HNN2.0, BioHorizon and NCPs CaRE Webinar on '*Implementation of the Nagoya Protocol in the EU: the EU ABS Regulation*'

27 September 2019

Participant questions

Questions relating to IMPLEMENTATION

Q: Who is in charge of making sure the regulations/legislation are being implemented?

- ➔ Any country that has decided (voluntarily) to establish access regulations for its genetic resources is then responsible for drawing up the provisions on access and benefit sharing. The conditions to share benefits from the utilisation of genetic resources are contained in private contracts (mutually agreed terms, MAT). The parties who concluded the contract (that is, the country providing access to the genetic resource and the user of the genetic resource) are both bound by the contract and are required to respect and implement it.
- ➔ All Parties to the Protocol have to implement the obligations to monitor user compliance under the Nagoya Protocol. This means that they have to implement compliance obligations in their country and establish checkpoints to monitor and check that users in their country have respected the ABS requirements of the country of origin.
- ➔ The EU ABS Regulation implements the compliance measures in the EU. It establishes an obligation on users of genetic resources to exercise due diligence when they acquire genetic resources (see article 4 of the EU ABS Regulation). Each Member State is required to:
    - implement the two checkpoints as identified in the EU ABS Regulation (1- at the stage of receiving funds for research; 2- at the final stage of development of a product),
    - check and monitor whether actors in that state are exercising 'due diligence' (article 9 of the EU ABS Regulation) and
    - apply penalties where infringements of compliance obligations under the Regulation (namely, infringement of article 4 or 7) occur (presentation slide 16).

Q: In contracts with countries that have such access regulations - isn't it their obligation to inform about it, so it can be considered in the contract?

- ➔ Under the EU ABS Regulation, when you utilise genetic resources obtained from other countries you have a responsibility to exercise 'due diligence'. This means that you must make your best effort to ensure that you are complying with the ABS rules of that country (established under the Nagoya Protocol).
- ➔ You have a 'contract' only if the country in question has ABS legislation. You need to acquire this information before signing a contract.
- ➔ The first thing you can do is to check on the ABS which countries have established access rights under the Nagoya Protocol through the ABS Clearing House (https://absch.cbd.int/). Countries party to the Protocol and with ABS legislations are obliged to put this information

in the ABS Clearing House (ABS CH). Please note, however, that not all countries have added all of the necessary information to the website yet. If no clear or satisfactory information can be found, you must get in contact with the competent authorities for ABS in the country where you want to access the genetic resource.

➔ Your partners from each country in question can be of help to clarify (also with the support of their 'national focal points'/competent authorities) whether or not access rights under the Nagoya Protocol apply in that country. If access rights apply, you must then contact the responsible authorities in that country to establish prior informed consent and agree the corresponding benefit sharing obligations.

Questions relating to SCOPE OF APPLICATION

******Please note that it is not possible to provide precise and detailed answers on the scope of application to general cases. In each case the temporal condition applies in addition to the geographic condition (see slide 10) and, depending on the source material and use, specialised international instruments on ABS may apply (see slide 11). Refer also to the decision tree on slide 20 regarding the application of the Nagoya Protocol at project level.******

Q: Do we need to follow the Nagoya Protocol when sharing biological samples of an animal (gut, skin, liver) for laboratory analyses (i.e., transcriptomics or histology)?

➔ The Nagoya Protocol applies to the Parties to the Protocol; i.e., to states. Users in the EU, including researchers, must follow the EU ABS Regulation.

➔ The important issue is to assess whether you have obligations under the EU ABS Regulation. To fall under the scope you need to engage in activities that are considered R&D on the genetic and biochemical composition.

Q: When working in one EU country and cooperating with another EU country that does not have access legislation, e.g., Czech Republic, do I need to obtain an agreement for sampling of biological material for research (e.g., taxonomy)?

➔ No. The deciding factor here is that the country from which the source material derives has not established access rights.

Q: If I collaborate with a researcher from a country with access legislation (e.g., Spain) or without access legislation (e.g., Czech Republic), do I need to obtain all agreements?

➔ If using genetic resources from a country which has enacted access rights, you must contact the responsible authority in that country regarding the obligations with respect to access and benefit sharing. The 'focal point' for the Nagoya Protocol in your own country, as well as the Competent Authority under the EU ABS Regulation may be able to help you with this.

