessarily realistic and clearly limits the extent to which the analysis can be generalized.
- The second limitation pertains to the fact that we concentrated on the relationship between the registered collection and the user who receives genetic resources from that collection. We excluded the relationship between the collection and the provider country

¹⁰ Full-length expertise available in German language under https://www.bfn.de/fileadmin/ABS/documents/ABS_Dokumente_ab_September_2015/20180618_Haftung_Registrierter_Sammlungen_gemaess_VO_EU_Nr.511_2014_.pdf.

¹¹ Off. J. of 20.5.2014 L 150/59.

¹² C. Chiarolla, Commentary on the ABS Provisions of the Draft Biodiversity Law of France, in: B. Cool-seat/F. Batur/A. Broggiato/J. Pitseys/T. Dedeurwaerdere (eds), Implementing the Nagoya Protocol, Brill/Nijhoff: Leiden/Boston, 2015, 77-114 (p. 89).

as well as the relationship between the recipient and the competent national authority (CNA).

- The third limitation is the assumption that registered collections submit to the regulations of the Nagoya Protocol (Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) required). Therefore, the question of when collections “utilize” – and **therefore** require PIC and MAT – is also excluded in the present analysis.

8.2 Interpretation of Article 4.7 of the EU ABS Regulation

The interpretation of Article 4.7 of the EU ABS Regulation is central to this analysis. In principle, the norm can be interpreted in three different ways: It can broaden the liability of collections (strict liability), it can shield them from liability, or it has no effect at all since it regulates something else.

Article 4.7 of the EU ABS Regulation stipulates:

“Users obtaining a genetic resource from a collection included in the register of collections within the Union referred to in Article 5.1, shall be considered to have exercised *due diligence* as regards the seeking of information listed in paragraph 3 of this Article.”

The BfN tender for this expertise was motivated by the widespread belief that Article 4.7 of the EU ABS Regulation increases the liability of registered collections. The underlying notion was that of a seesaw, i.e. the privileged treatment of one party comes at the expense of the other party. Article 4.7 EU ABS Regulation, so the argument goes, contains a privilege on behalf of the receiver of material from registered collections. Yet, the user of that material may still have to stop use under the last sentence of Article 4.5 of the EU ABS Regulation. Therefore, Article 4.7 of the EU ABS Regulation could be interpreted as a mechanism that shifts responsibility from the user to the registered collection.

From a tort lawyer’s perspective, the inferred transformation of the general process-oriented rule of “*due diligence*” under Article 4.1 of the EU ABS Regulation into a strict guarantee under Article 4.7 of the EU ABS Regulation is not at all intuitive. In principle, anyone is responsible to adhere to his or her **own** standard of care.

Therefore, we undertook **four inquiries de lege artis** in our expertise: a literal interpretation, an inquiry into the legislative history, a systematic analysis of Regulation (EU) No 511/2014 as a whole (2.1), and last but not least, an inquiry into the telos of “Regulatory *Due Diligence*” (2.2.).

8.2.1 Literal Interpretation, Legislative History and Systematic Analysis

The **literal interpretation** inquired into whether Article 4.7 of the EU ABS Regulation implies a legal fiction in favour of the receiver. The German language text version suggests this interpretation. The consequence would be a conclusive assumption that the user is diligent; the duty is shifted to the registered collection and the liability of collections is transformed into a causal (strict) liability. However, other language versions of the text suggest that it is a pro-

cedural regulation, implying (at least for German dogmatic culture) that the assumed fact is rebuttable.¹³ In German language versions of subsequent documents submitted by the European Commission (EC), the provision is indeed explained as a **rebuttable presumption**. Therefore, we find that the German version of the EU ABS Regulation is misleading in this regard. In accordance with the majority of the language versions, we interpret Article 4.7 as being procedural. It aims at the presumption of a fact, namely that PIC and MAT were sought as documented (not the law) – this fact is rebuttable. We conclude that Article 4.7 does not aim to substantively change the liability of registered collections from fault based to causal strict liability. The receiver retains the duty to exercise *due diligence*. The privilege enshrined in Article 4.7 of the EU ABS Regulation is the reversal of the burden of proof.

With regard to the **legislative history**, we found that Article 4.7 of the EU ABS Regulation did not change throughout the parliamentary process. Only the last sentence of Article 4.5 of the EU ABS Regulation was introduced at a later stage. The addressee of this norm, however, is the user, not specifically a registered collection. Based on the inquiry into the legislative history, a conceptual shift in the liability regime from negligence to strict liability cannot be inferred.

The **systematic analysis** examined the triangular relationship between the last sentence of Article 4.5, Article 4.7 and Article 5 of the EU ABS Regulation. In a binary world of two liability concepts (negligence and strict liability), three interpretations are possible. One possibility is to argue that the **final result** in Article 4.5, i.e. to “discontinue utilization”, transforms the fault-based standard of the general norm of Article 4.1 into a causal, strict liability, as indicated above. This then implies that collections would be held liable for any shutdowns, e.g. of production. The second possibility is to construe Article 4.7 as a shield against potential shutdowns – as users are considered to have exercised *due diligence* – with the effect that no damages could occur. As a result, registered collections would also be protected, very much like an umbrella. This concept would imply that the fault-based concept of Article 4.1. is not altered by Article 4.5. The third alternative is to argue that all three norms stipulate different things.

With regard to the systematic interpretation, we conclude that Article 4.5 of the EU ABS Regulation stipulates a liability that is of a **hybrid nature**. The law combines the duty standard with a conclusive result. It neither leaves the fault concept in Article 4.1 completely untouched, nor does it install a straightforward strict liability. *Tertium datur*. There are two modern models for such a combination: The liability of internet providers and *Due Diligence Liability* in the Convention on Contracts for the International Sale of Goods (CISG), the latter may be even more important for the given context.

The **liability of internet providers** ties the infringement by a responsible person to the provider company, which can stop the infringement. It submits the non-infringing internet provider to a duty standard with a final result: It might have the duty to delete the content from its server. In this case, a **dynamic duty** with escalating steps is applied, since the provider has to inform the infringer, check the content. In the end, if the infringing activity does not stop, it is up to the provider to delete the content. In a similar vein, the last sentence of Article 4.5 of

¹³ Acknowledging that other jurisdictions, e.g. France, recognize also the possibility of rebuttable legal fictions.

the EU ABS Regulation denotes a result-based endpoint and complements the basic norm in Article 4.1 of the EU ABS Regulation. Ordinarily, the user “exercises *due diligence* to ascertain that [...]”. Article 4.5 of the EU ABS Regulation now adds a provision in the event that **subsequent uncertainties** materialize – since normally the user, being diligent, would have asked the other party (i.e. the provider) for clarification. Subsequent uncertainties typically arise at the end of a transfer chain where persons/companies are affected which are not identical to those who/which fell short of their duties and contributed to the persistence of uncertainties. Consequently, Article 4.7 of the EU ABS Regulation has no operational meaning for Article 4.5 of the EU ABS Regulation beyond reversing the burden of proof. Within the system of Article 4 of the EU ABS Regulation, just like Article 4.5, Article 4.7 serves to complement Article 4.1 of the EU ABS Regulation.

The central location of the *due diligence* concept in Article 4.1 of the EU ABS Regulation suggests that the **CISG**-rules, especially as applied in the context of international corporate mergers and acquisitions,¹⁴ are supposed to shape the Regulation’s concept of liability. The CISG stipulates a so called “**defect liability**”. In essence, it denotes that the seller is only strictly liable for so-called **hidden defects**. The rationale is that open defects can be detected by the buyer. This is where *due diligence* comes in – International sales law is the origin of the due diligence requirements. However, under the CISG, *due diligence* is not the basis for liability (as in the EU ABS Regulation) but a defence instead: The buyer can only hold the seller liable for open defects, i.e. where the seller is notified of them. In addition, we found that *due diligence* liability under the CISG is always limited in scope – pure economic damages are not covered. Transposed to the given context, this means that the idea that the *due diligence* liability in Article 4.5 of the EU ABS Regulation would, as a matter of fact, encompass the liability for having to stop utilization is not in line with the origins of *due diligence* liability.

Thus, there are two strong systematic arguments against a clear-cut liability as the prevailing concept here. First, strict liability - for being an exception to the rule - requires explicit legislation and is usually coupled with mandatory insurance. However, Article 4.5 of the EU ABS Regulation is silent on collections. It only regulates “the user”. Second, *due diligence* liability under the CISG is limited in scope to direct damages and does not cover economic losses. Therefore, we conclude that Article 4.5 cannot systematically be interpreted as a provision that transforms a collection’s liability into a strict liability with respect to the mandated discontinuation of utilization.

8.2.2 The Telos of Due Diligence Liability

Finally, we looked for the telos of *due diligence* liability and inquired into related regulations for guidance on how to interpret the norm triangle. We compared the EU ABS Regulation with four selected product regimes, which contain privileging presumptions and include some

¹⁴ See also COM Guidance (2016/C 313/01), p. 11.

form of regulatory intermediary:¹⁵ tropical timber (Regulation (EU) No 995/2010¹⁶), personal data (Regulation (EU) 2016/679¹⁷), carbon emissions from large vessels (Regulation (EU) 2015/757¹⁸), and medical products (Directive 93/42 EEC¹⁹). We included medical products because of recent case law on the liability of intermediaries. The main questions were:

- What is the liability concept in the respective regulations?
- How are privileging presumptions (akin to the one in Article 4.7 of the EU ABS Regulation) construed?
- How are intermediaries conceived? Do privileges result in a burden-shift to intermediaries?

