Comments on the EU Discussion Paper for the Future Implementing Act in relation to Articles 5, 7, and 8 of the Regulation (EU) No. 511/2014

Introductory remarks

The German Biotechnology Industry Association (DIB) belongs to the world's largest industry associations for biotechnology, representing 10 major trade associations. DIB represents various industry sectors that use biotechnology such as health care and diagnostics, primary production and agro-food, animal health, textile finishing, pulp and paper, detergents, cosmetics and personal hygiene, renewable raw materials for materials and energy, industrial production such as bulk and specialty chemicals, pharmaceutical compounds, amino acids, enzymes and polymers.

DIB fully supports the objectives of the Convention on Biological Diversity (CBD) and of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Benefit Sharing of Benefits Arising from their Utilization. We welcome its implementation in the EU via the Regulation (EU) No. 511/2014 (hereinafter referred to as the basic Regulation), but have a number of concerns regarding some of its ambiguous language and, by association, its lack of legal certainty.

The biotechnology industry (hereinafter referred to as industry or the industry) fully supports the CBD underpinning the Protocol and stands ready to work with the EU Commission on ensuring the Protocol's fair and balanced implementation in Germany and across the EU.

A key driver in that process must be to ensure legal certainty for potential users of genetic resources in the EU. Wherever possible, workable and existing regulations should apply which also small and medium-sized enterprises can fulfill without extra administrative workload in their usual day-to-day activities. It is important to keep this administrative workload as low as possible. Otherwise both the use of genetic resources and the development of new products therefrom will be severely hampered. This would run counter to the objectives of the CBD as well as the Nagoya Protocol.

We therefore outline in the following paper a number of points which we consider should be addressed and/or clarified in the Implementing Acts based on the Discussion Paper circulated for the Stakeholders Meeting of 9 December 2014 as well as in its annexes so as to ensure an effective and balanced implementation of the EU Regulation.

Industry stands ready to continue the dialogue with national and EU authorities in developing these Implementing Acts and is happy to support its implementation. We urge the EU Commission to continue to actively involve stakeholders throughout the process of drafting the Acts.

Voluntary tools to assist compliance

Articles 5 and 8 of the Regulation (EU) No. 511/2014 provide for voluntary tools to assist users in complying with their due diligence obligations, such as registered collections and best practices. We support these concepts, which should allow users to be compliant with the requirements of the Regulation at a limited administrative burden and cost.

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Registered collections (Article 5)

The proposed concept of registered collections raises a number of legal issues and poses problems in its practical application:

- The scope of what constitutes a collection is not clearly defined.

- It is not obvious whether the term “collection” refers to virtually any collection of genetic resources or only to those which actually share their inventory with third parties.

- Two obligations impose a heavy administrative burden on a collection and are unworkable in practice, especially for small and medium sized enterprises or start-up companies:
  - “…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…”.
  - “…notify the competent authority of any changes in the information previously submitted to the competent authority…”.

- The list of sources of genetic resources (checkboxes from a) to g)) that is designed to provide information on the type of the collection seems scientifically and taxonomically imprecise. We suggest that the EU Commissions coordinates such a list with biological resource centers, such as the Leibniz-Institute DSMZ – German Collection of Microorganisms and Cell Culture and other stakeholders in specific business sectors to review the terminology and ensure precise and workable nomenclature.

- Reference is made to codes of conduct, manuals of procedures as indicative documents demonstrating the capacity of a collection to comply with the relevant requirements. These can be confidential business information or trade secrets and should be kept confidential by the Competent Authority or Commission. There is no indication that the provisions regarding collections also ensure business confidentiality.

- With regard to remedial actions, it is necessary to define a reasonable period of time to provide the holder of a collection with the opportunity to remedy deficiencies. The period must take account of the specificities of biological entities stored in a collection.

It is important to make this option applicable to the situation in practice and meaningful for collections and for users. The requirements collections have to meet in order to be eligible for an EU registered collection should not have a deterrent effect or even make it impossible for any collection to be registered.

Monitoring user compliance (Article 7)

Article 7 provides for two different checkpoints in time at which the declaration of due diligence should be submitted: at the stage of research funding and at the stage of final product

development. We would like to point out a few areas where clarification of the implementing acts is necessary.

Due diligence declaration at the stage of research funding (para. 1)

The Commission's Proposal only refers to public research funding and therefore implied that each user would only be likely to make one declaration depending on the academic or commercial nature of its activities: either at the stage of research funding or at the stage of commercialization. The consequences of the current Regulation are unclear, as any entity – be it a public institution or a private company – may be considered as a "recipient of research funding". The Implementing Acts explicitly acknowledge the burden represented by filing a declaration and that it should therefore only have to be done once. We believe that the Implementing Acts should restrict the applicability of paragraph 1 to a recipient of public research funding.

In addition, research funding as such is not defined. Is there a distinction made between research funding and the provision of services? Differences in interpretation between EU member states might create a trade barrier.

We suggest that the Commission clarifies the nature of private funding which is to be captured in the scope of this paragraph, especially to clarify that intra-company financing schemes are not meant to be included.

We welcome that such declarations only concern funding for research activities involving genetic resources.

