Chapter 5
Legal and Ethical Challenges: From Collection Management to Access and Benefit-Sharing

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Abstract Building, using, and managing zoological research collections are complex and demanding tasks, not only from a scientific point of view. In fact, scientists and collection managers are also embedded in a multifaceted sphere of conventions, regulations, and legislation. An important international framework for the exploration and conservation of biodiversity is the United Nations' Convention on Biological Diversity (CBD). However, the CBD does not only focus on conservation and sustainable use of biodiversity. It also sets out basic principles for a fair and equitable sharing of benefits arising from its utilization. Those principles have been implemented in national laws and international agreements on access and benefit-sharing, such as the Nagoya Protocol. In many cases, however, those laws turn out to be critical impediments for the access to and exchange of biological material, research results, and other information within the scientific community. The article will provide an overview on the concept of access and benefit-sharing, the Nagoya Protocol and its implementation in Europe and Germany, as well as challenges and recommendations for collection management. It will also shortly address other regulations affecting the preparation and transportation of zoological samples, i.e., the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), European legislation on animal by-products, and international rules for the air shipment of dangerous goods.

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5.1 Introduction: A Historical Perspective

Collecting, collating, and comparing specimens of animals, plants, and other organism are fundamental methods of taxonomy, the science of describing, naming, and classifying life on Earth. Carolus Linnaeus himself, the eighteenth-century pioneer of taxonomy, was a strong advocate of scientific collecting (Müller-Wille 2007). Linnaeus was engaged in a dense, international network of scientists with whom he intensively exchanged information and biological specimens, and he encouraged his students and colleagues to travel, to explore nature, and to collect specimens wherever possible (Sörlin 2000). During the Linnaean era, collections gained the importance as primary resources, archives, and laboratories for natural sciences they have today. The development of natural history collections was mainly driven by the scientific motivation to discover, describe, and classify organismal life (Pomian 1994); legal and ethical aspects were of minor importance. Ever since then, natural history collections play an important role not only in scientific research but also in collecting and exchanging collection material with other researchers and institutions. In the course of the twentieth century, however, other factors than the scientific interests of collectors, researchers, and institutions more and more influenced the way how scientific collection material was obtained and exchanged. Especially the increasing complexity of international environmental regulations and nature conservation treaties restricted the freedom of scientist and collectors.

The first important milestone was the inauguration of the "Convention on International Trade in Endangered Species of Wild Fauna and Flora" (CITES) in 1973, which was designed to monitor the transfer of protected species and to minimize the threat to species by international trade. In the 1960s it had been realized that the demand of products derived from threatened species, especially in Europe and the United States of America, resulted in an increased trade of such products. Species protected by CITES are listed in the three appendices of the treaty. CITES is implemented individually by national legislation of the parties of the convention. Any transborder transfer of protected species, no matter whether with commercial or noncommercial intent, has to comply with the respective laws of the country of origin and the destination country (see Textbox 1). However, the international community soon realized the potential impediments for research on

such species and established a simplified process for transfers between registered scientific institutions.

Besides CITES as the most prominent example, collectors and collections also have to comply with national conservation laws, veterinary regulations, and the rules and conditions of carriers or carrier organizations (e.g., ICAO and IATA for air transport). More recently, new European legislation on the import of the so-called animal by-products and regulations on the transportation of "dangerous goods" has become relevant for zoological collections. See Textbox 1 for an overview on these regulatory frameworks and the challenges arising out of them. Renner et al. (2012) provide a comprehensive analysis of the respective stipulations that need to be considered when collecting or transferring material from in situ or ex situ sources.

Textbox 1: Overview on Regulations Affecting the Preparation and Transportation of Zoological Samples

CITES. The "Convention on International Trade in Endangered Species of Wild Fauna and Flora" is, at the European level, implemented by the Council Regulation (EC) No 338/97 and the Habitats Directive (Council Directive 92/43/EEC), supporting the protection of wild fauna and flora. Some practical problems arise from discordant lists of protected species included in the respective annexes, with the European legislation being more inclusive by adding a fourth annex (D). CITES, however, provides simplified measure for the exchange of biological material of protected species between noncommercial research institutions, registered at the CITES secretariat. Currently this register comprises almost 800 research and collection institutions worldwide. Shipments between such institutions must be labeled accordingly and are, thus, exempt from CITES custom checks.