As a regulatory concept, *due diligence* implements a type of non-governmental self-regulation ultimately rooted in globalization: The essential function is transnational. It links the regulatory requirements of one country to enforcement in another country. Originally, the concept grew out of compliance with technical standards. Today, it has become a mechanism to import or export regulation, binding together regulatory regimes, which are otherwise territorially limited: With respect to data protection and carbon emissions from ships, we **export** EU regulation. With timber and genetic resources, we **import** regulation (without directly enforcing extraterritorial laws). The underlying model of *due diligence* is business administration, not law. Its core is dynamic information and not static law, squeezed into the binary code of legal and illegal. Typically, *due diligence* regimes install two mechanisms, namely an intermediary between the company and government authorities, and a presumption of compliance that verifies and/or documents the adherence to certain standards.

Tropical Timber – Regulation (EU) No 995/2010

Regulation (EU) No 995/2010 laying down the obligations of operators who place timber and timber products on the market (EU Timber Regulation) is a direct conceptual precursor to the EU ABS Regulation, with which it shares several attributes, the most notable of which is a dual system of privileged and unprivileged timber imports. For those imports that fall under either the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)-regime (Regulation (EC) No 338/97)²⁰ or the Forest Law Enforcement, Governance

¹⁵ C. Godt, „Due Diligence“ Modernes Umweltmanagement oder Regulierungsverweigerung? E.-W. Luthe/U. Meyerholt/R. Wolf (eds), *Der Rechtsstaat zwischen Ökonomie und Ökologie*, Mohr Siebeck: Tübingen, 2014, 115-132 (p. 126).

¹⁶ Off. J. L of 12.11.2010, 295/23; complemented by Implementing Regulation 607/2012 (Off. J. ABI.EU of 7.7.2012, L 177/16) and Delegated Regulation 363/2012 (Off J. of 27.04.2012, L 115/12).

¹⁷ Off. J. of 4.5.2016, L 119/1.

¹⁸ Off. J. of 19.5.2015, L 123/55.

¹⁹ Off. J. of 12.7.1993, L 169/1. The Directive has been repealed by the Medical-Devices-Regulation (EU) 2017/745, Off. J. of 5.5.2017, L 117/1.

²⁰ Off. J. of 3.3.1997, L 61, transposing the Convention on International Trade in Endangered Species of Wild Flora and Fauna, 1973 [CITES].

and Trade (FLEGT)-scheme (Regulation (EC) No 2173/2005),²¹ and are thus registered during border controls, a privileging presumption applies (“shall be considered to have been legally harvested for the purposes of this regulation”), which exempts importers from their *due diligence* obligations. Importers who first place such timber on the market can assume that the respective wood is marketable and therefore they are acting in good faith. For wood that is not covered by either a FLEGT-license or a CITES permit (so-called “green lane”), a general *due diligence* standard applies: Operators placing timber on the internal market for the first time shall exercise *due diligence* to minimize the risk of placing illegally harvested timber on the internal market.

However, timber importers can alleviate some of their *due diligence* duties by using a *due diligence* system established by an accredited monitoring organization, Article 4.3 EU Timber Regulation. Like registered collections, **monitoring organizations** are controlled by the competent national authorities and act as service providers for users. In the case of the EU Timber Regulation, they verify the proper use of their *due diligence* systems by timber importers. They have to have the appropriate expertise and the capacity to exercise their functions. The operational tasks of actually using the *due diligence* system (seeking information, assessing and mitigating potential risks) and the legal risk (liability²²) remain fully with the importer²³ – there is no shift of duties. In contrast to the EU ABS Regulation, the EU Timber Regulation contains a general prohibition of placing illegally harvested timber on the market, Article 4.1 EU Timber Regulation. There is no such prohibition regarding genetic resources. This may be why the EU-parliament insisted on inserting the rather potent mechanism of the last sentence of Article 4.5 of the EU ABS Regulation. For users obtaining genetic resources from a registered collection, acquisition in good faith is derogated from by means of the last sentence of Article 4.5 of the EU ABS Regulation.

Data Protection – Regulation (EU) 2016/679

The General Data Protection Regulation (EU) 2016/679 contains a somewhat hidden presumption of conformity in the first sentence of Article 42.2, which provides that data protection certification may be used for the purpose of demonstrating the existence of appropriate safeguards provided by processors of personal data located in third countries (outside the EU). Certifications are issued and renewed by certification bodies, which need to demonstrate a level of expertise regarding data protection in order to be accredited by the supervisory authorities. Certification, as such, does not exclude the liability of the data processor nor does it reverse liability by shifting it to the certifier. The duties, as stipulated by the Data Protection Regulation, remain with each participant (user-intermediary-public authority), which is

²¹ Off. J. of 30.12.2005, L 347. Licensing scheme within the FLEGT-Regulation. The respective licenses can only be issued by countries that have a Voluntary Partnership Agreement (FLEGT-VPA) with the EU in place, confirming that the timber productions at hand were logged in full compliance with the laws of the exporting country. FLEGT is the acronym for the EU’s Forest Law Enforcement, Governance and Trade Action Plan, which was established in 2003.

²² A. Fishman/K. Obizdinski, European Union Timber Regulation: Is It Legal? RECIEL 23 (2) 2014, p. 263.

²³ Client Earth, October 2011, p. 12, 13 (last accessed 30.05.2018).

even provided for in the Regulation itself: “A certification does not reduce the responsibility of the controller or the processor for compliance with this Regulation and is without prejudice to the tasks and powers of the competent supervisory authorities”, Article 42.4 EU Data Protection Regulation. It should be noted that the presumption of conformity, here, is an empty one.²⁴ There is no privileging presumption that the data processor is actually in compliance with the requirements of the Data Protection Regulation. The certification merely documents the security level regarding data protection laws for the individual whose personal data is being processed, much like the Technischer Überwachungsverein (Technical Inspection Association, TÜV) approval for medical products documents conformity with technical standards (see *infra*). Furthermore, as something inherently peculiar to the EU Data Protection Regulation, there is no reversal of the burden of proof: The processor has to actively prove that it is not in any way responsible for the event giving rise to the data protection violation, Article 82.3 Data Protection Regulation. A certification, here, may be used as an element by which to demonstrate compliance, but it can be a snapshot at most,²⁵ showing only conformity with the requirements of the Regulation for one particular moment in time – otherwise, any later infringements would not be contestable.

Because of its special nature with respect to accountability principle,²⁶ the EU Data Protection Regulation is only of limited usability as far as a direct comparison of privileging presumptions is concerned. The term *due diligence* itself may not appear in the Regulation, there is however a call for something which can only be described as a *due diligence* system in Article 24.1 Data Protection Regulation. A **clear separation of duties** and responsibilities of each actor (data processor – intermediary certification body – supervisory authorities), which excludes any shift of liability, is nowhere more apparent than in this Regulation. Furthermore, in accordance with the other instruments we examined, the EU Data Protection Regulation clearly shows that the **procedural safeguarding of information** (to prove compliance) is a core function of privileging presumptions.

Carbon Emissions from Large Vessels – Regulation (EU) 2015/757

Since January 2018, large vessels, have to carry “documents of compliance” **issued by an accredited verifier** when entering European ports. Compliance is directed towards information about the total amount of carbon-exhausts from a given ship, not towards compliance with emission caps. The duties rest with the ship owners (usually companies). They have to submit monitoring plans to the verifiers, which detail the methods chosen by companies to monitor and report the CO₂-exhausts from their ships. According to Article 7 Regulation (EU) 2015/757, companies have to review (and potentially adjust) their monitoring plans on an annual basis. The verifiers then review the monitoring plans for, inter alia, completeness and accuracy (Article 6 Regulation (EU) 2015/757) and check, whether reviews successfully culminated in modification of the monitoring report. Eventually, the verifier will issue timely lim-

²⁴ E. Lachaud, Why the certification process in the General Data Protection Regulation cannot be successful, Comp. L. & Sec. Rev. 32 (2016), 814 (820, 823).

²⁵ J. Eckhardt, in: H. A. Wolff/S. Brink (Hrsg.), Beck Online-Kommentar Datenschutzrecht, Beck: München (21. Ed. 2017) DS-GVO, Article 42.45.

²⁶ See also Article 5 Regulation (EU) 2016/679.

ited documents of conformity. The competent authorities will view these documents as (rebuttable) evidence of compliance – this is the privileging presumption contained in Article 19.1 Regulation (EU) 2015/757. The primary goal of these documents is not to guarantee material validity, but instead to allow for the transparency/traceability of controls.

Medical Products – Directive 93/42 EEC

In contrast to pharmaceuticals, medical products are **not** submitted to a prior **public** authorisation, which secures safety and for which a company is held strictly liable if it does not comply with the terms of the authorisation. Medical products are merely controlled by so called “notified bodies” – in Germany, this body is the TÜV. There is no strict liability in place, neither for the manufacturer, nor for the surveying verifier.

The verifier issues a “conformity statement” with technical standards, based on documentation provided by the manufacturer. The TÜV neither tests the product, nor does it check the company. It does not secure safety as such – only compliance with the respective technical standards. The statement allows marketability. For possible violations of the duty of care, the verifier is obliged to take out civil liability insurance.