Due diligence declaration at the stage of final development of a product (para. 2)

Competent authorities monitor users' compliance relying on the provision by the latter of a declaration of compliance "at the stage of final development of a product developed via the utilization of genetic resources" as far as commercial entities are concerned, which stage shall be defined by the Commission for different sectors in the Implementing Acts to be adopted as explicitly provided by Article 7.6 of the Regulation.

First, a declaration should only be made for products developed by utilizing genetic resources within the scope of the Regulation. The burden of proving that the Regulation applies to a particular genetic resource should lie with the enforcing authority; it is not for any party utilizing the genetic resource to prove that it does not apply. In the same logic a specific field should be included in the Annexes enabling a declaration that access and use is not covered by any obligations of the Regulation since it is outside the scope of the Regulation.

The Implementing Acts should also define which authority is competent in different scenarios. It should also foresee a simplified declaration procedure for products which are to be placed on the market in several Member States, by identifying a criterion to designate only one competent authority in such situations. DIB suggests that the declaration should be made to the Competent Authority of the Member State where the entity has its main (European) headquarters. (p.6, l.3-4)

We believe that no declaration should be made where the utilization has taken place outside of the European Union. According to Article 1 of the basic Regulation, it establishes rules governing compliance “in accordance with the provisions of the Nagoya Protocol”, which provides that parties are only competent to regulate compliance within their respective jurisdiction (Article 15). Furthermore, Implementing Acts shall be adopted by the Commission to establish the procedures for implementing paragraphs 1, 2 and 3 of Article 7. There is no legal basis in these paragraphs to extend the geographical scope of the basic Regulation (p.6, l. 24-25); and such a broad geographical raises questions as to compliance with WTO rules. The question referring to “utilization outside of the Union” in Annex C should therefore also be deleted. For completeness, it also needs to be noted that the definition of “entering the Union” used as trigger for this extraterritorial application, is unclear.

Reference is also made to the Annexes B and D related to traditional knowledge. These annexes include the question “are you at the same time submitting a declaration for the utilization of genetic resources for the same activity?” Since only use of traditional knowledge associated with genetic resources is within the scope of the Regulation, Annex B and D should only include questions that need to be specifically addressed for traditional knowledge.

Finally, the basic Regulation alternatively uses “product deriving from the utilization of a genetic resource” or “product developed via the utilization of genetic resources”. It is therefore critical that guidance is provided to establish a common understanding and define the exact nexus required between the final product and the genetic resource.

We suggest that the Commission clarifies the minimum link required between a genetic resource and a product to justify a declaration.

Best practices (Article 8)

We support the concept of best practices, which we believe will foster sectorial compliance. The procedure laid out for the recognition of best practices should however be accessible and flexible enough so as not to exclude any association of users of involved sectors. We note that the basic Regulation defines best practices as “a combination of procedures, tools or mechanisms” which “enables that user to comply with its obligations”. To that purpose, overseeing functions should be understood as a guiding rather than monitoring function.

In this respect, we are concerned with the definition in the Regulation (Article 3.10) of ‘association of users’, which refers to overseeing functions and how these latter seem to be characterized in the Discussion Paper. We understand the nature and extent of these functions is not to be addressed in the Implementing Acts and should therefore be clarified in the Guidance document to be adopted by the Commission. However, some of the procedural requirements as defined in the Implementing Act would already pre-empt most associations of users from adopting a best practice, such as providing a list of competent personnel (see also the point related to protection of personal data hereunder), as well as the vague notion of the declaration of absence of conflict of interest in overseeing the implementation of the combination of procedures, tools or mechanisms. We therefore believe that the concept of an overseeing function should be widely construed and should not require any in-house monitoring function from users’ associations.

We suggest that the Implementing Acts precisely define the different steps of the procedure and the timelines associated with each step. In particular, the Commission should have to make its decision to grant recognition as best practice within a defined timeframe, for instance one month from the Member States' deadline for comment (p. 8, l. 20). Besides, in cases where a "Best Practice" is not recognized or withdrawn, the Implementing Act should explicitly refer to the possibility to appeal the decision of the Commission (p. 8, l. 29).

We note that "other interested parties" are also entitled to adopt best practices, provided they have a legitimate interest in the subject matter of the basic Regulation or they access, collect, transfer or commercialize genetic resources (p. 7, l. 18-21). We are concerned that the first condition is too wide and suggests that both criteria are cumulative.

As pointed out above in relation to registered collections, we would like to voice the same concern with regard to confidentiality in relation to information to be submitted with regard to best practices. A list of competent personnel with copies of CVs, accompanied by a description of their duties should be kept confidential, or be protected as personal data by the Competent Authority or Commission. There is no indication that the provisions also ensure protection of personal data.

We believe that what constitutes "any changes or updates" to a best practice needs to be clarified. A new subcontractor or a change in the competent personnel should not be qualified as a change to the recognized best practice.

With regard to potential deficiencies in best practices (p.9, l. 11), it is of key importance that the Commission only act upon information if it is 'substantiated' information. If revisions can be triggered by any type of information, whether or not substantiated or supported by evidence, the legal certainty of best practices would be undermined and the administration for Competent Authorities, the Commission and applicants would become very burdensome.

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