Sveriges lantbruksuniversitet
Swedish University of Agricultural Sciences

Vice-Chancellor's Office

MINUTES

Workshop regarding guidance of the Nagoya protocol and EU ABS regulation for Swedish users of genetic resources

December 1st. 9.30-15.00 at Swedish University of Agricultural Sciences, SLU.
The workshop was held as a webinar.

Contributors at the workshop:
Jens Sundström, Senior Lecturer, SLU, Chair
Sebastian Bromander, Legal Counsel, SLU
Inkeri Ahonen, Naturvårdsverket
Yvonne Lundell, Naturvårdsverket
Tomas Roslin, Professor, SLU
Aysegül Sirakaya, Legal Advisor at ABS Int & Phd at Ghent University
Scarlett Sett, Nagoya Protocol Compliance Officer, Kiel University
Dennis Eriksson, Researcher, SLU
Johan Dixelius, Research Advisor, Uppsala University

Jens Sundström welcomed the participants and introduced the day and briefly the SLU:s compliance work regarding the Nagoya protocol (NP). We will talk about how the Swedish Environmental Protection Agency and the universities can help researchers in issues regarding the NP. This day is mainly to help the universities to help their researchers as well, but the day will include elements on practical issues.

The NP includes a lot of terms and elements that might be complicated. It is in an entirely new language and today we will expect some prior knowledge.

We are "the users" of genetic resources and we will therefor need to sign the relevant agreements in order to access the resources, and the focus will mainly be on how to particularly develop PIC and MAT.

SLU started its NP-work in 2018 and have done some awareness raising activities around the university and prework on designing PIC:s and MAT:s, as well how these needs to be registered and stored. In 2019 the LIFEPLAN-project received 150 MSEK which needed a specific effort in establishing methods for the practical implementation. The established SLU Nagoya group includes researchers from all faculties, legal counsel as well as administrative support.

Sebastian Bromander (SLU): Current routines at SLU is simplified 1) preparatory work: is the NP applicable, or not?, 2) contacts with countries of origin, 3) drafting contracts, 4) registration, and 5) declaration of due diligence in the digital tool DECLARE. The legal support and the SLU Nagoya group is available already from stage 1. SLU has developed a pathfinder with yes:s and no:s in order to find out what specific needs your project have. All projects are basically unique based on the nature of the genetic resource and which the country of origin is.

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Q&A: *How do we deal with genetic resources from non-country resources, e.g. the Antarctica?* Genetic resources from high seas and international waters are still unregulated but they are subject to present negotiations.

What about migratory genetic resources that move across boundaries? The simple answer would be that it is the country for accessing the resource that is counted. Aysegül mentions that there are some transboundary agreements regarding joint-species that is in the region. There might be some regulatory shopping to find the easiest legislation and decide to do

A provider country that has not signed NP might still have a competent authority to access resources? The EU-legislation is regarding the general compliance to the NP but you will still have to comply to the national ABS legislation.

If we have local collaborators does the NP apply? It depends on the national legislation of the provider country, but in general you need PIC:s and MAT:s. You might need to declare that you didn't need a permit if the country doesn't have an ABS.

Sweden hasn't any ABS-legislation, is there a list on countries without ABS-legislation? ABS-clearing house might have a list of countries, but it is continuously changing. Check with national focal points if there is any limitations.

What about gene sequences in the database? Right now digital sequence information is not part of the NP, but this is under international discussions and a change is at hand. However, not clear how! Some countries do already regulate access to DSI and their publishing. Even if it is publicly available, it might not be openly accessible for future studies. The EU legislation is perhaps already including DSI.

What do you do when the national focal point doesn't answer? Answer later!

Inkeri Ahonen and ***Yvonne Lundell*** (Swedish Environmental Protection Agency):

• Inkeri: The roles and responsibilities of the SEPA. National legislation about use and the provider country's national legislation concerning ABS. EU ABD regulation No 511/2014 = due diligence.