Animal by-product legislation. EU Regulation No. 1069/2009 and its amendment (EU No. 142/2011) give detailed rules on the import of the so-called animal by-products (defined as entire bodies or parts of animals, products of animal origin, or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos, and semen). Even though recent amendments allow derogation of veterinary inspection if samples agree with the concept of safe sourcing or safe treatment, legal import of such consignments is at the discretion of the national authority of the member state of destination, with (EU) No. 142/2011 setting out the minimum requirements. The minimum period for notification to veterinarian border inspection posts for animal by-products (e.g., preserved biological material returned from fieldwork in the checked luggage) is 12 h prior to arrival. Safe treatment includes, e.g., fixation in 4 % formalin, preservation in ethanol (min 96 %), drying (only for insects and spiders),

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and boiling or warm water maceration (in case of mammals) with subsequent hydrogen peroxide cleaning of bones.

Dangerous Goods Regulations. Postal carriers and airlines have strict rules for the transport of the so-called "dangerous goods" (especially flammable liquids or corrosive chemicals). All substances used for fixation and preservation of zoological collection material ("safe treatment" as described above) are restricted for transport, e.g., under the Universal Postal Union's Convention, the International Civil Aviation Organization (ICAO), or the corresponding Dangerous Goods Regulations of civil airlines under the International Air Transportation Association (IATA). Under ICAO/IATA Special Provision A180, however, biological material treated with either ethanol, isopropanol, or formalin solution is not regarded as dangerous goods, if specific packing and marking requirements are met. This has been adapted by the UPU recently in their Model Transport Framework Agreement under point 1.11, which recognizes the exception of certain dangerous goods provided for in the ICAO/IATA Dangerous Goods Regulations, and thus allows preserved specimens for transportation.

Renner et al. (2012) provide further details on the abovementioned regulations, including proper documentation of postal shipments, custom law, and clearance, and discuss observed practical problems.

5.2 Access and Benefit-Sharing: The Concept and Its Implementation

Another groundbreaking event in international policy was the adoption of the Convention on Biological Diversity (CBD) during the United Nation's Conference on Environment and Development in Rio de Janeiro in 1992. The CBD finally came into force in December 1993. It is not only remarkable because the conservation and sustainable use of biodiversity were for the first time acknowledged as an official objective of international policy. It also reflects an important change of paradigm: genetic resources (see definitions in Textbox 2) were no longer considered common heritage of mankind, but member states were given the sovereign rights over the genetic resources within their borders. It is open to countries to grant free or to restrict access to their genetic resources and to establish requirements for a fair and equitable sharing of benefits arising from the utilization of those resources. Thereby, the CBD introduced an economic aspect to biodiversity.

Textbox 2: Glossary on Access and Benefit-Sharing (ABS)

Access. The acquisition of genetic resources (GR) or associated traditional knowledge (TKaGR) from a providing country. This term has not been defined in the CBD or the NP and may, thus, be used differently by some countries or organizations. The European Union limits this term to the acquisition of GR or TKaGR from providing countries that are parties of the NP.

Benefits. Not defined in the NP, but may be (1) monetary when research and development leads to a commercial product (e.g., royalties, milestone payments, licensing fees) or (2) nonmonetary (e.g., technology transfer, enhancement of research skills, sharing research results, research partnerships, access to scientific information and research results).

Convention on Biological Diversity (CBD). A United Nations' treaty that came into force on 29 December 1993. It has three major objectives: (1) the conservation of biodiversity, (2) its sustainable use, and (3) the fair and equitable sharing of benefits arising from the utilization of genetic resources.

Genetic resource (GR). Any material of plant, animal, microbial or other origin that contains functional units of heredity and that is of actual or potential value (Definition according to CBD).

