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Yttrande över utkast till vägledningsdokument för samlingar och forskningsinstitutioner kopplat till EU ABS-förordningen 511/2014 (Nagoyaprotokollet).

Yttrandet har på rektors uppdrag utarbetats av Områdesnämnden för naturvetenskap. Ärendet har beretts av professor Catarina Rydin, Institutionen för ekologi, miljö och botanik. Kommentarerna berör i princip uteslutande dokumentet "Sectorial Guidance for Research Institutions".

Draft comments of the ABS Sectorial Guidance Document

This document is a response to the Sectorial Guidance Document produced by the EU Commission and intended to aid scientists and collection holders when establishing if their research activities fall within the scope of the EU Access and Benefit Sharing (ABS) Regulation, and clarifying their due diligence obligations under the EU ABS Regulation.

In general, the document is most welcome and very helpful, with general explanations as well as specific case studies that take clear examples from scientists' point of view. It will certainly help scientists to assess their obligations and take appropriate action.

A general comment is, however, that basing the entire matter on the concept "R&D" is confusing. R&D deals with (technological) development and "useful" innovation (a definition of R&D is given on page 8: "*two intimately related processes by which new products and new forms of old products are brought into being through technological innovation*"). Yet, the document repeatedly states that basic scientific activities are included in R&D. Although it is positive that the EU acknowledges that basic research is a necessary foundation for virtually all technological and societal advances, the leap is made too explicit and too strong here. The probable consequence is an unnecessary aggravation of curiosity-driven basic research activities, which is contra-productive and unfortunate in a longer perspective.

A more reasonable interpretation of the Nagoya Protocol and the EU ABS Regulation would be that they should be applicable to applied research and commercialization of scientific discoveries only, and not to non-commercial basic scientific activities. Likewise, it is important that the Nagoya Protocol and the ABS Regulations do not lead to unexpected and unwarranted control of scientific activities, for example a shift from the utilization of modern analytical methods based on molecular data, to traditional methods that have their foundation

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in times before DNA data became accessible to scientists and before modern scientific methods became common practice. See further below.

Clarifications needed

A few clarifications are needed in the document. There are also two unfortunate misconceptions that need attention and correction (see below).

First, there are too many abbreviations in the document (ABS, R&D, PIC, MAT, MATT). Although most of them are spelled out upon first mention, some are not (e.g., PIC and MAT). And even if they have been spelled out the first time, the use of so many abbreviations is unwarranted since it lowers the accessibility of the document. If the authors wish to educate the reader regarding these concepts, it would be better to specify both the spelled out meaning and the associated abbreviation, every time. For example: "The scientist has to document prior informed consent (PIC) before utilising….".

Second, it is unclear from the document (as well as from previous information seminars) how the concept "genetic resources" should be interpreted. From the majority of the text in the document, it seems implied that it refers only to the genetic material itself, meaning that the regulations are only applicable to research that investigates or utilises DNA. From the background text, however, it instead seems to refer to (entire or parts of) organisms ("*any material of plant, animal, microbial or other origin containing functional units of heredity*"). This leaves the reader with uncertainty regarding for example morphological studies, where organisms that contain functional units of heredity are studied, but not the heritable material (the DNA) itself. Among specific questions that need answers are:

- Does the concept "genetic resources" refer to the actual DNA molecules? Or to entire or parts of organisms (that contain DNA)?
- Related questions: Do evolutionary morphological studies, for example of fossils that by definition are more than one million years old and therefore never contain any functional DNA, fall within the scope of the EU ABS regulation?
- How about archaeological material, which is ancient but young enough to contain detectable DNA? For example from mammoths or Neanderthals.
- Would observations and "experimental observations" of organisms for ecological or evolutionary purposes, in the lab or in the field, fall within the scope of the EU ABS Regulations? Among examples of work included in such studies are:
    - Documentation of the pollination process by observing plants and pollinators.
    - Conducting non-destructive experimentation in the field, for example temporarily cover flowers in bags to exclude insects from accessing them.
    - A subsequent molecular phylogenetic analysis of the study objects, together with data from GenBank, to verify the identity of the studied organisms.