Step 1. Collection of genetic resource => Step 2. Using genetic material in EU/Sweden. If the provider country isn't part of the NP the Swedish authorities have no mandate, but the provider country might take action. If the provider country is member to the NP SEPA is supervising the ABS

SEPA is responsible for: Information, guidance, communication, and training activities; represent Sweden in the EU ABS Expert group; Reports to CBD and EU every fifth year; Process applications according to the EU ABS Regulation. During 2021: EU and international work will be prioritized; and guidance.

• Yvonne: SEPA is responsible for guidance and supervision (two different and separated activities). Controlling that the users are showing due diligence and checks will start during 2021. The universities need to take the relevant measures to try and comply to the legislation internationally and nationally and that access is done in a legal way.

Q&A: *Do SEPA discuss with competent agencies in other countries?* We have meeting within the EU, and discuss how to do the complying checks.

How about penalties if someone is not complying? We will have a meeting and discuss, ask for relevant documents, the user might have to go back to the provider

country. If the Swedish EPA suspect an environmental crime, we hand over to police and prosecutor. Penalties are not handled by SEPA.

Where is the legal responsibility? At SLU the university as a legal person is applying and not the individual researcher. The prefect will sign the agreement, and SLU will be penalised if not complying. Some countries have sent researchers to jail or have thrown out people from their countries if they lack permits at field work.

Tomas Roslin (SLU): The project LIFEPLAN. A concrete example of a project affected by the NP. Mostly focusing on insect ecology and with a wide global collaborations. What species are present in different parts of the world? Abundancy? Changing in populations? The idea is to make sense from a massive amount of data. The aim is to predict what kind of biodiversity that appear in different parts of the world and what will we see in the future with climate change. Available biodiversity is basically a picture where people are doing inventories. We need a more systematic sampling!

Collection of insects, spores, etc and then DNA extraction and sequencing. The NP will affect the research and we can't turn the blind eye to this. Nations outside of NP are also very well aware of the ABS of biological resources. The funding agencies are now aware of the necessity to show due diligence. You might be requested for additional clarifications from the funding agencies, even after you have got an approval of the grant.

In LIFEPLAN there is collection of "soups" rather than individual species. Species identification is done after processing. All kinds of permits from many countries that need to be signed by the head of department. Collections are done locally with national partners, but also that needs agreements.

Q.&A.: Microbiology in the samples are included in the agreements. We do not do a full genom sequencing.

If the species is common and appear all over the world do we still need an agreement? Yes, according to country of origin.

Aysegül Sirakaya (ABS Int. & Gent University): The ABS framework aims to create trust and shared benefits, as well as developed opportunities to do research also in the provider countries. Access – Benefit-Sharing – Compliance in the user country

ABS Clearing house provide information about countries as reported by the countries – but they might have ABS-legislation that you will need to address. The web-information might be out of date. Best contacts are your local collaborator if you have such and ask them what they know about local legislation. However, they are probably researchers and do not necessarily know the legal details. In some cases you might also be required to have local partners, but you are still responsible for having all the right permits. Researchers do need legal advice in these matters. Ays has analysed different countries ABS-legislation and there are similarities and differences. "There is no one-size-fits-all solution!", each case is unique. Sometimes there are different national competent authorities for different genetic resources, and there might be different kinds of permits for different kinds of resources.

Before negotiation you need to know what you want to do and on what genetic resources, and what kind of benefit can you contribute with to the provider country. Funds, workshops, equipment, training programme, access to data.

As early as possible you need to survey countries and legislation and get the permits before collecting!!! You might get prison! Never promise a benefit you cannot provide!

Q&A: *How can I find a relevant expert that can help me? Where do we find a relevant legal advisor?* That is a good and relevant question…

ABS is all about trust!

Sebastian Bromander (SLU): How to draft the documents needed.

Prior Informed Consent (PIC), Mutual Agreed Terms (MAT), Material Transfer Agreement (MTA), Memorandum of Understanding (MOU), Collaboration protocol… You may have seen these kind of documents related to NP but you don't necessary need all these documents. It's up to the Provider country to decide how the permit process should look like in their country. It's common that some documents are merged into one document, e.g. MAT incorporated in an MTA or PIC and MAT are combined in one permit document.

ABS contracts are not that different from other kind of contracts. Like other contracts you need to describe what you want to achieve, what each party should do and when to do it, managing risks, handling more specific questions related to the project, how disputes should be solved, etc.