In the “Silicon”-case decided by the Court of Justice of the European Union in February 2017, the Court ruled that the exact duties of verifiers are determined by the EU Directive autonomously in the first place. Only where the liability regime is not stipulated or not in full by European Union’s law itself, liability is governed by national law. While the Directive was silent about the disputed duty to perform unannounced inspections on-site, the Court interpreted this silence as evidence that – then – there must be no general duty to perform on-site inspections. However, if there is concrete evidence of danger, the verifier has to react and secure safety – otherwise it will be liable. This indicates a dynamic conception of the duties of the verifying bodies.

The lesson to be learnt for the given context is the following: Article 5 EU ABS Regulation, which determines the duties of collections, is silent on liability. Consequentially, for collections registered under Article 5, liability is to be based upon national law. A strict liability standard is an exception to the rule and requires positive regulation. More importantly, the provision does not mandate collection holders to take out insurance. This link between mandatory insurance and augmented forms of liability is a characteristic of all strict liability regimes recognized by the EU and its Member States.²⁷ That registered collections and their duties are construed in a different manner is further support for the argument against the EU ABS Regulation establishing a result-based strict liability for registered collections.

8.2.3 Conclusion

Our analysis reveals that Article 4.7 EU ABS Regulation stipulates a presumption of facts and is **procedural** in nature. It does not presume that “PIC and MAT are correct” (material validity), but it presumes that PIC and MAT were accessed. This reading is supported by

²⁷ Cf. the decisions of the Cour de Cassation (France) (Ch. Com.) from 8.3.2017 and 14.6.2017, commented by S. Mirabel and printed in *Le Droit Maritime Français* 2017, S. 596 ff. und S. 612 ff.

statements of the Commission,²⁸ which indicate that *due diligence* “is not intended to guarantee a certain outcome” but to ensure that “the necessary information related to genetic resources is available all throughout the value chain”. The privilege of Article 4.7 EU ABS Regulation is limited to the fact that those who receive genetic resources from registered collections do not have to seek PIC and MAT themselves. It neither reverses the ABS-duty, thus shifting it to registered collections, nor does it create strict liability. These findings are supported by the telos inquiry. It reveals that the core of all *due diligence* systems is risk management as a dynamic concept. The duty of care shifts over time and depends on the circumstances. The function of the intermediary is to raise the level of information and transparency. An intermediary does not take over responsibilities outside the stipulated realm; the respective presumptions only reverse the burden of proof and change the level of required evidence. Overall, the concept of *due diligence* remains intact: Each player in the chain retains its duties. The regulation itself does not stipulate any shift, duplication, or extension of these duties.

8.3 What is the Standard of Care for a Registered Collection?

8.3.1 The Dual Structure of Article 5 of the EU ABS Regulation

What exactly are registered collections required to do under Article 5 of the EU ABS Regulation?

As a matter of principle, the standard of care for registered collections can be found in Article 5 EU ABS Regulation; the legal basis is national law. Interviews conducted with technical experts evidenced that they clearly distinguish between the five requirements in Article 5.3 of the EU ABS Regulation: Sub-sections (a) and (c) to (f) are deemed to be technical requirements demanding **technical** expert knowledge, whereas sub-section (b) is deemed to be something else.

Sub-sections (a) and (c) to (f) stipulate the application of standardized procedures in the course of the collection’s workflow as well as the collection and documentation of externally and internally generated **scientific-technical data** for reasons of **traceability**. With regard to these technical requirements, it is common sense among scientists that the standard of care cannot be absolute. Scientific documentation is ubiquitously faulty. This is inherent to science. Although documentation should be correct for its own sake, single entries are often wrong for various reasons, which are elaborated upon in our study (e.g. spelling errors, mixing-up badges). As far as incoming material is concerned and ABS and MAT mistakes rest on objectively faulty scientific documentation, the standard of care, by law, cannot be strict but is – on grounds of reasonableness - limited to a professional, careful and mindful comparison of data, which might give rise to doubts.

This supports the finding made for Article 4.7 of the EU ABS Regulation above (*supra* 2): What matters, is the individual standard of care. The yardstick for the standard of care is the function of a collection: It is the intermediary function to secure the information right at the beginning of the utilization chain between providers and later users. As an intermediary, the

²⁸ COM Guidance (2016/C 313/01), p. 11.

instrument of “registered collections” is installed to raise the trust of both provider states and users. It is not installed to serve the interests of European users only. In contrast, since users have always trusted public collections, it seems that having “registered” collections as an instrument, should primarily increase the trust of providers.

In contrast, sub-section (b) requires “**supply only with documentation**”. The central question for the expertise to answer was whether this duty implies that collections have to examine the (legal) correctness of PIC and MAT. More concretely: Is there a duty to perform a legal inquiry into whether the provider country is a party to the CBD and the Nagoya Protocol, or if the signing authority is competent? What is the duty of care in a situation in which a scientist plausibly argues that he applied for PIC and MAT but received no answer? We argue that the requirement in sub-section (b) to “supply with documentation” is different from “legal examination”. The full text states: “supply only with documentation providing evidence that the resources were accessed in accordance with applicable ABS-legislation”. We interpret this norm as being **descriptive**, referring only to the process of documentation. It does not require the collection to “provide evidence on third party rights”, which is a standard formulation for legal service contracts. The documentation has the function of presenting evidence for the fact that PIC and MAT were sought. In legal philosophy, the requirement to “provide evidence that the resources were accessed in accordance with applicable ABS legislation” qualifies as a so-called “**normative fact**” (in German: “Normtatsache”).²⁹ These are hybrids between facts and norms but are to be treated as facts. Whereas Eike Schmidt’s analysis on how to deal with normative facts was geared towards delineating the tasks of legislation and the judiciary, we propose to transpose his ideas to delineate the tasks of an executive agency and a scientific collection. The collection’s task must be limited to reviewing the **plausibility** and **completeness** of facts. They do not have an enforcement duty. Therefore, they do not owe an in-depth legal analysis by law but merely an informed, educated review of the data and its completeness. We resort to the *due diligence*’s risk based approach: The more problematic and dubious the source region, the higher the standard of care would have to be. This is similar to what the Timber Regulation asks for in Article 6.1, sub-section (b) Regulation (EU) No 995/2010 by requiring the prevalence of illegal timber harvesting in the country of harvest be taken into account in the risk assessment. Apart from the above-mentioned arguments, however, any collection is free to provide an additional legal service on a contractual basis to check for “third party rights” on top of the regulatory required standard of care, e.g. like the German Collection of Microorganisms and Cell Cultures (DSMZ) does.

8.3.2 Survey of Technical Mistakes and Challenging MAT-provisions

Recognizing that collections are intermediaries, we made three observations at the outset that inform our survey on technical mistakes and challenging MAT-provisions:

- The benchmark for the duty of care regarding external mistakes is less strict than for internal mistakes: The collection has control over its own (internal) processes.

²⁹ E. Schmidt, Der Umgang mit Normtatsachen, in: C. Broda/E. Deutsch/ H.L. Schreiber/H. J. Vogel (eds), Festschrift R. Wassermann, Neuwied/Darmstadt: Luchterhand, 1985, 807.

- The situation with regard to incoming material (*infra* 1-4) is different to the one regarding outgoing material (*infra* 5).
- The law clearly distinguishes between **subjective and objective standards**: In CISG case law, subjective capacities are irrelevant (lack of staffing, money, time and experience does not shield against liability). The rationale is that the professional standard does not care about internal shortfalls. The “objective” standard denotes what the recipients can rightfully expect. This is determined by the collections’ role in science, the material collected and by the goals of the collection itself (e.g. being a service-provider).

We identified five particularly challenging situations with regard to technical errors and specific MAT-provisions, such as use-restrictions:

1. In the category of **external mistakes regarding incoming material** (accession), the depositor might submit no PIC/MAT. He/she might argue that the country of origin has no legislation in place, research is free, or authorization was requested but not obtainable. We take the position that the standard of care for registered collections requires the collection to demand that the supplier of genetic resources submits a respective declaration. Article 5 does not require the collection to perform a legal review, as stated above. However, in a situation where the authorization is not obtainable for political reasons (the presumption is: timely limited), the material can be deposited in the collection for a reasonable time, but it cannot be transferred to third parties. At the same time, the scientific standard regarding the principle of reproducibility/verifiability of scientific results must not be undermined.
2. Regarding **external mistakes when transferring material** to third parties, the essential element of defect liability can be transposed to this context (even if the CISG would not directly apply). It seems reasonable to offset the duty to check for external mistakes with the respective *due diligence* of the professional recipient. The standard here is whether the recipient “ought to have known”.
3. A more complicated situation arises where the supplier of genetic resources requests **secrecy**. According to Article 7.5 of the EU ABS Regulation, business secrets are to be respected. However, Nagoya-relevant information cannot be kept secret. Thus, the challenge here is to distinguish business secrets from Nagoya-relevant information: The country of origin is certainly Nagoya-central, and must be disclosed (unlike, for example, the exact geographical coordinates of the discovery). If a supplier demands this information to be kept confidential, the resource cannot be stored in the registered part of the collection. The omission of this information when transferring material will result in liability of the collection.
4. **Accessions with use restrictions**. When taking in a sample which is restricted by a contractual “no deposit”- clause, the collection evidently violates its duty to exercise *due diligence* as the acceptance of this material violates the contract. As a Nagoya-collection, they are expected to conduct a plausibility test, and this is not plausible. They violate the invested trust of the supplier (unless it is collusive). The situation is similar with regard to restrictions such as “no commercial use”. If such material is supplied as a Budapest-deposit (patent filing), which mandates transfer to interested (commercial) third parties, collections would act in a grossly negligent way by accepting it. Not only would they violate a duty vis-à-vis the provider country, they would al-

so make a process-related mistake by accepting material into the collection of which they know that it will be used in a way that is not in compliance with the contract. The same is true for collections, which cannot assure that use restrictions will be processed properly. If that is the case, a registered collection should not accept material with such a restriction into its collection.

