Discussion document on the Implementing Act – Comments from the Natural History Museum, London

The Natural History Museum carries out non-commercial biodiversity research, focussing particularly on taxonomic and systematic work, and supports implementation of the Convention on Biological Diversity, particularly through activities congruent with those set out for the Global Taxonomy Initiative by CBD COP, the Global Strategy for Plant Conservation, and the Aichi Biodiversity Targets. It holds collections of plants, animals, microorganisms and minerals (including soils) totalling more than 80 million specimens. DNA is sequenced from more than 30,000 specimens annually, the information from these sequences being used in taxonomic and systematic publications and published in scientific journals and online. We acquire more than 350,000 specimens a year arising from more than 2,000 sources; that is to say, potentially accompanied by more than 2,000 permits with PIC and MAT. A proportion of these will have their DNA sequenced either as a part of a research project or to facilitate identification. However, the researcher or other staff member or student responsible for the sequencing is unlikely to be the same individual that accessed the specimens from the providing country and is likely to be sequencing specimens from many different acquisitions. In contrast, specimens from a single acquisition (i.e. covered by a single permit) may be sequenced as a part of many different projects, over many years.

We note that Article 8a of the Nagoya Protocol states that "In the development and implementation of its … regulatory requirements, each Party shall: (a) 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, taking into account the need to address a change of intent for such research". We hope that the Commission will view the comments and questions below in this context.

There is a continuing need to promote the free operation of science within the European Research Area and effective collaboration beyond the EU to ensure development of basic knowledge, competitiveness and innovation. The Implementing Act will inevitably affect this science, in that it engages with non-commercial biodiversity research. The impact on this of different wordings and options with respect to the Implementing Act must be understood at this stage before finalisation. The current wording in the Discussion Document and its Annexes is based on an inadequate model of the scientific process and international biodiversity collections collaboration and, if employed, will have adverse impacts in the EU and in collaborating countries.

We have particular concerns and suggestions for each of the Articles as addressed in the Discussion Document and its Annexes.

1. Article 5 of the basic Regulation - register of collections

1.1. General questions;

a) Is it intended that the compliance checks be funded by Governments of member States, , or passed on to the Collection Holder? Given that supplying Genetic Resources to third parties as outlined in the EU Registration is not core business for the Natural History Museum, and would in any case result in a net cost through the management of supply and delivery of materials, additional charges would further discourage adoption of the Registered Collection model.

b) If a part of the collection of an institution is Registered, does transfer of GR from that Registered Collection to a researcher within the institution require the same protocols and provision of information as to a researcher in a different institution? We would hope that streamlined

processes would be acceptable for both collection and researcher, as long as both were bound by the same set of institutional policies and processes.

1.2.Minor details:

c) Discussion Document P. 2, line 29. Where the text states "per collection **and** part thereof" can we assume the meaning is "per collection **or** part thereof"?

d) Discussion Document P. 3 line 9. The document states "In a situation where only part of a collection is to be included in the register, the description and the distinctive (**biological**) features of that part will have to be specified." It is likely that in some cases the distinctive feature might be managerial or to do with preservation type rather than biological, and that other biological entities of the type present in the Registered Collection will be held in unregistered collections in the same institution. Removal of the term "(biological)" would obviate this problem.

2. Article 7 of the basic Regulation – monitoring user compliance

Although template report forms are provided, to minimise the cost of providing reports we would wish to investigate the potential of delivering such reports electronically, using outputs directly from our data management systems. We would welcome an undertaking to facilitate this approach.

2.1. Due diligence declaration at the stage of research funding

The Natural History Museum, like other users in the non-commercial biodiversity research sector, will incur costs in reporting due diligence where this is required:

a. to develop our data management systems to store and provide the information required for reporting, where this is not already possible;

b. staff time to input the information that will be required for reporting into our institutional databases to cover the possibility that a report might be required;

c. staff time to make reports.

These costs cannot be estimated without clarity on terms and concepts used in the discussion document, so we can understand their applicability or otherwise to our work. Moreover, without such clarity we cannot manage the information appropriately and it will be difficult to be compliant. We are also naturally reluctant to incur such costs for information that is not required by the Regulation, nor by the ABS Clearing House; currently there are several information items included which come under this heading.

Costs will also be incurred by Checkpoints who have to manage declarations. These will relate to the number of declarations made, which depend on the same set of unknowns.

The uncertainties in the current draft relate to:

a) The content of the declaration form;

b) the point at which the declaration is made;

c) the meaning of utilization under the Regulation, and how this applies to our activities.

a) The content of the declaration form;

Article 7 paragraph 1 of the Regulation requires recipients of research funding involving the utilization of genetic resources "to declare that they exercise due diligence in accordance with Article 4". In contrast, the form provided as Annex A to the discussion document requires details that are only relevant to Regulation Article 7 paragraph 2, where these requirements are detailed.

The impact of the proposal in the Discussion Document could be considerable, and the value questionable. Under our interpretation of the Regulation we would propose that the Museum makes a declaration covering all research funding it receives (such funds are managed by the Institution not the individual staff members). This would take no more than a few hours per year for the Institution.

Such a simple declaration is sufficient to alert the National Checkpoint that utilization may take place at the institution and allow them to take appropriate monitoring action. In contrast (and assuming that some of our activities can be classed as 'Utilization' under the regulation, which we doubt) a worst-case scenario would require several thousand forms to be completed and submitted each year – assuming 10 minutes per form and ca 10,000 forms per year within the next three years, which would require us to spend at least one person-year per year declaring due diligence. This is a conservative estimate, given that a single research project may involve sequencing the DNA of specimens covered by hundreds of different permits.