➔ If using genetic resources from a country that has not established access rights under the Nagoya Protocol, then you don't need to have prior informed consent (PIC) and benefit sharing obligations do not apply.

Q: If I sample biological material from a particular country (e.g., Czech Republic) and bring it to Germany for taxonomic research (photos, morphological measurements, but not genetic analyses), do I still need to obtain all agreements?

➔ If the source country has established access rights under the Nagoya Protocol, you need to comply with the ABS rules of the country. This is not the case for the Czech Republic as they do not have access legislation, so no permit is needed. If you are not doing R&D activities,

then you are not under the due diligence obligation under the EU ABS Regulation (see the horizontal guidance document and refer also to the decision tree contained on slide 20.)

Q: How do H2020 Associated Countries go about Nagoya? Same obligations? / **Q:** If the user of genetic resources in a H2020 project is an entity established in an Associated Country, e.g. Norway, do they have to comply with the EU ABS regulation?

- ➔ The due diligence declaration must be submitted to the competent authority of the member state where the coordinator or beneficiary is established.
- ➔ For multi-beneficiary grants, the project coordinator may make a single declaration. Alternatively, each beneficiary whose activities fall within the scope the EU ABS Regulation must make an individual declaration.
- ➔ If the coordinator or beneficiary is established outside the EU and the relevant research activity takes place inside the EU, the declaration must be submitted to the competent authority of the Member State where the research is carried out.
- ➔ Beneficiaries established outside the EU and carrying out research outside the EU are not concerned by the EU ABS regulation. They may have to comply with their own national ABS legislation (if any) and with the ABS legislation of the country providing access to the genetic resources.

Q: If we use mice (also genetically modified), cells, transfectious vectors, viruses, etc. for research purposes do we fall under the scope of the EU ABS Regulation? Is the utilisation considered R&D? We are a non-profit research organisation. The results of our research are always published and so shared with society.

- ➔ Yes, even as a non-profit organisation you fall under the scope of the EU ABS Regulation if you are undertaking R&D activities using genetic resources from a country with access legislation. If are not doing R&D (for instance, if you are merely making a description of the taxa), you are not under the scope of the EU ABS Regulation. However, you might still need to respect the ABS legislation of the country providing access.

Q: Do we need to follow the EU ABS Regulation when examining biological samples (e.g., DNA-barcoding and morphological studies on insects) just for taxonomic or ecological surveys (absolutely non-economic purposes)?

- ➔ No, if your activity is not R&D (ecological survey is not considered R&D) than you do not have to comply with due diligence obligations under the EU ABS Regulation. However, if the samples come from a country which has established access rights under the Nagoya Protocol, you might need to need to comply with those national laws.

Q: How does the EU ABS Regulation apply in relation to genetic resources bought from commercial sources?

- ➔ If you buy the genetic resources on the market, as a commodity, you have no obligations under the EU ABS Regulation. However, if you use the genetic resources not as a commodity, but to do R&D activities on the DNA, you should go back to the provider country to see if you need prior informed consent (PIC) and mutually agreed terms (MAT). If you acquire genetic resources from an intermediary (buying genetic resources from a commercial provider), the intermediary should provide you with relevant information to enable you to comply with due diligence obligations. See the Horizontal Guidance document.

Q: Can a country decide to join the five countries to regulate access? And if yes, how will we be informed about this?

- ➔ This would appear to be a misunderstanding. Each country decides at the national level whether it wishes to establish access rules to the genetic resources of that country. The five EU Member States that have established rules have each established access rules for *their* genetic resources based on the provisions of the Nagoya Protocol. They have not agreed a special set of access rules between and in cooperation with one another that others can decide to join in with.
- ➔ All signatories to the Protocol should have established a 'national focal point' where information about the national situation should be available. Also refer to the ABS Clearing House website (https://absch.cbd.int/).

Q: Is it possible or even intended that the access rights and sharing of results should be covered in research/cooperation contracts?

