



SUMMARY RECORD OF THE ABS CONSULTATION FORUM

3RD MEETING, 18 DECEMBER 2017

1. Welcome and adoption of the agenda

The Chair welcomed all participants and the agenda of the 3rd meeting of the ABS Consultation Forum was adopted as it stood.

2. Revision of the rules of procedure

Participants of the 3rd meeting of the ABS Consultation Forum approved an amendment to Article 2 of the Rules of Procedure concerning the composition of the Forum. The amendment establishes that any member of the Forum representing civil society and professional organisations that has neither attended any meetings nor provided any written comments for a period of three consequent meetings shall be deemed not to have sufficient interest to be part of the present Forum and may be excluded from it, after having had the opportunity explain itself.

3. Update by the Commission about DECLARE

The Commission informed stakeholders that since September 2017 the EU-wide IT tool DECLARE for submitting due diligence declarations (DDD) is available for the first checkpoint, i.e. for the DDD at the stage of receiving research funding, and that for the second checkpoint it should be made available in the 1st quarter of 2018. Each user of the system needs to register by requesting the Competent Authority (CA) in the country where the organisation is based to give him/her access. All information on designated CAs in the EU is available on the [Europa website](#).

4. Update by the contractor about the development of the draft guidance documents for upstream users

The contractor presented the state of play on the development of two additional guidance documents for upstream users: collection holders and public research institutions. The intent of these new guidance documents is to assist upstream users in identifying whether the EU ABS Regulation is applicable to their activities, and consequently help them to define their due diligence obligations. These documents complement the sectorial guidance drafts for downstream users and similarly were developed with the help of guidance drafting groups. The contractor provided an overview of the major features of collection holders and public research institutions with regard to ABS. In summary, while both groups of actors are upstream in the R&D chain, their attitude and knowledge of the ABS Regulation strongly differ. Several additional issues were identified as not yet resolved (i.e. status of laboratory strains, phylogenetic research, and the intentionality of access).

5. Update by the Commission about ongoing discussions on unresolved issues

EC reported about the discussions on unresolved issues in forthcoming guidance that were held with the Member States' experts in the course of 2017. For many issues (such as those concerning subcontractors, human biome and zoonotic diseases induced by human-originating viruses, routine modifications and tests, and keeping of documentation at the end of utilization) solutions had been found, for others (such as commercial varieties, animal breeding and pure taxonomy) the process was advanced and solutions were emerging. Some discussion was still required with regard to derivatives, and no common ground had yet been found between the Member States' experts on large scale screening. EC presented the summary for each of these issues.

6. Presentation on large scale screening from various sectors

Presentations on large scale screening (LSS) experiences were given by each of the following sectors: research, collections, pharmaceutical, animal breeding, biotechnology and food and feed, plant breeding, bio-control, cosmetics. Although each sector showed its specific features and needs when carrying out LSS, it was highlighted that there is a need to identify commonality. For most sectors it is necessary to have easy access to a large set of biological samples in order to assess what material will be further used and for which purpose, therefore the sector representatives saw it as important to identify a threshold or some criteria to limit the administrative burden.

7. Derivatives - chemical modification and the notion of continuum

The Consultation Forum decided to set up a small group to develop criteria concerning the applicability of the ABS Regulation to chemically modified derivatives. The group is asked to work on examples that will help assessing when chemical modification of derivative is of the kind that such derivative still remains in the scope of the Regulation, and when the derivative subject to such modification falls out of its scope. Various representatives of sectors present at the Forum volunteered to take part in this group.

The issue was also further discussed and a representative of the cosmetic sector gave a presentation focused on an index for quantification of chemical similarities. It was concluded that the task to measure biological and chemical characteristics at the same time is a challenging one.

On the notion of a continuum from genetic resource to derivative, a presentation was given on the International Chamber of Commerce's proposal about the way to address the issue. It was claimed that there needs to be a relation between the genetic resource and the derivative. The concept of "combined access" requires an ascertainable level of continuity between the R&D activities conducted on a derivative and the generation of the derivative from the genetic resource. Such continuity is expected to exist in cases where: the R&D activities conducted on a derivative form part of a research project covering the genetic resource and including the generation of the derivative; a user has generated the derivative or commissioned a third party to produce the derivative in a research collaboration or as a specific service (e.g. under a service agreement); the derivative is acquired from a third party together with PIC and MAT conditions that cover R&D activities on the derivative. Such continuity would not be expected to exist in cases where: the derivative is acquired from a third party as a product available on the market and it is transferred without PIC and MAT conditions that cover R&D activities on the derivative.

8. Update by the Commission about development of sectorial guidance documents: approach and way forward

The way forward on the draft guidance documents was discussed. EC suggested that, given many common elements in the various sectorial guidance documents as well as similar challenges, it might be better to prepare a single additional document (or at most two additional documents – one each for upstream users and downstream users), and potentially also revise the horizontal document with respect to issues where the interpretation needs to be adjusted or where further clarification is needed. Preparing one or two guidance documents focusing on main issues (and revising the horizontal guidance as needed) instead than 9 different documents would significantly speed up the process of their adoption.

8. A.O.B.

The next meetings of the ABS Consultation Forum will be organised in the first semester of 2018.

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