A declaration of due diligence under Article 7(1) and as explained in the Discussion Document is made prior to any utilization taking place. Arguably, because there is no utilization at this time it does not fall under Nagoya Protocol Article 17 (1)(a)(i) and is not required to be reported through the ABS Clearing House and is of no particular value to the Providing Country. The questions in Part B of the form are in any case not required by the ABS Clearing House – what is their function?

We note that the researcher(s) who sequence the DNA of an organism may not be the individual(s) who accessed the GR in the first place, and consequently the statement on Annex A "An internationally recognised certificate of compliance was issued for **my** access to the genetic resource" is inappropriate.

b) The point at which the declaration is made;

If it is understood that we utilize genetic resources (see below) then we would find clarification on when a declaration is to be made and what it covers valuable. As noted, many different researchers and others may sequence the DNA of specimens from a single acquisition; do each of them have to make a separate declaration as a part of their project, or can a single declaration be made to cover all of their work? The numbers of declarations that this might lead to are discussed in the section above.

Much of our work is not funded under separate external research grants but is a part of the work of the institution covered by core funding. Some of the work involving sequencing is not research but is simple identification. We assume that where there is no separate 'research funding' the requirement for a declaration is not triggered.

If it is accepted that a declaration of due diligence can cover all of the GR accessed under a permit a further question arises. If some of the GR is loaned to a third party (usual practice for taxonomic institutions) who intends to sequence genes from the specimens, and *if this is utilization*, must that third party also make a declaration?

c) The meaning of utilization under the Regulation, and how this applies to our activities.

As noted, our staff sequence DNA as a part of non-commercial taxonomic and systematic research, comparing the sequence results in order to, for example, develop hypotheses of the relationships of the plants and animals they study or understand diversity. This does not seem to us to be be 'research *and* development', and we maintain that in these activities we are not utilizing genetic resources. In order to gain some clarity we would welcome answers to the following questions as they apply to non-commercial biodiversity research:

a. Is sequencing DNA 'utilization'? This is something routinely undertaken as part of non-commercial research and for identification purposes.
b. Is comparing sequences from different organisms in order to form a hypothesis about whether they are the same 'utilization'?
c. Is comparing many sequences to construct a tree of hypothesised relationships 'utilization'?

2.2. Due diligence declaration at the stage of final development of a product

A report is required when "the result of the utilisation is" "placed on the Union Market" or "sold or in any other form transferred to a natural or legal person" inside or outside the Union. If the answer to any of the questions on the meaning of utilization posed above is 'yes' then it appears that under the

current wording of the discussion document a further report will be triggered for non-commercial taxonomy work.

The result of non-commercial taxonomic and systematic research is generally a widely-distributed scientific paper and, in the case of research involving DNA sequencing, the sequence data being uploaded to a public database such as that operated by EMBL. We would recommend that it be made clear that such activities do not trigger a reporting requirement. It may be helpful to consider that a research paper may report on the sequencing of genes from hundreds of specimens collected under hundreds of permits. For example, a recent paper[1] taken at random involved genomic sequencing of 173 insect species from 21 countries, many almost certainly each from different collecting events and thus potentially representing 173 different permits and consequently generating 173 reports (the time needed to compile these being more than 34 hours at 10 minutes per form). The research result was a phylogeny of insects. Because papers of this nature typically draw on unpublished sequences supplied by scientists globally (an additional 31 such samples were used in this paper), and these scientists may not be operating under legislative requirements that require them to share permit details, information for all of these reports may not be available.

The paper referred to above was a genomics paper; the Web of Science on a fairly simple search returns more than 2,000 non-human genomics papers annually, and widening the search to 'DNA' retrieves nearly 40,000 annually. Some will be based on single species, others on multiple species. It can be anticipated that over time an increasing proportion of genetic resources sampled for such papers will be from Parties to the Nagoya Protocol. We believe that should reports be required for all separately-accessed specimens it would create a significant impediment to the research (delivery of non-monetary benefits) and create management problems for the Checkpoints concerned.

In the same paper the sequences obtained were compared to more than 20 reference sequences from public databases (GenBank); we assume that because these data are on public databases no report would be expected; can this be confirmed?

3. Article 8 (Best Practices)

We are committed to adopting and implementing Best Practices for ABS, and have been working with several consortia to develop these as they apply to different areas of our work (Consortium of European Taxonomic Facilities, Global Genome Biodiversity Network). However, we do not understand how some of the requirements outlined in the Discussion Document can be met.

- The applicant is "required to state whether they are established in accordance with the requirements of the Member State, in which they are located". For members of a multinational consortium is this the MS of individual institutions or the Consortium Secretariat?
- The application is required to include a "List of competent personnel with copies of CVs, accompanied by a description of their duties." The NHM has more than 300 scientists on its staff whose duties may include access to and collection or Genetic Resources, and the consortia we are working with each have more than 5,000 scientists spread across member institutions; it is anticipated that all of these be listed, or only one appropriate representative from each institution?
- Applicants are also required to provide a description of "how they will ensure the oversight of the procedures, tools or mechanisms". For the consortia to which we belong there is no mechanism to deliver such 'oversight' and we cannot see how this might be achieved. These are not associations of which membership is required to be able to carry out our activities, but voluntary associations developed to offer mutual support and build multi-national

1

Gillett CPDT, Crampton-Platt A, Timmermans MJTN, Jordal BH, Emerson BC, Vogler AP. Bulk De Novo Mitogenome Assembly from Pooled Total DNA Elucidates the Phylogeny of Weevils (Coleoptera: Curculionoidea). Molecular Biology and Evolution 2014;31(8):2223-2237. doi:10.1093/molbev/msu154.

partnerships. Clearly we have management systems ourselves, but for associations of users such as those we belong to we think this requirement is unrealistic.