- ➔ Yes, access and benefit sharing also applies to research activities. The ABS rules are not intended only for economic activities but apply to 'utilisation' generally (see slide 11).
- ➔ I think there is a bit of confusion here: the sharing of results can be a form of non-monetary benefit sharing and can be covered under the conditions of the cooperation/research contract if the parties decide so (but this depends on the country providing access to the genetic resources.
- ➔ Access rights are established under national legislation of the country from which the genetic resources in question come and one has to respect what they establish and comply with what they require. Some countries may have facilitated access for research purposes; for instance, a researcher might not need prior informed consent (PIC; permit) but simply enter into an agreement between universities. Another country may establish that a researcher only needs to have a research permit but does not need to sign mutually agreed terms (MAT).

Q: Would it be sufficient to agree with the researchers from the providing country to agree on access and use?

- ➔ No. The researchers from a particular country do not 'own' that country's genetic resources and so are not entitled to make this 'agreement'.

Questions relating to PROJECT-RELATED CONSIDERATIONS

Q: At what stage do you need to start access regulation negotiations when applying for a research project (e.g., H2020)? How can sample exchange between countries be regulated, if a consortium is still incomplete or a partner changes during the project (development phase)?

- ➔ Under Horizon 2020, on the basis of what has been established under the EU ABS Regulation, the timeframe for the submission of the due diligence declaration for the project in question – where such a declaration has been deemed necessary – spans the period between the first instalment of the grant until the submission of the final report (at the latest). See art. 5(2) of the Implementing Regulation.
- ➔ This submission date will be no later than the final report (see slide 17). To avoid any possible difficulties, the consortium should already take any necessary steps to comply with due diligence obligations if the research project falls within the scope of the EU ABS Regulation.

Q: The coordinator of a recently approved H2020 funded project has informed the European Commission (via the continuous reporting module of the Funding and Tenders Portal) that our project falls within the scope of the EU ABS Regulation. We have, therefore, been requested to submit the due

diligence declaration to the competent authority of the Member State concerned. Is this something each individual partner must do, or just the coordinator on behalf of the consortium? And how do we proceed with this?

- ➔ This is a choice for the consortium or the different partners involved in the project. One declaration is enough and the partners/consortium can decide that it is the role of the coordinator to submit this declaration (slide 17). See article 5(3) of the Implementing Regulation.
- ➔ *As Dr. Ciacci stressed during the webinar, she is not directly involved in Horizon 2020 and so cannot provide detailed answers on practicalities of project implementation. Nevertheless, certain aspects in this regard are answered in slide 21 et seqq. of the presentation. For more practical information, contact your project officer and/or your National Contact Point to help identify the appropriate contact person in the DG Research and Innovation.*

Q: Does the project coordinator have to submit the due diligence of all partners together with any of the reports required by European Commission via the Funding and Tenders Portal (e.g., final report)?

- ➔ The principal requirement is that the coordinator lodges the due diligence declaration to the competent authority in his or her country. The coordinator should check with the responsible project officer in the Commission or REA whether they also require a copy but to the best of my knowledge, they do not require a copy of the due diligence declaration.

Questions relating to SOURCES OF INFORMATION

Q: Is there any way to check whether the use of a particular genetic resource is restricted by any country?

- ➔ Check with the ABS Clearing House (https://absch.cbd.int/) and with the national authorities in the country.

Q: Do the member states have national contact points to address questions? If so, where can a list of these contact points be found?

- ➔ The signatory states to the Nagoya Protocol should each have 'national focal points'. The details of the national focal point for a particular country should be accessible on the ABS Clearing House website (https://absch.cbd.int/). Not all of the signatory countries have added the necessary information as yet, however.
- ➔ The EU Member States have indicated their competent authorities for the EU ABS Regulation on the Europa website: https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/For%20EUROPA%20-%20Competent%20Authorities%20under%20the%20EU%20ABS%20Regulation.pdf

Q: Is there any template for this Due Diligence Declaration?

- ➔ The templates (for the 1st checkpoint and the 2nd checkpoint) are in the Annexes to the Implementing Regulation. The due diligence forms in the Commission's DECLARE IT tool are based on these templates. The following information in relation to the DECLARE IT tool may provide some helpful information: https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Question%20and%20answer%20users.pdf.

Q: Can you please comment on the DECLARE database?

- ➔ Refer to slides 26 and 27 and see also https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Question%20and%20answer%20users.pdf.