MAT stands for mutual agreed terms, and those terms does not have to be in a specific contract called MAT, but can be included into other agreements such as an MTA. Typical issues to handle in MAT is which genetic resource to access, what kind of research that will be done, benefit-sharing with the providing country, third-party use, terms for changes of intent.

Templates and model clauses? No one-size-fits-all ABS contract, but templates make the drafting easier, faster and more efficient. Sebastian described the elements of a MTA with incorporated MAT clauses from LIFEPLAN. Consider and be creative about benefits that you can provide to the provider country. It doesn't need to be about money!

And keep track on your documents! It is not enough to do right; you also need to be able to show that you've done right!

Q.&S.: MAT could be made with different national/local actors. However, it depends on the provider country's legislation.

Who should start drafting the contracts? If possible the researcher, because the researcher knows the details of the project and what he/she wants to achieve with the research.

All universities and most other organisations have some kind of legal support that could contribute with legal advice, it is important that the legal adviser and the researcher is communicating in order to understand the relevant details and legal snags.

SEPA will check that due diligence is performed, show responsibility.

Where do you keep the documentation? At SLU both central (Public 360-tool) and a copy at department level. The documents should be kept for 20 years so you need to know where you file your documents.

How do you identify a relevant document? You would like to see it from the competent authority as well as certain elements. It should state the involved actors, and allowed activities. Double check with the country's competent authority.

If you have a resource that is available in different countries? There is regulatory shopping trying to find less strict countries and in some cases countries are "black-listed" for international collaboration since they are too complicated to work with.

What about pre-Nagoya samples can I work freely with it and commercialized? Some countries had ABS regulations prior to Nagoya, some are retroactive for earlier collections, and some prior permits can be "updated".

Scarlett Sett (Kiel University): Experiences from the work as ABS contact point at Kiel University.

Awareness raising: Inform that it might have implication also for other people than the ones working with medical and microbiological research. Tried to make the department heads and senior project managers understanding the need to comply. Developing the information on the homepage. Collaboration with the tech transfer team at the university. Targeted departments to get opportunity to give a lecture about the NP.

Institutional policies: Internal guidelines. Developed a simplified step-by-step guide including the researcher's responsibilities and the university.

Tracking system: Storage of documents is not decentralised.

Q.&A.: *What is the experience from the German competent authority*? Only good so far.

Have you worked with the herbarium? Have they changed their methods? We have two big collections at KU, we want to register them as established collection. If you just store as a collection it's not a part of NP, but if you transfer the material to a third part.

What do you do when a foreign guest researcher bring material? It is important to get the relevant documents to prove that the material is legally obtained. What happens when the researcher leaves and the material stays or is transferred to other places?

Whole day Q.&A.: *What to do when a provider refuses publications sequences?* If they refuse you can't do much about it! Should you proceed with the research without publishing this element?

How do you negotiate when the provider demands extensive benefits? In some cases you can provide something but not all and this could be a part. It is important to be transparent and honest! It all about trust.

The focal point unsure of the national legislation and stops communicating? You might try to encourage the focal point with contributing with interpretations of national legislation. If a country has a legislation you will have to have a permit – it is a due diligence situation or not? It is probably not worth taking the risk!

How many declaration will you work with within LIFEPLAN project? Not yet determined.

What about researchers in the humanities and social sciences? We haven't dealt with cases involving traditional knowledge. It is important to stress that it is about traditional knowledge related to genetic resources, so it is not all traditional knowledge.

Johan Dixelius (UU): Coordinating the UU work with NP.

Johan especially appreciated that the SLU Nagoya working group has shared our process to other universities. Sometimes there is a distance between administration and the researchers, but this is a context where this need to be bridged. It is important that the function is in the central university and that the information reaches out to the researchers in a dialog. UU has not gone as far on the NP-track as for instance Kiel University or SLU. Johan appreciated the international outlook from Ays and Scarlett. The LIFEPLAN project presented by Tomas Roslin was fascinating and showed the complexity of the process to do right according to the NP. It is clear that there are lots of different issues that need to be addressed and solved in order to help our researchers.

General comments

It might be need for a joint-universities' help desk!

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