Mutually agreed terms (MAT). An agreement reached between the providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties.

Nagoya Protocol (NP). A subsidiary agreement to the CBD that implements Article 15 (ABS) and Article 8j (traditional knowledge). The NP came into force on 12 October 2014 and its full title reads: "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."

Prior informed consent (PIC). The permission given by the competent national authority of a provider country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework. It is a legal document that states what the user can and cannot do with the material.

Traditional knowledge (TK). There is currently no generally accepted definition of TK. The interpretation of the World Intellectual Property Organization (http://www.wipo.int/tk/en/tk/) might, however, be helpful to understand the concept: "[TK] is knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity." The Nagoya Protocol only covers TK associated with genetic resources (TKaGR), not TK as a separate element.

Utilization of genetic resources. To conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (definition according to the Nagoya Protocol).

The general provisions on access and benefit-sharing (ABS) are laid down in Article 15 of the CBD. According to this, access to genetic resources shall be subject to a "prior informed consent" (PIC) of the providing country's governmental authority and shall be based on "mutually agreed terms" (MAT), which have to be negotiated between the providing country and the user. Thus, since 1993 the access to biological material in the wild or in collections is inevitably linked with ABS. Many countries later on established national access legislation, which scientists need to take into account when collecting biological samples in the field or acquiring genetic resources from such countries. In some countries, ABS regulations turned out to be quite obstructive even for basic research on biodiversity, mainly due to intransparent or overly strict access regulations and bureaucratic difficulties in obtaining the necessary permits (e.g., Jinnah and Jungcurt 2009; Martinez and Biber-Klemm 2010).

The ultimate objective for introducing an economic aspect was to generate revenues that help developing countries to conserve their biodiversity (Rosendal 2000), to prevent the so-called "biopiracy," and to control the exploitation of genetic resources. Providing countries aimed at having control over the flow of their genetic resources through the different instances of scientific use and commercialization, i.e., through the so-called genetic resources value chain. In that sense, basic research and scientific collections are considered to be relevant intermediary players along that value chain, even though their focus is clearly noncommercial (Brahy and Louafi 2007; Martinez and Biber-Klemm 2010). During the negotiation process toward an international regime on access and benefit-sharing, the scientific community was very actively involved and demanded that such a regime should provide for a continuous facilitated access to genetic resources for noncommercial research purposes (Schindel et al. 2009).[1] In spite of those efforts, however, the apprehension prevailed that the transition from noncommercial research to applied research and commercialization remains blurred in many instances and that exemptions for noncommercial research would create loopholes for the commercial exploitation of genetic resources (Buck and Hamilton 2011). In fact, traditional scholarly standards such as the exchange of biological samples and the publishing of research results, knowledge, and information on genetic resources may eventually facilitate the subsequent use of genetic resources and associated information by third parties (Laird et al. 2002). Therefore, national and international ABS laws and regulations usually also cover the noncommercial use of genetic resources by scientists and scientific collections.

This holds true also for the Nagoya Protocol (NP, Textbox 2), a supplementary agreement to the CBD that entered into force on 12 October 2014. The NP is the result of a long political debate about an international regime on access and benefit-sharing (Buck and Hamilton 2011). It specifies the provisions laid out in Article

[1] Based on Schindel et al. (2009), it was suggested to define noncommercial research as "research with the goal of adding knowledge to the public domain, without restrictions or proprietary ownership."

15 of the CBD, including the provisions on traditional knowledge (TK) associated with genetic resources (Article 8j, CBD), and calls upon member states to introduce legislative measures governing access to genetic resources and compliance of users. Since the coming into force of the Nagoya Protocol, scientists (and other users of genetic resources) have to consider ABS at two different levels: (1) when obtaining genetic resources, they have to abide by the providing country's ABS laws and comply with any mutually agreed terms and (2) when utilizing genetic resources, they have to fulfill the national compliance legislation in their home country.