5. The accession situation is to be distinguished from the **transfer of “use restricted” material** to third parties (“outgoing material”). In principle, restrictions are common practice and therefore unproblematic. The collection is not responsible for the user. It is not an extended arm of the national enforcement agencies of the provider countries. A use restriction is not a straightforward prohibition but only a duty to re-negotiate. However, the situation is different with regard to “non-commercial use” clauses. While parties often feel safe when using this clause, the term is in fact highly misleading. Its content is determined by legal traditions – and differs respectively: In industrial countries, commercial use starts with placing a product on the market (intention of making profit). Research before that moment (regardless of who conducts it) can then be qualified as non-commercial use. In most developing countries, however, commercial use is marked by the transition from basic to applied research and thus depends on the respective actors. Whose definition prevails in case of a conflict?

Since it is a part of public law, PIC authorization is governed by the law of the provider country. The MAT, in contrast, is governed by the contractual statute (between the provider state and the user). That means it is **not** up to the collection to re-define the terms of the contract. Therefore, the DSMZ has rightfully changed its standard terms and conditions recently. We argue that the transfer of “non-commercial use” restricted material to commercial partners requires a **three-step-test**: (1) When a collection transfers material to non-experienced recipients, it is necessary that the collection clarifies the term. Otherwise, the recipient will be deceived. (2) When the collection transfers a “non-commercial use”-restricted sample to a multinational, we consider the transfer contract null and void for being collusive. Damages for contractual liability could therefore not be adjudicated. The EC rightfully interprets a clause stipulating “non-commercial use” as “no transfer to third commercial parties”.³⁰ Again, it is the (external) expectation of a registered collection that determines the informational duties. (3) The limitations stated here do not apply, however, when the country of origin understands “non-commercial research” as industrialized countries (here: the place of residence of a registered collection) do, i.e. as extending until market placement.

8.4 Contractual Limitation of Liability

With regard to contractual limitations of liability, we found no peculiarities. Liability can be limited in kind, in time and in amount, as far as the usual limits are respected (these are stricter in Europe than in the US³¹). Liability can exclude slight/ordinary negligence but not

³⁰ EU Sectorial Guidance Document - Collections (Version V 3.0. of 22.12.2017), p. 20.

³¹ L. A. Dimatteo, *International Contracting: Law and Practice*, Wolters Kluwers: Alphen, 3rd edn 2013, pp. 173-179.

gross negligence. One can reduce deadlines and the amount if these limits remain reasonable. The exclusion of “liability for the legal analysis of third party rights” would, under normal conditions, simply be declaratory and would not regulate anything. However, if the collection had contractually taken over the service of examining existing third-party rights, such an exclusion would be void. One cannot exclude liability for primary contractual duties.

8.5 Conclusion

We conclude that the key rationale of what registered collections ought to do in order to meet the standard of care is epitomized by the question “Do collections have the duty to monitor the change of intent of their recipients?” We argue that this is **not** the case: Article 5 of the EU ABS Regulation aims to install registered collections as intermediaries. Neither are they extensions of the enforcement agencies of provider countries nor extensions of the provider state itself. Consequently, it is not within the purview of collections to inform the provider states about potential changes of intent by the users. Equally, they do not become risk absorbers for recipients, as they do not issue guarantees in the vein of “free from third party rights”. Their function is to “secure information in the chain”.

Discussion

In the discussion, the EC confirmed that registered collections are not a checkpoint but that their main function is to secure information and to lower risk that genetic resources have been obtained in contravention of ABS rules. One participant suggested that the need to provide documentation contributes to lowering risk and is an improvement on the past, when there was often little or no documentation accompanying genetic material in collections.

A number of reasons were identified as to why collections are not in a position to check if PIC and MAT are formally correct. It was noted there are issues of practicality and feasibility, e.g. there are no standards in the bilateral ABS system, there are language barriers etc., meaning that no collection would have the ability or resources to check all the documentation. A couple of participants highlighted the need for a balanced and practical approach, which takes into account what is possible for collections to do, such as checking whether there is access legislation or a national focal point (NFP) and whether the relevant documents have been provided. In order to check the documentation is legally correct, collections would have to go back to each provider country and ask for conformation, which is not regarded as the role of the collection when accepting material. It was pointed out that documents, e.g. signature, time stamps etc. can be falsified but the role of the collection is to conduct a “plausibility check” only and not an in-depth legal check of the documents.

It was reiterated that users still have to look at the documentation provided by registered collections, i.e. the user still has a due diligence obligation which cannot be taken away. One participant noted that only the individual researcher knows what he or she is doing with the material and can check whether this is in accordance with the conditions of PIC and MAT and that many researchers often do not disclose to the collection or perhaps even colleagues what they are doing, e.g. due to competition. One participant also commented that many commercial users do not necessarily do commercial research on genetic material received

from collections, i.e. they also do basic research such as referencing functions, comparing samples for taxonomic purposes etc.

Prof. Godt confirmed in the discussion that according to her legal analysis, the EU ABS Regulation does not place strict liability on collections. The decision by the EU court on medical products was referred to again and it was noted that this decision indicates that where liability of the intermediary is envisaged by an EU regulation, this must be coupled with compulsory insurance. As there is no need for registered collections to take out insurance, it was concluded that strict liability is not likely to be intended by the EU ABS Regulation.

9 Application for Acknowledgement of Best Practice under Article 8 of Regulation (EU) No 511/2014: The CETAF Code of Conduct & Best Practice

Dirk Neumann

Organisation representing the CETAF Legislations and Regulations Liaison Group (in alphabetical order: Johan Bodegård (†), Swedish Museum of Natural History, Stockholm; Ana Casino, CETAF, AISBL c/o Royal Belgian Institute of Natural Sciences, Brussels; Peter Giere, Museum für Naturkunde Berlin; Lars Erik Johannessen, Natural History Museum, Oslo; Christopher C. Lyal, Natural History Museum London; Anne Nivart, Muséum national d'histoire naturelle Paris; Ole Seberg, Natural History Museum of Denmark, Copenhagen; Hendrik Segers, Royal Belgian Institute of Natural Sciences, Brussels; China Williams, Royal Botanic Gardens, Kew).

The Consortium of European Taxonomic Facilities (CETAF) is an association of 59 Natural History Collections and Botanic Gardens, which is represented in 21 European countries. Researchers at CETAF institutions conduct collection-based bio-sciences (mainly taxonomic and systematic research), i.e. Life Sciences (zoology, botany, paleobotany, archaeozoology and anthropology), Earth Sciences (e.g. geology, mineralogy, paleontology), and heritage sciences (testimony of the history of natural sciences found in libraries or art collections of the CETAF members).

The collection size of the individual CETAF member institutions varies from 25,000 to 80 million collection objects, and the overall number of objects curated in CETAF collection surpasses 1.5 billion specimens, which represents more than 80 % of the world's described species. Some of these objects can and are utilised in the sense of the Nagoya Protocol by the 2,000 CETAF scientists and over 6,000 scientific visitors that visit CETAF institutions for their research annually. Many other objects are not utilised but are still of great scientific value.

The history of CETAF dates back to 1996, when 10 major European collections started to collaborate more closely under a Memorandum of Understanding. In 2009, CETAF members decided to form a non-profit association uniting European Natural History Collections and Botanical Gardens. This was accomplished by the official recognition of CETAF as a legal body under Belgium law in 2012 and the appointment of a General Secretary. Soon thereafter, on the initiative of German CETAF members, the ABS working Group (Legislations and Regulations Liaison Group) was established. In December 2012, CETAF organised a first workshop addressing different legal aspects when handling and shipping biological material to which the DG Environment of the European Commission was also invited. Since then, CETAF has supported the drafting and implementation process of Regulation (EU) No 511/2014 (EU ABS Regulation) through comments and submissions.

Collections Managed by CETAF Members

From the initial drafting of the CETAF Code of Conduct, it was clear that because of the heterogeneity and complexity of the member collections, which include objects in natural history

and botanical collections as well as plants in botanical gardens, and because of the fundamental differences in the management of the collection objects, it would be impossible to design a uniform management system that could support registration of entire collections of CETAF members under Article 5 of the EU ABS regulation. This is a fundamental difference to, for example, culture or microbial collections, where stored (living) collections have the same management requirements, irrespective of whether a business case could be made out of registering collections under Article 5 of the EU ABS Regulation.

The focus of the development of management tools for CETAF members in the CETAF Code of Conduct and Best Practice was consequently (i) identification of common principles in the maintenance, management and accession of objects curated in CETAF collections, and (ii) developing suitable transferrable tools and deliverables that build on these commonalities while recognising and accommodating the different operational modalities employed by members.

