Statement

Verband | Biologie, Biowissenschaften & Biomedizin in Deutschland

Statement on the proposed implementing acts for Regulation (EU) 511/2014

Based on the minutes of Stakeholder Meeting (December 9th 2014) and the respective Discussion Paper provided by the European Commission, including annexes A to D.

Motivation

The German Life Sciences Association (VBIO - Verband Biologie, Biowissenschaften und Biomedizin in Deutschland) is Germany's largest association for life sciences. Its about 35,000 members represent individuals, life science organisations and other institutions. Our members represent the entire spectrum of life sciences, from the molecular and cellular to the organismic and ecological levels. Our members are employed in schools, universities, administrations and research institutions, or work as free-lancers.

The Regulation (EU) No 511/2014 affects basic life science research in various fields like taxonomy, biodiversity or biotechnology. The implementation of Articles 5, 7 and 8 will be of major relevance for our members mostly doing non-commercial research in collections, research institutions, and universities.

Thus, VBIO takes the opportunity to comment on the current stakeholder debate.

General remarks

Research performed in universities is to a large extent characterized by limited, mostly project-bound resources.

Considering role, scope, structures, personal and financial resources of university collections, we doubt whether they are prepared to register (Article 5) or to play an active role in associations of users (Article 8 – Best Practice).

Researchers in universities not associated with a larger collection in the institution are even more affected as they hardly have access to administrative support familiar with Access and Benefit Sharing regulations.

Thus, researchers based at universities will hardly benefit from any alleviation the instruments "Registered collections" and "Best practice" might offer upon installation. Therefore, university-based research is particularly affected by the proposed regulations.

The European implementation acts – in combination with national laws likely not harmonized EU-wide – will raise the hurdles for exchanging biological material. As an example, we expect further legal challenges within the frame of international exchange programmes through which researchers visit other universities and research institutions to work with their own samples there. This will hamper European scientific cooperation and may have the potential to stifle international research networks co-funded by the Commission.

Furthermore, Regulation EU 511/2014 and the relevant implication acts will obstruct basic research on biodiversity as well as ´applied´ activities like monitoring invasive species as a cross-sectorial and cross-border challenge. In our view, Regulation EU 511/2014 is not in accordance with EU programmes funding basic research in future relevant areas like biodiversity and climate change. It also contradicts the commitments of the Commission and

the Member States to ensure their responsibilities in cross-boarder issues like monitoring or coordination of biodiversity policies.

Concept, wording, definitions

We would like to emphasize, that basic research on taxonomy and biodiversity nowadays often involves the sequencing of DNA for organism identification (e.g. DNA barcoding) or for establishing phylogenetic relationships between species. The different comments issued by the Commission do not allow us to assess in detail, which scientific activity will trigger due diligence. We strongly recommend that the above addressed non-commercial research activities may not trigger due diligence.

> ***>>> We suggest that a statement similar to "the triggering moment will be the utilisation. In case of a simple analysis of genetic resources without subsequent utilisation, no declaration will be needed" (comment of the* Commission during the *stakeholder meeting on December 9th – according to the minutes) is included in the discussion paper itself.***

We believe that there is currently no common understanding of which scientific activities on genetic resources fall under the term 'utilization' versus 'research and development' and which of them trigger due diligence. Different interpretations of these terms are likely the reasons for the huge discrepancies in the impact assessment of the proposed implementing acts, which various stakeholders have presented so far.

In accordance with the overall objectives of the Nagoya Protocol we suggest to distinguish between 'non-commercial' and 'commercial' uses rather than between 'basic research' and 'research and development'. Whilst for the first distinction (non-commercial <> commercial) critical check points (e.g. market entrance) can be identified, the second discrimination (basic research <> development) has proved to be inapplicable.

> ***>>> To provide legal certainty for all stakeholders, we recommend identifying clear-cut and practicable definitions for the terms* '*utilization*' *and* '*research and development*'*. These could be included within the supplementary guidance documents already announced.***

Article 5: Register of collections

The register aims to facilitate due diligence for third party users of genetic resources. By this, the Commission without any need goes far beyond the requirements of the Nagoya Protocol.

Nature, frequency (Discussion paper, page 4, line 9ff) and the applicability criteria will put an immense additional administrative load on personnel dealing with due diligence aspects in such collections (especially in small, mostly multidisciplinary university based collections) as well as on the authorities in charge of the auditing.

The overall practicability of the register of collections can be questioned. The majority of collections lack the necessary personnel and financial capacities to undergo the initial registration process and the regular verification process every three years. In addition, also large museum collections do not seem to be enthusiastic about such a registration process.

Article 7(1): Due diligence declaration at the stage of research funding

Article 7(1) stipulates that "the Member States and the Commission shall request all recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4."

The details requested in Annex A - especially points 3 (due diligence), 5 (restrictions in MAT) subsequent applications and commercialisation, and 6 (subsequent applications and

commercialisation in MAT) are comprehensive and – at this early stage - far beyond the concise declaration which is claimed by Article 7(1).

We would like to point out that in practice it will be difficult for most basic research projects to meet the requirements of Annex A at an early stage - if they are capable to meet them at all. Concerning non-commercial research we neither see the advantages nor the necessity to demand a comprehensive due diligence declaration like Annex A.

> ***>>> We propose that for non-commercial research the early-stage due diligence declaration should be tight, general and non-bureaucratic.***

According to the specifications documented in the funding application, the recipient of research funding will be responsible for due diligence and reporting. With respect to museums and other collections, the genetic resources will normally be integrated into the existing collections. If sufficient financial resources are available, the general organisation structure of a collection allows to implement internal governance structures to cope with this responsibility (e.g. compliance agent).

The establishment of a similar governance structure in a multi-disciplinary university is even more difficult to achieve, as ABS compliance management is not at the core of university´s duties. High fluctuation of personnel and frequent cooperation projects will make it very costly to implement a compliance system for ABS.

Article 8: Best Practices

Generally, getting their “Best Practices” accredited might be advantageous for associations. However, considering the comprehensive list of information that associations will have to provide as a prerequisite for the accreditation – especially the list of ‘supporting information’ (Discussion paper, page 7/line 36 to page 8/line 6) – it will be challenging and likely costly for any association to apply successfully for accreditation. This instrument might be suitable for strong associations with industrial background – which are usually close to commercial application. However, it will be of little help for the majority of individual scientists who are not associated with a collection and perform non-commercial basic research.

Berlin, January 9th 2015