Within the European Union, the relevant obligations of the NP are implemented by EU Regulation No. 511/2014.[2] According to this regulation, each EU member state has to designate a competent national authority which has to monitor and check users of genetic resources and associated traditional knowledge. In Germany, this will be the task of the Federal Agency for Nature Conservation (Bundesamt für Naturschutz), in collaboration with some other federal bodies (Bundesanstalt für Landwirtschaft und Ernährung, Robert-Koch-Institut, Patent- und Markenamt). Each user of genetic resources is obliged to undertake due diligence in order to obtain and utilize genetic resources in line with the provisions of the Nagoya Protocol and has to keep all relevant documentation for a minimum of 20 years after ending the utilization of a specific genetic resource. The competent national authority is entitled to undertake on-the-spot checks of users and to issue sanctions against illegal utilization of genetic resources (e.g., penalties and seizure of the resources). Furthermore, users of genetic resources or associated traditional knowledge have to report to the authority in the event of (1) receiving external funding for research projects involving genetic resources or (2) bringing a product based on genetic resources on the European market. Especially the first checkpoint is most relevant for biodiversity researchers and collections and will, without doubt, increase the bureaucratic burden in basic research considerably. Here, the European legislation unfortunately did not follow the provisions of the NP, which requests each member country to "create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes" (Art. 8a, NP). The EU regulation does not govern access to genetic resources of EU member states. Instead, each member state may establish access laws individually, and in some European countries (e.g., France, Hungary, Spain), such legislation is already in place or underway.

[2]Full title: "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." This regulation is applicable since the coming into force of the Nagoya Protocol, with the exception of Articles 4 (on user obligations), 7 (on monitoring of users), and 9 (checks) becoming applicable with one year delay on 12 October 2015.

5.3 Challenges Arising from the Nagoya Protocol and Its Implementation

Most of the challenges for biodiversity researchers and collections stem from the rather imprecise and insufficient terminology used in the CBD, the Nagoya Protocol, and their European and national implementations. When the term "genetic resources" was defined 25 years ago as "material containing functional units of heredity and with actual or potential value," it was targeted at living material suitable for analysis of DNA or other biochemical compounds, but not on preserved material as found in collections. Today, DNA can be extracted from almost any biological material, even from plant remains hundreds of years old or from subfossil bones. Thus, "genetic resources" is far more inclusive than originally intended, and ABS may affect research disciplines that are only indirectly linked to biology, such as earth sciences (genetic resources present in water or soil samples) or archaeology.

Even more challenging is the definition of "utilization" as "research and development on the genetic and/or biochemical composition of genetic resources" (see also Textbox 2). "Research and development" remain undefined and what is covered by "utilization" is unclear. Will there be a divide between classical morphological studies (which do not touch the "genetic or biochemical composition") and studies involving analysis of DNA or other molecules extracted from biological material? Does the act of downloading and analyzing sequence data from online databases imply "utilization of genetic resources" in the sence of the Nagoya Protocol? These questions are just two examples that illustrate the dimension of the problem. It is obvious that collection management is challenged with additional documenting and reporting requirements covering all relevant instances of utilization within the institution and any transfer of material. In view of these new challenges, the Consortium of European Taxonomic Facilities (CETAF), the major European network for natural history collections, developed a set of guidance documents including a code of conduct, a general use statement that should guide MAT and PIC negotiations, and a more detailed description of best practice for taxonomic collections (available from the organization's website, www.cetaf.org). Similar standards have been developed by other stakeholder groups, such as the Global Genome Biodiversity Network (GGBN, for DNA repositories), the World Federation for Culture Collections (WFCC, for collections of microorganisms), or the International Plant Exchange Network (IPEN, for botanic gardens). Those provide general guidance on compliance with legal and ethical challenges arising from the CBD and the Nagoya Protocol. The actual workload and responsibility, however, will be on the collection managers in each institution.

