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Directorate F - Global Sustainable Development
ENV.F.3 - Multilateral Environmental Cooperation

MINUTES OF THE ABS CONSULTATION FORUM

2ND MEETING, 6 MARCH 2017

1. Welcome and adoption of the agenda

DG ENV's Director of Global Sustainable Development welcomed all participants. While the first meeting of the ABS Consultation Forum had focused on the horizontal guidance document on the scope and the core obligations of the EU ABS Regulation, the second meeting would focus on seven sectorial guidance documents. She also highlighted other ongoing efforts by the Commission (EC) to implement the EU ABS Regulation in an effective and proportionate manner. The agenda was adopted as it stood.

2. Update by the Commission on recent international developments and on the implementation of the EU ABS Regulation

The Nagoya Protocol COP-MOP2 had taken place in Cancun (Mexico) from 2 to 17 December 2016. For the first time, there were concurrent meetings of the Parties to Convention on Biological Diversity, the Nagoya Protocol and the Cartagena Protocol. Overlapping issues such as synthetic biology and digital sequence information benefited from the concurrent organization of the meetings. COP-MOP2 made 14 decisions, inter alia, on rules of procedure for the Compliance Committee, on a process towards criteria for the recognition of "specialised international ABS instruments", on digital sequence information, and on a potential global multilateral benefit sharing mechanism. As one of the follow-up measures, the EU and its Member States (MS) will have to work on coordinated input to the multilateral process on DSI.

3. Information about the process of ratification of the Nagoya Protocol and the implementation of the EU ABS Regulation

Fifteen MS are already Parties to the Nagoya Protocol, Malta recently ratified, and ratification processes are also on-going in several other MS. The implementation of the EU ABS Regulation is varying between different MS but in many cases lagging behind. "EU Pilots" have been addressed to MS non-compliant with the requirements of the EU ABS Regulation (in particular the duty to designate competent authorities and set up a penalty system).

Two additional guidance documents for "upstream" users (research institutions and collections) are foreseen. They will be developed following a process very similar to the one use for the drafting of sectorial guidance documents (establishment of drafting groups involving stakeholders, drafting process, organization of workshops, etc.). The workshops are envisaged to take place before the summer break.

The EU-wide IT tool DECLARE (for submitting due diligence declarations) is currently being tested and will be made fully operational soon. DECLARE will be linked with the ABS Clearing House, so that competent authorities can transmit relevant documentation via this system.

4. Update by the EC and the contractor on the development of the sectorial guidance documents

Updated guidance documents integrating the comments previously received were sent out on 10/02/17. Another revised version will be delivered to the EC by 31/03/17 and the contract of the consultant with regard to the sectorial documents will then be over. The EC together with the MS will continue to work on the guidance documents, most importantly on the unresolved issues and on the presentation of the guidance.

The intention is not to repeat in the sectorial guidance documents the clarification already provided in the horizontal guidance document. Some issues such as intent of use and the role of subcontractors are of horizontal nature (and hence potentially would be best placed in the horizontal guidance document). EC indicated that the form of the guidance document is not decided (it may be a consolidated document or seven sectorial ones). Some stakeholders stressed the importance of keeping the current formats (i.e. 7 sectorial documents).

5. Discussion on the draft sectorial guidance documents

The discussion was structured along the chapters of the sectorial guidance documents. Chapters 1 and 2 generated few comments and most of the discussion focused on the issues that had not been resolved (chapter 3). In addition to the issues already identified as unresolved (such as large-scale screening, cut-off point for obligations passed on to later generations for plant and animal breeding, human microbiome, sub-contracting etc.), some stakeholders drew attention to an apparent tension between various interpretations of "research and development" (in the horizontal guidance document and in the OECD's Frascati Manual, respectively), when applied to specific examples. It was stressed that a clear definition of research and development is needed.

It was also felt that the issue of derivatives deserved more attention in the guidance documents and that a coherent approach should be applied across the sectors. Some of the discussion concerned also the issue of modifications to a genetic resource which result in "synthetic" or "chemical derivatives". Many stakeholders argued that the products of such modification should be considered out of scope of the EU ABS Regulation, as they result from human intervention and chemical reactions, and that including them in the scope would broaden the scope of the Regulation significantly beyond its original intention.

With regard to regulatory tests, some participants claimed that, for the sake of legal certainty, guidance should result in putting regulatory tests within the scope of the Regulation, in a way which is not dependent on the result of the trial tests (as proposed in the current drafts). Others saw the tests as mostly out of scope of the Regulation or its applicability as being dependent on the results of the trial tests.

On large-scale screening, many arguments were raised against including such activities in the scope of the Regulation, mostly linked to the administrative burden that would otherwise result.

With regard to microbial organisms residing in or on humans, many participants declared that it should be considered out of scope of the Regulation, even if this meant that different interpretations were to be applied to pathogens and to (other parts of) the human microbiome.

On sub-contracting, all stakeholders agreed that the interpretation proposed in the draft biotechnology guidance document should be followed across the board. This interpretation requires however legal endorsement.

As for the cut-off point or plant and animal breeding, from the discussion it became apparent that the issue was not seen as a concern anymore. However, a representative of the plant-breeding sector drew attention to an additional challenge for the sector, namely the need to report in a due diligence declaration on numerous sources used in the development of a plant variety, and the resulting administrative burden. It was agreed that a separate meeting with plant breeding stakeholders would be organized in order to further discuss these matters.

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