The following two examples may illustrate the differences in the collections:

The Royal Botanical Gardens, Kew houses a herbarium with 7.5 million vascular plants, a fungarium with 1.25 million fungi, a living collection with over 30,000 species (non-static plants seeding independently in the garden), a seed bank with approximately 2 billion seeds (which are continuously propagated to maintain the germination capacity of this collection), over 42,000 accessions of frozen DNA and tissue collections and archives with books, artwork, prints and drawings with over 1 million objects partly including information on the traditional use and purposes of the depicted or described species.

The Bavarian Natural History Collections in Munich (Staatliche Naturwissenschaftliche Sammlungen Bayerns, SNSB) are among the most diverse Natural History Collections in CETAF, including plants, seeds and fungi in the living and preserved collections (Botanical Garden and the Botanical State Collection), preserved animals (Zoological State Collection), archaeological and anthropological objects and reference skeletons (State Collection for Anthropology and Paleoanatomy), as well as paleontological, geological and mineralogical collections. Intuitively, anthropological, paleontological and geological collections might be considered outside the scope of access and benefit sharing (ABS) legislation. However, anthropological and paleoanatomical collections are frequently targeted for ancient DNA-sequencing (e.g. for isolation of medieval plague strains from human bone fragments or for research on animal bones to investigate domestication). In addition, palaeontologists may utilise recent sponge and coral species to support phylogenetic placement of fossils.

All items mentioned above might be utilised directly or indirectly, for example, associated organisms such as symbionts, ecto-/endoparasites, viruses or bacterial strains, or excavation material might be examined and utilised for ancient DNA analysis. While botanical and zoological collections are often arranged and managed in taxonomical units, large parts of the collections are managed and stored according to their nature (e.g. DNA and tissues), context or authorship (scientific artwork in books and on artwork), or the objects are part of bulk samples and are awaiting processing and individual accessioning (with single bulk samples usually containing thousands of specimens to be sorted). Parts of the same object may be stored in different units of the same institution, which is usually the case with cryo-preserved DNA collections, refrigerated or frozen tissue collections and corresponding reference specimens in the dry or alcohol based main collections. While single DNA-extracts are managed

according to their position on storage racks in freezers, tissue collections are usually arranged in numerical fashion (e.g. ascending tube numbers in boxes). Both need to maintain individual references to taxonomically ordered original specimens curated in the main collections, which are typically managed not at an individual level (e.g. only one fish per jar or one insect per drawer) but with one container holding many specimens, i.e. a “one-to-many” relationship of units. For example, one drawer of pinned insects usually contains different species or even genera collected from multiple localities by different collectors on different collecting dates.

Documentation of utilised genetic resources and the utilisation itself requires individual recognition of specimens and users to be possible. Therefore, a central element in the CETAF Code of Conduct and Best Practice is understanding how we usually utilise our museum objects and at which stage we can apply, for example, unique identifiers. Permit management and linkage to specimens and utilised or subsampled parts of those objects must be possible and practical on an individual level – but more importantly – in a one-to-many-relational context. There are no separate collections for “utilised” samples, which means existing data and specimen/sample management systems need to be adjusted to accommodate information on utilisation and users. Even more importantly, such systems need to manage information on ABS agreements that CETAF members enter into, which may extend far beyond the Nagoya Protocol and which do not only apply when genetic resources are utilised.

Shaping the Code of Conduct and Best Practices

From the above, it is clear that a strict focus on utilised genetic resources alone is unhelpful and that CETAF members are in need of overall ABS management schemes which can be easily applied for the diversity of collections. Because of the different composition of the collections in individual CETAF institutions (not all cover the same collections areas or manage and store them in the same way), CETAF members require enough flexibility to adjust ABS management to the actual needs of the individual collections. Because certainty is needed on agreements and the legal provenance of all biological material entering collections, ABS procedures must be compatible with all parts and areas of the collections and must not be restricted to a subset which is ‘utilised’. Therefore, the ABS Group invested a great deal of effort during the drafting of the CETAF Code of Conduct and Best Practice to ensure its applicability to all collections held by CETAF members.

It is impossible to establish a “one-size-fits-all” management system because of the complexity of the existing collections, their management routines, data management needs, and their institutional and policy backgrounds.

Therefore, the CETAF Code of Conduct and Best Practice uses the more inclusive term ‘biological material’ instead of ‘genetic material’ in many cases, as it more broadly and accurately covers our activities and what we acquire or collect. Working with and using ‘biological material’ may or may not be considered utilisation in the sense of the Nagoya Protocol and thus may or may not fall under the Nagoya Protocol or EU ABS Regulation. However, if utilisation does take place, applying the CETAF Code of Conduct to ‘biological material’ provides legal certainty and transparency for CETAF members. Due diligent behaviour is not only a requirement under Article 8 of the EU ABS Regulation and addressed in the complementary

measures in Article 13 of the same regulation, it is also encouraged in Article 20 of the Nagoya Protocol. More importantly, it is the key element to retain trust of provider countries and to minimise fears of misuse of their genetic resources in the light of the ongoing 'biopiracy' debate. Application of a broad, inclusive Code of Conduct and Best Practice also helps CETAF members to reduce risks associated with legal non-compliance (e.g. with the EU ABS Regulation) or contracts established with Providing Countries and to reduce risks to their reputation.

The CETAF Code of Conduct and Best Practice includes the following elements:

1. The CETAF Code of Conduct: the agreed principles by which we govern our activities.
2. The Best Practice: the way in which we implement those principles, including recommendations for policies and processes. This is the central element in the package of documents and covers the following areas: Policies, data management and curation, staff training, access to genetic resources when conducting fieldwork and their subsequent utilisation, utilisation by third parties (including guest researchers visiting CETAF institutions), benefits sharing and disposal of collections or specimens.
3. The Statement of use of Biological Material: outlines the uses of biological resources (specimens).
4. The Glossary: definitions and explanation of terms used.
5. Practical Advice on implementing the Code of Conduct and Best Practices
6. The Material Transfer Agreements (MTAs): Terms and conditions of specimen transfer and change in ownership.

The CETAF Code of Conduct and Best Practice is designed to support CETAF members in developing compliance policies and processes at an institutional level. These should address the requirements of national regulators who conduct user checks of collections using a risk-based approach and should minimise the administrative load for both sides at the same time. The CETAF Code of Conduct was circulated to all CETAF members in September 2013 for comment and it was approved by the CETAF General Meeting in May 2014. The Best Practice was approved by the CETAF General Meeting in 2015.

Recognition by the Commission – the Process so far

The package of documents was submitted to the European Commission (EC) for recognition under Article 8 as the CETAF Code of Conduct and Best Practices. The initial version was submitted in January 2016. Comments and requests for modification were received on 16 July 2016. A revised version and explanatory notes were submitted in December 2016. A response to this version was received by CETAF on 4 September 2017, in which the EC and European Union (EU) Member States noted their appreciation of the efforts made by CETAF on the Code of Conduct and Best Practices, but additional revisions were still requested. This was done and the package was submitted for a third time on 14 December 2017. It was circulated to the Member States by the European Commission in March 2018.

1. A main point of concern raised was that CETAF should govern the implementation of Best Practices at the collections of the CETAF members. However, CETAF has no legal mandate for this and this would be beyond the requirements of the EU ABS Regulation, which clearly states in paragraph 1 of Article 8 that the oversight of the Best Practices is distinct from the “effective implementation by a user” (paragraph 2). The CETAF Legislations and Regulations Liaison Group exercises the oversight function and will revise and improve the CETAF Code of Conduct as required. Changes to the Code of Conduct are communicated by this group to the ABS representatives at the CETAF member institutions, which are nominated by the CETAF members. This review system makes sure that CETAF members are informed of any changes by their ABS representatives, which ensures that internal procedures based on the adaptation of the CETAF Code of Conduct are revised and adjusted if required by implemented national ABS laws. This creates an active communication and feedback system, which is supported through annual meetings and training activities.
2. CETAF was asked to align the Code of Conduct more closely to the EU ABS Regulation. As stated in our resubmission, there are two reasons why the document was phrased the way it was. Firstly, compliance with the Regulation sits within the wider area of compliance with ABS requirements under Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) with provider countries. The CETAF Code of Conduct and Best Practice is a response and commitment of CETAF members to meet ABS requirements and obligations laid down in the Convention on Biological Diversity (CBD) and the Nagoya Protocol as well as by the EU ABS Regulation. It seemed to be an unnecessary duplication and could create confusion to deal with these two aspects of ABS in separate documents, which would have been necessary to follow this suggestion. Secondly, not all CETAF members are situated in the EU. It is crucial for CETAF that products and deliverables developed by CETAF are applicable for all CETAF members, including CETAF institutions in Switzerland and Norway. The submission of the CETAF Code of Conduct is a bottom-up response to meet ABS requirements, “in accordance with the requirements of [the EU ABS] Regulation”. We note that there is no indication in Article 8.1 that there is a legal requirement that the recognition of Best Practices needs to fit exclusively with the EU ABS regulation. That said, we added text to clarify the areas where compliance with the Regulation requires certain actions.
3. The response expressed the concern that the CETAF Code of Conduct and Best Practice does not describe one clear workflow that all CETAF members have to implement. However, as stated above, the complexity of CETAF collections and the different management systems employed by members makes a one-size-fits-all solution impossible. CETAF favours an output-oriented approach that is widely applicable by CETAF members for their collections. Uniform, rigid procedural systems that do not reflect individual circumstances cannot be implemented. Workflows without local ownership at CETAF member institutions would run a high risk of failure. The CETAF Code of Conduct and Best Practice is intended to be a strong and reliable support for members to analyse their policies and procedures and to implement appropriate systems to deliver compliance. Therefore, it requires CETAF members to develop or ad-

just internal procedures so that they meet the required legal standards. It should be emphasised that CETAF members agreed to this in May 2014 and by recognition of the Best Practice management tools in 2015, i.e. prior to the official submission for recognition.

