Deutsche Industrievereinigung Biotechnologie

Comments on the draft of the EU Implementing Regulation (EU) No …/… laying down detailed rules for the implementation of Regulation (EU) No 511/2014 as regards the register of collections, monitoring user compliance and best practices

Introductory remarks

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.

A key driver in the process of implementing the Nagoya Protocol must be to ensure legal certainty for potential users and providers of genetic resources in the EU. Workable 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 a number of points which we consider should be addressed and/or clarified in the draft of the *"Commission Implementing Regulation (EU) No …/… laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices"* as well as in its annexes so as to ensure an effective and balanced implementation of the EU Regulation.

It can generally be taken for granted that access to genetic resources *in situ* and *ex situ* without the authorization of the country of origin is more of a theoretical exception. This would constitute a violation of the CBD (misappropriation, misuse) and is equally to be condemned as access without obtaining a PIC. The industry draws attention to the fact that binding regulations should be exemplified by normal cases, and not by exceptions (e.g. misappropriation), since anything else would be a serious threat to any efficient and practicable procedure.

Article 15 (3) requires CBD Parties to facilitate access for environmentally sound purposes and not impose restrictions that are counter to the CBD. The current overall impression industry has from this draft regulation is that the EU Commission's focus is strictly on extensive control instead of fostering the sustainable use of genetic resources and thus triggering investments in its protection and conservation.

We urge the EU Commission to continue to actively involve stakeholders throughout the process of drafting the regulation.

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Recitals

(3) & (4) "…utilisation of genetic resources and traditional knowledge associated with genetic resources…"

- Recommendation: We suggest adding the following specification: *…that fall within the scope of the Regulation (EU) No 511/2014*.

- Explanation: A declaration should only be made for products developed by utilizing genetic resources that fall within the scope of the Regulation (EU) No 511/2014. We believe that this specification is an important element for achieving high legal certainty for users.

(4) "In order to effectively address all activities that utilise genetic resources and traditional knowledge associated with genetic resources within the Union, the declaration should, in those cases, be made by the person selling or in any other form transferring the result of the utilisation to another person that carries out those activities."

- Recommendation: Delete this sentence.

- Explanation: This lies outside of the scope of the Regulation (EU) No 511/2014. The seller of the result of the utilization of a genetic resource is not the user any more. With regard to legal certainty, our view is: When a genetic resource is transferred, the original obligation of the acquiring company will be passed on by contract - using the sMTA - to the next user, who will then enter with complete responsibility into the modalities of the CBD – thus assuming the obligation to notify for example a new intended use, which had not been recorded in written form in the PIC, to the country of origin, and to share all resulting material benefits with the country of origin.

(4) *"Effective monitoring of user compliance within the Union must also address cases where the result of the utilisation is sold or in any other form transferred outside the Union without placing a product on the Union market."*

- Recommendation: Delete this sentence.

- Explanation: According to Article 1 of the Regulation (EU) No 511/2014, 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). There is no legal basis in the paragraphs 1, 2 and 3 of Article 7 to extend the geographical scope of the Regulation (EU) No 511/2014. Such a broad geographical scope raises questions as to compliance with WTO rules. The question referring to "…utilization…sold…outside …the Union…" in Annex IV, Part A, 3. (e) should therefore also be deleted.

Articles

Article 2 Register of collections

- Recommendation: Define the scope of what constitutes a collection.
- Explanation: 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. 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. The requirements in this draft have a discouraging effect on holders of collections.

Article 4 Frequency and nature of checks on collections

Paragraph 3 (c) examination of whether samples of genetic resources and related information of the collection concerned have been properly documented;

- Recommendation: Specify, such as “documented according to ….[regulation…]…”
- Explanation: “…properly…” is highly unspecific and does not provide legal certainty.

Article 5 Remedial Actions

- Recommendation: Define a reasonable period of time for the party concerned to take corrective actions.
- Explanation: 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.

Article 6 Due diligence declaration at the stage of research funding

Art. 6.1 “…the utilisation of genetic resources and/or traditional knowledge associated with them”

- Recommendation: We suggest adding the following specification: … *that fall within the scope of the Regulation (EU) No 511/2014.*

- Explanation: A declaration should only be made for products developed by utilizing genetic resources that fall within the scope of the Regulation. We believe that this specification is an important element for achieving high legal certainty for users.

Article 7 Due diligence declaration at the stage of final development of a product

- Recommendation: We suggest adding the following specification: …genetic resources…*that fall within the scope of the Regulation (EU) No 511/2014.*

- Explanation: A declaration should only be made for products developed by utilizing genetic resources that fall within the scope of the Regulation. We believe that this specification is an important element for achieving high legal certainty for users.

Article 7, 2 (d) the result of the utilisation is sold or in any other form transferred to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

- Recommendation: Delete.

- Explanation: This lies outside of the scope of the Regulation (EU) No 511/2014. The seller of the result of the utilization of a genetic resource is not the user any more. With regard to legal certainty, our view is: When a genetic resource is transferred, the original obligation of the acquiring company will be passed on by contract - using the sMTA - to the next user, who will then enter with complete responsibility into the modalities of the CBD – thus assuming the obligation to notify for example the new intended use, which had not been recorded in written form in the PIC, to the country of origin, and to share all resulting material benefits with the country of origin.

Article 7, 2 (e) the result of the utilisation is sold or in any other form transferred to a natural or legal person outside the Union.

- Recommendation: Delete this sentence.

- Explanation: According to Article 1 of the Regulation (EU) No 511/2014, 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). There is no legal basis to extend the geographical scope of the Regulation (EU) No 511/2014. Such a broad geographical scope raises questions as to compliance with WTO rules. The question referring to

"utilization outside of the Union" in Annex IV, Part A, 3. (e) should therefore also be deleted.

Article 10 Recognition and withdrawal of recognition as best practice

Artilce 12 Deficiency in best practice

- Recommendation: Include the possibility for user associations/registered collections to appeal the decision of the Commission.

Article 11 Information on subsequent changes to a recognized best practice

Article 11, 1 "…informed of any changes or updates…"

- Recommendation: Clarify what "…any changes or updates…" constitutes.
- Explanation: 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.

Article 12 Deficiency in best practice

Article 12, 1 "…Commission receives information regarding repeated or significant cases of non-compliance Voluntary tools to assist compliance…"

- Recommendation: Add "…substantiated information…"
- Explanation: With regard to potential deficiencies in best practices, it is of key importance that the Commission only acts 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.

Annex V

No. 6 , 3. Member State(s) where the users implementing a best practice overseen by the association or the other interested party operate:

- Recommendation: Specify the "…absence of conflict of interest…" and how to ensure it.

- Explanation: 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 best practices and user associations with overseeing functions. But, it remains unclear how to operationalize a voluntary user association and ensuring total absence of conflict of interest at the same time. “User associations” are alliances of users that share one specific interest. The expectations from the Commission do not appear to be appropriate, because voluntary “user association” cannot totally avoid conflict of interest.

No. 6, 5 Copies of financial statements for the last two financial years or other substantiating documents where financial statements are not required due to the legal nature.

- Recommendation: Delete.

- Explanation: We doubt that there is a legal basis for this requirement. It is also completely unclear how this requirement contributes to the overall objective of ensuring compliance with the provisions of the Nagoya Protocol. The EU Commission seems to focus strictly on extensive - and in this case not comprehensible - control instead of fostering the sustainable use of genetic resources and triggering investments in its protection and conservation.

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