A clarification is also needed regarding case 10. It implies that commercialization without PIC and MAT is allowed under the EU ABS Regulation as long as it is not done by the use of the actual DNA molecules of the organisms but by means of other molecules of the organism. Is

Stockholms universitet

this interpretation correct? See also the question above on whether the concept "genetic resources" refers to DNA or to (parts of) organisms that contain DNA. A more reasonable interpretation would be that any commercialization of biological material and organisms should lead to shared benefit with the country of origin, not utilisation explicitly of DNA molecules (with or without commercial purpose).

Misconceptions that need attention

The most important misconception in the text concerns taxonomy, species identification, bar-coding, classification and phylogeny.

In case 2, it is stated that sequence information obtained "*only for the purpose of identification or classification (such as is often the case in DNA bar-coding)*", does not fall under the scope of the EU ABS Regulation. Similarly, in case 4, it is stated that "*Taxonomic identification of genetic material, in the form of verification of received material by morphological or molecular analysis, even when relying on DNA sequence information, is not considered to constitute utilisation in the meaning of the EU ABS Regulation...*". However, in case 8 it is stated that "*large-scale phylogenetic analyses*" do fall within the scope of the EU ABS Regulation. See also case 16.

This is confusing. Moreover, this separation of taxonomy and classification on the one hand, and phylogeny on the other hand, is a misconception that has to be remedied. Both alpha-taxonomy and deeper level classifications are almost always based on phylogenetic analyses (which are typically but not necessarily based on DNA sequence data). **Phylogenetic work can therefore not fall within the scope of the EU ABS Regulation if taxonomy and classification do not, since the latter two are consequences, an outcome, of the former**. If this is not recognised there is a considerable risk that future taxonomic work and classification would no longer be based on scientific work and evolutionary (i.e. phylogenetic) analyses, but rather on personal opinions of the scientist. Such a consequence would be a huge step backwards and strongly counter-productive from a scientific point of view.

Furthermore, the question regarding whether or not phylogenetic work falls within the scope of the EU ABS Regulation seems in fact to have conflicting answers in the two documents. While case 8 in the Sectorial Guidance Document clearly states that phylogenetic work falls within the scope of the EU ABS Regulation, case 24 in the Collection Holders' document states that phylogenetic work is not considered to fall within the scope of the EU ABS Regulation. This must be clarified. Note that the words "large scale" (phylogenies, see case 8) do not clarify anything. Does "large scale" refer to the number of analysed samples? Or to the taxonomic rank in focus? Something else? Even an alpha-taxonomic project, aiming to describe a single species and define its boundaries, may be based on a phylogenetic analysis of dozens of samples or more. And similarly, a study aiming at providing a new familial classification of a group of organisms would typically be based on a phylogenetic study of hundreds of specimens. But both projects would, thus, be based on phylogenetic analyses.

Stockholms universitet

A second misconception is found under heading "Sources of genetic resources" on page 6. It is stated that: *"More uncommonly, they may be involved in activities collecting genetic resources from in situ conditions in other countries"*. And later under heading "Due diligence obligations" it says: *"This applies in particular to the actions of visiting scientists and students who may introduce genetic resources from foreign origin, often their home country, for research purposes."* However, field collection conducted by European scientists during travels to other, often remote, areas of the world is not uncommon. It is (or has at least been until now) very common and constitutes an important basis for scientific observations of organisms in their natural environment, as well as for international collaboration. Scientists that conduct such collecting have sought appropriate permissions according to national legislation and the Convention on Biological Diversity prior to the journey, often with aid from local scientists.

Unresolved issues

Case 14 could be easily resolved by stating that as long as the purpose and outcome of the studies are basic scientific, they do not fall under the ABS-regulations. But as soon as any kind of commercialization is aimed for or accomplished, they do.

Similarly, regarding the example under heading 3.1: "*Large scale screening of genetic resources and assessing the value of selected genetic resources*, it could be argued that alternative two is the most reasonable approach since all the samples are analysed with the intention to find useful and perhaps commercially valuable substances.

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