4. The response expressed concern regarding the conditionality of the language, for example, the use of the words “shall” and “should”. We removed much of the conditionality in the revised version, but in other cases it was unavoidable. In some cases, it is present because of the weak and ambiguous definitions in the Nagoya Protocol and the EU ABS Regulation. An additional point is that biological material can be used without being utilised and is thus out of scope of the EU ABS Regulation – much taxonomic work relies solely on morphological examination, for example. While due diligence refers to the judgment and decisions that can reasonably be expected from a person or entity in a given situation before intended utilisation, legal requirements under the EU ABS Regulation only apply in cases where utilisation actually takes place.
5. It was suggested in the response that the acquisition of biological material without due diligence would not be compliant with the EU ABS Regulation. However, as noted above (and in a number of meetings during the development of the Regulation), the overwhelming majority of genetic resources contained in the biological material acquired will never be utilised and thus will not fall under the EU ABS Regulation. For example, the SNSB collections recently received 2,5 to 3 million butterflies in more than 20,000 insect drawers (requiring an extension of the existing building in order to be accommodated!). Materials stored in collections without being utilised are out of scope of the Regulation so this SNSB acquisition does not fall under the EU ABS Regulation. It should be noted that even for biological resources that will not be utilised, the CETAF Code of Conduct and Best Practice proposes application of due diligence where it is reasonably possible. It also notes the requirement for due diligence if any specimens are taken from such collections to be utilised within the meaning of the EU ABS Regulation and the Nagoya Protocol, i.e. if SNSB researchers select one of the 3 million butterflies for utilisation. Two additional bullet points were added to the documents clarifying any ambiguity and stating clearly that due diligence is required when material is acquired for utilisation.
6. The resubmitted document package included many small changes and additions to respond to comments from the EC and Member States, and we provided a lengthy explanation of the changes made, including the points above and some other critical issues.

Second round of comments – September 2017

1. Many of the points above were accepted by the EC and the Member States, including CETAF’s reasoning on the oversight function of the CETAF Legislations and Regulations Liaison Group.
2. The request for CETAF to develop one set of common tools and mechanisms to be applied by all CETAF members was raised again. A related point was a perceived lack of advice to guide CETAF members on the development of ABS compliant pro-

cedures. In response, a “Practical Advice” Section (Annex 5) was added which provides checklists for CETAF members, which they should use when developing or adjusting internal procedures for given situations as outlined in the Best Practice section of the Code of Conduct. The MTAs have also been modified to guide CETAF members through their requirements when transferring, exchanging or receiving biological material or genetic resources through the selection of different tick boxes. Examples of successful tools and procedures developed and implemented by some CETAF members in the past two years as a response to the proposals in the first Code of Conduct were added to our resubmission as deemed appropriate by the drafting committee. These reflect the variety of collection scenarios among our members. The flexibility of the CETAF Code of Conduct and Best Practice is the key feature that addresses this complexity and the decisive factor which allows its successful application by all CETAF members.

3. A clearer programme for training CETAF members and for obtaining feedback from them was suggested. In response, training for the implementation of the Code of Conduct and Best Practice will be offered on annual basis (the fourth of these training events was held at the Natural History Museum, London, on 27 April 2018). These events also provide the forum for feedback on issues, although ABS representatives from member institutions can contact the members of the ABS Working Group at any time.

Third submission

The CETAF Code of Conduct and Best Practice was resubmitted to the EC on 11 December 2017. The CETAF Legislations and Regulations Liaison Group dedicated a lot of time and considerable effort to cover as many potential situations as possible that our members may need to deal with and to improve the second version. We certainly recognise that the document package has improved as a result of the responses from the Commission and the Member States and our own increasing experience with the requirements of the Nagoya Protocol.

While single Member States may doubt its applicability, many CETAF collections have received positive feedback from their Competent National Authorities (CNAs) on the CETAF Code of Conduct and Best Practice. CETAF has also received considerable encouragement from the EC. Two other applications for recognition of Best Practices under Article 8 of the EU ABS Regulation have been withdrawn, and our understanding is that the CETAF submission is currently the only active proposal. Official recognition is required so that CETAF members have legal certainty when adjusting their internal procedures and policies; permit management schemes need to be developed and established and database systems need to be enhanced to allow simultaneous management of acquired samples, utilised sub-samples and any linked permits. It is very unfortunate that the recognition process has been so lengthy. Further delay in the official recognition of the CETAF Code of Conduct and Best Practice will lead to missed opportunities and delay in the development of these deliverables.

Discussion

In the discussion, the EC confirmed that it had circulated CETAF's re-submitted documents and at the time of the meeting, it was waiting for comments from the Member States. The EC indicated that there would be no limit to number of submissions and re-submissions that could be made until all issues with the documents are resolved and that feedback from the Member States would be very helpful.

It was commented that, like the registration of collections, Best Practices are another voluntary instrument to lower the risk of non-compliance with the EU ABS Regulation. A question was posed as to why the CETAF collections have not considered becoming registered. Mr Neumann indicated that registration is seen as requiring a large investment of resources with little or no return for the collections.

The EC acknowledged that there are many good things in CETAF's proposed Code of Conduct and Best Practice. However, it was emphasised that the purpose of Best Practice is not only to recognize principles but to provide concrete tools for users, making it challenging for the Best Practices not to be too general. Mr Neumann highlighted the complexity of the different CETAF members, noting that it is not possible to have fixed management schemes that would be appropriate for all actors. It was pointed out that the Best Practices provide points that can be incorporated into the individual workflows of each collection and that the lack of funding does not allow CETAF to create detailed work flows for all different types of collections. Mr Neumann indicated that a lot has been achieved so far by CETAF and that more has been done by the collections than by industry in this regard.

The point was raised that Best Practices are ultimately addressed to users and not to collections. Although collections are not utilising material when simply receiving and storing it, it was noted that if the material is to be utilised at a later point if there is a change of intent, the relevant documentation must be in place when the material enters the collection.

One participant indicated that the presence of Best Practices will be taken into account by CNAs during user checks and that having Best Practices establishes a certain amount of trust, i.e. it shows CNAs that due diligence is taken seriously by the institute or entity that has adopted the Best Practice. However, the opinion was also expressed that CNAs are not necessarily looking at outputs but the relevant procedures which have been put in place. Although it was acknowledged that there is a lot of useful information in the documents prepared by CETAF, some concern was expressed that CETAF may not be the right association to put forward Best Practices, e.g. because of the diversity of the members, the lack of oversight and because it takes an output-oriented approach. It was also commented that because the Best Practice is to be recognised under the EU ABS Regulation, it has to be aligned with that regulation.

According to Mr Neumann, some typical provider countries have indicated that they are happy with the Best Practices prepared by CETAF and are glad to see that ABS issues are being addressed. In his opinion, implementation of the Code of Conduct and Best Practice can help to increase the credibility of researchers and collections in Europe and potentially shield them from claims, e.g. biopiracy or being a loophole, by provider countries or non-governmental organizations.

10 Awareness Raising and Capacity Building: Measures to Inform/Involve User Sectors in Member States

Results of an Online Survey of (Potential) Users in Germany

Ellen Frederichs

German Federal Agency for Nature Conservation

From August to October 2017, the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) conducted an online survey, the main purpose of which was to determine the relevance of the Nagoya Protocol and the Regulation (EU) No 511/2014 (EU ABS Regulation) to potential users and their level of awareness regarding their obligations under the legislation. A total of 2630 potential users, who had been identified during an earlier BfN study, were contacted and asked to participate voluntarily in this survey.

The aim of the survey was firstly to raise awareness amongst potential users by introducing the BfN as the competent national authority (CNA) and by drawing attention to the implementation of the Nagoya Protocol. It was also intended to get an impression about whether the Nagoya Protocol was relevant to those institutions and entities that had been identified in the previous study and their state of knowledge. We were also interested in finding out whether the answers provided would show certain patterns regarding potential risks in the various sectors. Finally, we also asked for feedback on the perception of the Nagoya Protocol and ideas for additional awareness raising measures. The survey was not meant to serve as a scientific study, i.e. with results that could be generalized, but it was rather intended to provide an initial evaluation.

The survey had some preliminary questions where participants were asked to indicate to which of the eight given sectors they belong, their education, their position and the department in which they work.

The main questions focused on the potential utilization of genetic resources and whether utilization was funded by the participant's institution, products had been developed from genetic resources, genetic resources had been acquired from collections or any due diligence measures had been taken.

A set of knowledge-based questions also tested whether the participants knew when a due diligence declaration has to be submitted or what the ABS Clearing-House (ABSCH) is about. The participants were also asked if they knew about certain key terms and functions of the Nagoya Protocol and the EU ABS Regulation.

