



SUMMARY MINUTES OF THE ABS CONSULTATION FORUM

1ST MEETING, 21 JANUARY 2016

1. Opening and welcome

The Chair, Mr Hans Stielstra (Deputy Head of Unit ENV.E2), welcomed all participants and thanked the stakeholders concerned for their willingness to form ad-hoc groupings of organisations in the interest of allowing for maximum diversity of representation within the given overall number of seats. The agenda of the meeting was adopted as proposed.

2. Update from the Commission about the development of the sectorial guidance documents

The Commission informed about the preparation of the sectorial guidance documents. The sectors to be addressed are the following: biotechnology, cosmetics, animal breeding, plant breeding, pharmaceuticals, bio-control, food and beverage. The contractor assisting the Commission in preparation of the guidance document had been selected, and the work on the project would start in the immediate future. The involvement of stakeholders – sector representatives as well as public-interest groups – is foreseen at several stages of the documents' preparation, and a dedicated workshop is planned for each of the sectors. Consultation with Member States authorities is also included in the work plan.

3. Overall objectives of the forum and rules of procedure

The Commission explained the overall objective of the Forum, which is to serve as a platform for exchange of information related to the implementation of the EU ABS Regulation between all interested parties (stakeholders, Member States' authorities, the Commission). In addition, the Forum should provide advice and expertise to the Commission in relation to the implementation of the ABS Regulation.

Prior to the meeting, the Commission had distributed draft rules of procedure, which were based on the standard rules of procedure for Commission expert groups. One amendment to the proposed text was approved by the members of the Forum. The rules of procedure were subsequently adopted.

4. Guidance document

In the remaining part of the time, the discussion in the Forum concentrated on the draft guidance document on the scope of the ABS Regulation, as prepared by the Commission with assistance of Member States' experts. A lot of comments and suggestions were gathered during the discussion.

On *temporal* and *geographical* scope, the following issues were raised, among others: applicability of the Regulation to access measures which have not been published on the ABS Clearing House; already existing access laws which might not be compliant with the Nagoya Protocol; potential direct applicability of the Protocol in some jurisdictions; the definition of "provider country"; digital information derived from genetic resources; differences in obligations between 2014 and 2015 deadlines as set up by the EU ABS Regulation; "transition situations" (suggestion to change the title of this section); limitation of the temporal scope at the end of utilisation (in particular in the context of plant breeding).

On *material* scope, some comments concerned specific examples given in the draft documents, while other comments related to the way "functional units of heredity" were conceptualised in the draft guidance. Inclusion of pre-commercial trials in the notion of utilisation and the due-diligence process in relation to research and development activities carried out on commodities were also raised as issues. Further discussion took place with regard to the section on derivatives (and more specifically the issue of chemical compounds) and sequencing data in public domain. In general it was felt that examples were very helpful although some members of the Forum claimed that specific examples may lead to confusion. It was agreed that representatives of different sectors will provide further examples of activities which fall within the notion of utilisation and outside of it.

On *due diligence*, many comments were raised concerning the ABS Clearing House. Other comments concerned liability vis-à-vis subsequent users, where some felt that the guidance document should not pronounce on the issue as it was not covered by public law, whereas others felt the concept should be better explained. Questions were raised also on transfers between entities of the same company and whether they would fall under Article 6(2)(d) of the Implementing Regulation; whether the notion of genetic resources covers also commercial (plant) varieties; and whether an internationally recognized certificate of compliance is personalised or generally applicable. It was suggested to consider inclusion of a flow chart in the section concerning due diligence, and many comments were received concerning specific wording in that section.

On selected *sector-specific* issues, questions concerned the relationship of the horizontal guidance with the future sectorial guidance documents. With regard to *health* issues, more specific criteria for the application of Article 4(8) of the EU ABS Regulation were called for. Other health issues raised relate to the on-going processes of exchanging pathogen samples in non-emergency situations, and to the criterion of intentionality of access. On genetic resources for *food and agriculture*, it was noted that only plant genetic resources were addressed in the document, and that animal breeding should be addressed in a separate, sector-specific guidance document. The relationship between the Nagoya Protocol and the UPOV Convention was also discussed, where some Forum members claimed that the plant breeders' exemption could be interpreted as a specialised international ABS instrument within the meaning of the Nagoya Protocol, whereas others claimed that the current text unjustly implied a hierarchy between different international legal instruments and a possible interference with patent law.

The Commission clarified the remainder of the *process for adoption* of the horizontal guidance document: the document will be re-drafted in the light of the comments received; subsequently it will be subject to consultation with other departments (DGs) of the Commission; and finally, it will be submitted to the College of Commissioners for adoption.

5. Information from Member States about the process of ratification of the Nagoya Protocol and implementation of the EU ABS Regulation

Some Member States informed about progress towards national ratification of the Protocol (UK, NL).

6. AOB

It was noted that it would be useful to have an overview of planned access legislation in the Member States. The Commission said it was ready to share such information if and when it had it at its disposal.

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