5.4 How to Handle ABS? Recommendations for Researchers and Collection Managers

Some general recommendations to collection managers and researchers can be drawn from the legal framework and its implications as discussed above. Those recommendations are laid out in detail in CETAF's Code of Conduct and Best Practice and shall be given here in a condensed form:

1. Institutions and researchers should *acquire* only such biological material that has been obtained in line with the Nagoya Protocol and the providing countries' legislation (no matter whether from in situ or ex situ sources). This affects the standard procedures for field trips, which need to take into account some time prior to collecting for obtaining PIC and MAT from the competent national authority (besides obtaining other permits, such as research or collection permits). The same applies to accepting incoming material from other countries that are parties to the Nagoya Protocol, either through loan or unsolicited shipping or brought in by students, colleagues, or guest scientists. Information on each country's access regulations and competent authorities can be found on an internet portal maintained by the CBD secretariat, the ABS Clearing House (https://absch.cbd.int).
2. Institutions need to *manage* collections and associated data in a way that the provider of the biological material can be traced at any instance in the collection and research workflow and that any related terms and conditions are easily accessible. All relevant information on access to genetic resources, especially whether documents such as PIC and MAT are needed (restricted access) or not (free access), as well as the documents themselves and information on utilization of the material (who, when, how, etc.), should to be stored permanently. For transfers to third parties (permanent or temporary), documents on the legal status of the respective genetic resources may need to be forwarded.
3. Researchers and institutions should be sure on the status of biological material and *use* it only in line with the terms and conditions under which it was acquired. Special consideration should be given to any restrictions regarding specific analytical methods, the publication of research results or information (e.g., DNA raw data), and the transfer to third parties. If the researcher or an institution intends to use the material in a way not covered by the original terms and conditions, the respective competent national authority should be contacted in order to seek new PIC and negotiate new MAT. Note that all original agreements might become void in case of infringements, deliberate or unintentional.
4. Any *benefits* derived from the utilization of genetic resources must be shared fairly with the providing country and the local cooperation partners as agreed in negotiated terms. In the noncommercial context of basic research and natural history collections, this is usually done by nonmonetary benefits such as the transfer of knowledge, capacity building, joint publications, etc. It is recommended to document such benefit-sharing (including that undertaken

during field work, such as training of local students) and to present it to authorities and the public in order to increase trust among providers of genetic resources.

5. Institutions are advised to develop *internal policies*, guidelines, and workflows that help to comply with ABS. Such policies need to address all relevant steps of acquisition, storage, utilization, and transfer of genetic resources and associated information. It is also necessary that institutions train their staff and inform scientific visitors about the principles of access and benefit-sharing and the legal and practical implementations.

5.5 Conclusions and Outlook

To be clear, the principle of access and benefit-sharing is a very meaningful and politically essential instrument that helps implementing the CBD. The three major objectives of the CBD have equal weight, and therefore the conservation of biodiversity goes along with its sustainable utilization and the sharing of benefit arising thereof. Institutions and researchers that want to contribute to the exploration and conservation of biodiversity have the moral obligation to act in line with the spirit of the CBD and the provisions of the Nagoya Protocol. Nevertheless, the obligations laid out in the NP and the respective European and national legislation add a considerable bureaucratic burden to already existing laws and regulations biodiversity researchers and collections have to comply with.

Existing standards and best practices developed by the scientific community (e.g., CETAF, GGBN, WFCC; see above) might help individual scientists and institutions to understand and abide by those regulations. A broad adoption and implementation of such standards by the scientific community will also help to increase transparency and trust among providing countries, which might in the long term lead to simplified procedures on access and utilization for noncommercial scientific purposes. At the present stage, however, a substantial alleviation of the situation, e.g., by a registering system for scientific institutions comparable to CITES, is not in sight. On the contrary, there seems to be a trend among providing countries to grant access to their genetic resources only with very strict MAT, including prohibition of transfer to third parties. Free exchange of materials, research results, and other information within the scientific community is, however, one of the fundamental principles of science since Linnaean times, as recently stressed by the CBD's Global Taxonomy Initiative. However, this might now become compromised. Therefore, scientists should build and engage in strong scientific networks, get involved with policy and decision-making and make their voice heard.

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