To get an idea about acceptance and perception of the Nagoya Protocol, the participants had the possibility to say whether they agreed with some statements, for example, that access to genetic resources should be regulated, that the Nagoya Protocol would hamper access to genetic resources or that it would contribute to legal certainty.

Finally, we asked what sources of information the participant had used so far to inform themselves about the Nagoya Protocol and what would help to further raise awareness about their obligations.

The survey was based on multiple choice questions. Sometimes only one answer was possible, e.g. the question about which sector participants belong to, and sometimes multiple answers were possible. For the evaluation, an internal system of values was developed in order to estimate the extent to which a participant is affected by the Nagoya Protocol and the EU ABS Regulation and the chance of them complying with their due diligence obligations.

In order to encourage participation, the survey was conducted in an anonymous way.

We received 292 responses, which corresponds to a response rate of 11,1%. Most participants came from the biotechnology sector (22%) and from basic research (17%). 15% of the respondents indicated that they come from a sector which had not been identified in the survey, e.g. people working in multiple sectors, museums, in diagnostics or nature protection. Participation from the biocontrol (0,7%) and animal breeding sectors (1,4%) was very low.

The education level of the participants was rather high, with 31% of the participants having a bachelor/master degree and another 55% holding a PhD or being a professor. 76% of the participants worked as management personnel and 47% came from the research and development department of their institution.

With respect to the relevance of the Nagoya Protocol, 45% of participants answered that they do not do research on genetic resources. While 88% of the participants from the cosmetic sector gave this answer, more than 50% of the respondents in each of the other sectors said that they would do research on genetic resources, e.g. 84% from basic research and 61% from biotechnology. One possible interpretation of the responses from the cosmetic sector might be that the question only referred to genetic resources and not to derivatives like oils or resins from plants.

A total of 47% of the respondents said they do not receive private or public funding for research on genetic resources. The majority of the respondents from basic research (64%), cosmetics (62%) and pharmacy (51%) said that they do not develop products from genetic resources.

41% of the participants indicated that they do not obtain genetic resources from collections.

Evaluation of the answers to the knowledge-based questions showed that around 75% of the participants have little knowledge about the Nagoya Protocol and the EU ABS Regulation. For instance, the terms "Access and benefit sharing" and "Prior informed consent" were unknown to almost half of all the participants. The term "ABS Clearing-House" was unknown to 61% of the participants. These figures seem to be understandable when one considers that almost half the participants did not see themselves as being within the scope of the regulation. 20% of participants knew when a due diligence declaration has to be submitted.

26% of participants indicated that they had an internal system to trace genetic resources back to the provider and 14% stated there was a person responsible for issues related to the Nagoya Protocol in their institute/company.

With respect to the perception and acceptance of the Nagoya Protocol, 80% of the participants agreed that access to genetic resources has to be regulated and 75% agreed that benefits arising from the utilization of genetic resources should be shared. 57% were of the opinion that bureaucracy has increased as a consequence of ABS regulations and 33% agreed with the statement that the Nagoya Protocol hampers access to genetic resources.

Another 47% ticked the box “don’t know/no answer” for this item. 41% of all participants said that the Nagoya Protocol would contribute to legal certainty, which could be interpreted as a positive signal.

Regarding sources of information about the Nagoya Protocol and the EU ABS Regulation, participants mainly named the internet and their professional surroundings. However, some also indicated that they get information from information events and publications. For further awareness raising activities, participants indicated that information events, consultants and the exchange of experiences could potentially be helpful.

This “first glimpse” into the potential users showed that although at least half of the participants are affected by the Nagoya Protocol and EU ABS Regulation, they do not seem to be very well informed about this and thus seem to be unprepared for their due diligence obligations. The question about whether half the potential users are really outside the scope of the EU ABS Regulation is open. It is possible that these participants have not fully understood the scope of this legislation. Based on the different level of knowledge among the participants, it does not appear that a reliable differentiation of potential risks in the different sectors is possible, especially because two sectors were underrepresented. The survey was intended to raise awareness and it helped the BfN to get an impression about the participants and how well-prepared they are to meet their obligations. Finally, it clearly showed that there is a need for further awareness raising measures, which are currently being planned.

Discussion

In the discussion, it was pointed out that the development of the survey instrument was a learning experience and through collaboration with colleagues at the BfN, the survey instrument was improved substantially during that process.

Awareness Raising and Capacity Building – A German Project to Inform Collection Holders and Involve them in the Implementation of ABS

Ute Feit

German Federal Agency for Nature Conservation

Background

Collections are important suppliers of the genetic resources that are used in Germany. Regulation (EU) No 511/2014 (EU ABS Regulation) foresees the creation of a register of collections within the European Union (EU), the aim of which is to support users in fulfilling their due diligence obligations. The registration of collections is therefore an important tool for the implementation of the Nagoya Protocol and for establishing legal certainty. In order to promote the implementation process and the willingness of collections to become registered, it is essential to inform collection holders about their key role in the implementation of the Nagoya Protocol and to train them accordingly.

Objective of the Project

To tackle the awareness raising and capacity building processes that are needed, the German competent national authority (CNA) has launched a project (11/2017-09/2018) to inform collections in Germany and to support them with respect to the challenges they face with the implementation of the Nagoya Protocol and the EU ABS Regulation. The objectives of this project are to:

- develop a model to inform the collections strategically and effectively,
- develop collection specific awareness raising materials to better inform those collections,
- take into account how best to inform the different collections from a didactic point of view, and
- stimulate the awareness raising process in a large number of collections by informing them in their own environment.

Process

As part of the project, different training modules will be developed for collections, which will result in a complete one-day seminar.

The development of the training modules will be accompanied by a specially created project working group made up of representatives from different types of collections. This will ensure that the heterogeneity of the different collections in Germany is adequately taken into account from the outset.

The content of the different training modules will range from conveying information (e.g. on regulations and definitions) to an interactive exchange with representatives from collections

on their role in the implementation process and the need for action within their institutions. The seminar will be first presented to the project working group in a test run.

The feedback and experiences from this test run will be evaluated and the seminar documents will be subsequently revised and adapted as required. The tested and revised seminar will finally be offered and conducted as an in-house seminar (preferably at the invitation of the collections) at four geographically strategic locations in Germany to include additional collections.

The content of the individual training sessions during the one-day seminar are structured as follows:

Information

- Introduction – background information on ABS
- ABS Regulations
- Definitions from the Nagoya Protocol and Regulation (EU) No 511/2014 (e.g.: collection, users)

Awareness Raising

- Role of collections in the context of the Nagoya Protocol
- Discussion about the different types of collections and their day-to-day work
- Identification of any need for action

Interactive Exchange

- Reflection on own and institutional actions (e.g. activities by the collection, research)
- Use of checklists
- General and collection/sector type specific frequently asked questions (FAQs)
- Examples of implementation
- Existing use cases
- Identification and classification of own examples
- Collection specific processes and recommended actions

Awareness Raising and Capacity Building Measures to Inform/Involve Users in Poland

Bożena Haczek

Ministry of the Environment, Poland

Awareness raising and capacity building measures are necessary for the successful implementation of the Nagoya Protocol. Poland has undertaken many actions in that regard, including the organization of conferences, workshops, training sessions and bilateral meetings with various interested sectors and institutions.

Since 2014, an annual ABS conference has been organized by the Ministry of the Environment. It is a whole day conference which brings together up to 150 participants from various sectors, scientific institutions, non-governmental organizations and public authorities. At the beginning, this conference was aimed at raising awareness and the exchange of information on new developments in ABS at the international and national levels. Later, it became a discussion platform on practical arrangements and the implementation of ABS. The last conference in 2017 dealt with international ABS regulations, access legislation of selected provider countries, implementation of the European Union's (EU) access and benefit sharing (ABS) regulations, ABS issues in other international fora (Food and Agriculture Organization, World Health Organization, United Nations Convention on the Law of the Sea), the European Commission's (EC) guidance documents, the Polish ABS legislation and the responsibilities of the Inspectorate for Environmental Protection with respect to ABS user checks.

Some training sessions were provided, e.g. for the Council of Botanical Gardens and Arboreta and the inspectors from the Inspectorate for Environmental Protection. Several sectoral meetings were organized with various actors, including among others, representatives from the following sectors: cosmetics, pharmacy, plant breeding, the seed sector, animal breeding, and biological sciences. Several lectures were done for students of biology, zootechnics, protection and breeding of pets and wild animals, and biotechnology at the University Centre for Environmental Studies and Sustainable Development of the Warsaw University and the University of Life Sciences in Warsaw.

In 2015, a survey was carried out on awareness of the Nagoya Protocol and Regulation (EU) No 511/2014 (EU ABS Regulation) among collections of genetic resources, the procedures used in their everyday work and level of interest in becoming registered in the EU's register of collections. 119 collections of various genetic resources were identified in Poland. 40 of these collections answered a survey, of which 10 indicated that they are interested in the EU register. In opinion of 5 of these collections, they have almost fulfilled the required criteria for registration.

Taking into account results of the abovementioned activities, we can see that year by year, there is a growing number of institutions and individuals interested in ABS issues. There is growing cooperation and understanding between authorities and the potential users of genetic resources. One can see visible changes from "no interest" to proactive behaviour by potential users, who are asking more and more questions and undertaking some relevant activities. Awareness raising and capacity building should be ongoing activities and there is a need to develop the most appropriate and effective tools and measures for this purpose.

11 Way Forward and End of Meeting

When the meeting was closed, the organizers thanked the participants for their attendance, the high level of engagement and open discussions over the two-day workshop. It was highlighted how much progress had been made by the CNAs since the first meeting in 2017 and that they are no longer “in the dark” on a number of issues. At the same time, it was acknowledged that there is still some way to go with implementation. The importance of continued and improved information exchange between the CNAs was highlighted, not only so that the CNAs can learn from one another but also to ensure that a harmonized approach to implementation of the Regulation (EU) No 511/2014 is taken and that the related issues are dealt with in a consistent way. It was acknowledged that the exchange of information at this early stage is particularly important as many of the CNAs have similar problems and questions, and it was concluded that the Vilm CNA meetings provide the ideal setting to continue such exchange within the European Union.

12 List of Participants

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

10 to 14 March 2018, INA Vilm, Germany

No.	Name	Institution / Address
1	Bednarz, Louise	Swedish Environmental Protection Agency, Sweden
2	Burchardi, Markus	Carl von Ossietzky University of Oldenburg, Germany
3	Ciacchi, Mery	European Commission
4	von den Driesch, Marliese	Federal Office for Agriculture and Food (BLE), Germany
5	Dubravka, Stepic	Ministry of Environment and Energy, Croatia
6	Errboe, Gry	The Danish Environmental Protection Agency
7	Feit, Ute <i>Chair</i>	Federal Agency for Nature Conservation (BfN), Germany
8	Dr. Fernandez Pinos, Maria del Carmen	Ministry of Agriculture and Fisheries, Food and Environment, Spain
9	Frederichs, Ellen	Federal Agency for Nature Conservation (BfN), Germany
10	Prof. Dr. Godt, Christine	University of Oldenburg, Germany
11	Greiber, Thomas <i>Chair</i>	Federal Agency for Nature Conservation (BfN), Germany
12	Dr. Haczek, Bozena	Ministry of the Environment, Poland
13	Jacquemyn, Egbert	Agency for Nature & Forestry (ANB), Belgium
14	Jank, Sebastian	Federal Agency for Nature Conservation (BfN), Germany
15	Jankiewicz-Damska, Magdalena	Chief Inspectorate of Environmental Protection, Poland
16	Juul Jensen, Eva	Environmental Protection Agency, Senior Policy Adviser, Denmark
17	Karger, Elizabeth	Consultant, Germany
18	Lohtander-Buckbee, Katileena	Finnish Environment Institute, Finland
19	Neumann, Dirk	Bavarian Natural History Collections, Germany
20	Dr. Nouak, Andrea	Ministry of Sustainability and Tourism, Austria
21	Rolfova, Eliska	Ministry of the Environment of the Czech Republic
22	Rusanen, Mari	Natural Resources Institute Finland
23	Dr. Scholz, Amber	Leibniz Institute DSMZ, German Collection of Microorganisms and Cell Cultures
24	Ujj, Zsuzsanna	Ministry of Agriculture, Hungary
25	van Winkoop, Abel	NVWA Netherlands Food and Consumer Product Safety Authority

13 Program



Program

Meeting of the European Competent National Authorities implementing the Nagoya Protocol and the corresponding EU Regulation

Isle of Vilm, Germany
April 23 - 26, 2018

After entry into force of the Nagoya Protocol and the corresponding Regulation (EU) No. 511/2014 the European 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.

Following the successful meeting of European CNAs last year in Germany on the island of Vilm, the Nagoya CNA–Unit of the German

Federal Agency for Nature Conservation (BfN) will organize once more a platform for exchange in 2018.

The upcoming informal meeting will complement the half-day meetings of EU CNAs occasionally taking place before EU ABS Expert Group meetings in Brussels. It will provide an ideal opportunity to identify, present and discuss challenges as well as possible solutions on all relevant topics related to the implementation of Regulation (EU) No. 511/2014, in particular on first registration processes of collections, experiences in user controls and checkpoint communications as well as on any best-practice-procedures, tools or mechanisms for exercising due diligence.

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 future work of the EU CNAs.

Monday, 23.04.2018

Arrival of the participants at the island of Vilm

18.30 *Dinner*

20.30 Welcome and brief introduction to the meeting

- THOMAS GREIBER, FEDERAL AGENCY FOR NATURE CONSERVATION

21.00 *Informal get-together*

Tuesday, 24.04.2018

08.00 *Breakfast*

**09.00 Implementation of Regulation (EU) No. 511/2014:
Status quo and current challenges**

- EU COMMISSION: MERY CIACCI

**09.30 Risk-based plans / selection of potential users /
remote inspections / onsite inspections** (*ca. 15 min.
presentations*)

- PRESENTATION OF FIRST EXPERIENCES AND VIEWS BY

- DENMARK: EVA JUUL JENSEN, GRY ERRBOE, DANISH ENVIRONMENTAL PROTECTION AGENCY
- GERMANY: THOMAS GREIBER, SEBASTIAN JANK, FEDERAL AGENCY FOR NATURE CONSERVATION
- NETHERLANDS: ABEL VAN WINKOOP, NETHERLANDS FOOD AND CONSUMER PRODUCT SAFETY AUTHORITY
- POLAND: MAGDALENA JANKIEWICZ-DAMSKA, MINISTRY OF THE ENVIRONMENT
- SWEDEN: LOUISE BEDNARZ, SWEDISH ENVIRONMENTAL PROTECTION AGENCY
- UK: SLIDES PRESENTED BY THOMAS GREIBER ON BEHALF

11.00 *Coffee/tea*

11.15 Risk-based plans etc. (continued)

- DISCUSSION: ALL MEMBER STATES

12.00 **Brief update: Any implementation progress in other Member States** *(max 5 min. slots)*

- UPDATES BY OTHER PARTICIPANTS
 - AUSTRIA
 - BELGIUM
 - CZECH REPUBLIC
 - CROATIA
 - FINLAND
 - HUNGARY
 - SPAIN

12.30 *Lunch*

14:00 **Practical scenarios**

(MEMBER STATES TO HAND IN CASES BEFORE THE MEETING)

- CASE 1: DEVELOPMENT OF RECOMBINANT PROTEINS
- CASE 2: TRACING THE TRANSPORT OF NITROGEN THROUGH ECOSYSTEM WITH ISOTOPES
- CHINA
- CASE 4: LUNDBECK
- OTHERS?

15.30 *Coffee/tea & cake*

16.0 **Round of "stupid" questions**

- COMPANION ANIMALS: MARI RUSANEN, NATURAL RESOURCES INSTITUTE FINLAND

- MEMBER STATES TO POSE QUESTIONS AND RAISE IMPLEMENTATION CHALLENGES (ANY QUESTION IS A GOOD QUESTION)
- DISCUSSION

17.00 **End of day 1**

18.30 *Dinner*

20.00 *Informal gathering*

Wednesday, 25.04.2018

08.00 *Breakfast*

09.00 **Registration of collections under Article 5 of Regulation (EU) No. 511/2014 – first application**

- DR. AMBER HARTMANN-SCHOLZ, GERMAN COLLECTION OF MICRO-ORGANISMS AND CELL CULTURES (DSMZ)
- QUESTIONS & ANSWERS

10.30 **Potential liability of registered collections – legal implications of Article 4 (7) of Regulation (EU) No. 511/2014**

- PROF. DR. CHRISTINE GODT, UNIVERSITY OF OLDENBURG
- QUESTIONS & ANSWERS

11.15 *Coffee/tea*

11.30 **Discussion**

- MEMBER STATES ONLY

12.30 *Lunch*

14.00 **Best practices under Article 8 of Regulation (EU) No. 511/2014 – application for recognition by CETAF**

- DIRK NEUMANN, BAVARIAN NATURAL HISTORY COLLECTIONS & BAVARIAN STATE COLLECTION OF ZOOLOGY (ON BEHALF OF CETAF)
- QUESTIONS & ANSWERS

15.30 *Coffee/tea*

- 15.45 **Awareness raising and capacity building – measures to inform / involve user sectors in Member States**
- GERMANY: RESULTS OF POTENTIAL USER SURVEY & PROJECT ON STAKEHOLDER CAPACITY-BUILDING, ELLEN FREDERICHs & UTE FEIT, FEDERAL AGENCY FOR NATURE CONSERVATION
 - POLAND: BOŻENA HACZEK, MINISTRY OF THE ENVIRONMENT
- 17.00 **Way forward & end of meeting**
- 17.30 *Reception at the invitation of the German Federal Agency for Nature Conservation (BfN)*
- 21.00 *Informal gathering and farewell*

Thursday, 26.04.2018

07:30-09:00 Breakfast

07.25 First boat from the Isle of Vilm, arrival in Lauterbach at 7.35

08.25 Boat from the Isle of Vilm, arrival in Lauterbach 8.35

Train connection from Lauterbach/Mole at 8.00/9.00, arrival in Bergen auf Rügen at 8.20/ 9.20, direct train from Bergen auf Rügen at 9.27 to Berlin Central Station, arrival at 13.16

09.20 Boat from the Isle of Vilm, arrival in Lauterbach at 9.30

Train connection from Lauterbach/Mole at 10.00, arrival in Bergen auf Rügen at 10.20, direct train from Bergen auf Rügen at 10.55 to Berlin Central Station, arrival at 15.16



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.