Stakeholder consultation on forthcoming Commission implementing measures under Articles 5, 7 and 8 of Regulation (EU) No 511/214 – ABS Regulation

Summary of modifications proposed for inclusion in the draft implementing act upon consideration of the comments provided by stakeholders

Regarding provisions implementing Article 7 of the ABS Regulation and the related Annexes

- Simplification of the declaration under Article 7(1) of the EU ABS Regulation;
- A definition of "funding" for the purpose of the relevant Article in the implementing act;
- A clarification in the definition of "placing on the Union market", so that placing on the Union market does not include pre-commercial trials;
- Deletion of the reference to filling in a declaration when a product was developed outside of the EU;
- Merging of the declarations for genetic resources and for traditional knowledge associated with genetic resources under both Article 7(1) and Article 7(2) of the ABS Regulation;
- For both Annexes concerning declarations, i.e. at the stage of receiving funding and at the final stage of development of the product (Annex A and C of the discussion paper):
    - An option to file one declaration for a number of genetic resources;
    - Modification of point 3 b) to take account of the situation that not the same person within the organization might be responsible for filling in the declaration and obtaining the access permit;
    - Provision for the possibility that there is access legislation in a country, but no prior informed consent is required for a given genetic resource;
    - Clarification of the scope of confidentiality under the Annexes.

Regarding provisions implementing Article 5 and 8 of the ABS Regulation and the related Annexes

- Addition of another verification possibility (whether the transfer of material has been done in compliance with conditions specified in mutually agreed terms);
- Deletion of the reference to "biological" distinctions when defining parts of collections;
- Modification of the table of categories of collections;
- Further clarification of the notion of "interested parties";
- Reflection of the need for "interested parties" to both have legitimate interest in the development of best practice and be somehow involved in the value chain;

- Specification of the timeframe for Commission action during the process of recognizing best practices;

- The need to motivate the Commission's decision when granting or withdrawing recognition as "best practice" was added;

- Replacement of the requirement to provide CVs of relevant personnel by the requirement to describe qualifications of the relevant personnel.

Some other comments, having been carefully considered, are not proposed for inclusion in the draft implementing act, mostly in view of the existing provisions of the EU ABS Regulation.

- As for the call for simplifying the requirements concerning registered collections, these requirements stem from Article 5(3) of the Regulation and as such cannot be modified in an implementing act;

- The notion of "result of utilisation" will be subject to further clarification in a guidance document;

- While proposed the language the overseeing of best practices has been modified, the overseeing function as such is kept in the Commission's proposal, given the provisions of the Regulation;

- The Commission's decision to grant or withdraw recognition as "best practice" can be appealed; however, no specific internal administrative review procedure is put in place, which could have been considered;

- The requirement to pass on relevant information to subsequent users cannot be waived, given that it stems from Article 4 of the EU ABS Regulation;

- The calls for making the applications and documents under Article 8 (Best practices) publicly available by default and for ensuring data protection of information gathered under Article 8 have not been specifically addressed, access to these documents being subject to general rules under Regulation (EU) No 1049/2001 on access to documents;

- The call to define (narrowly) the scope of changes made to a best practice of which an applicant needs to inform the Commission has not been followed, given the language of Article 8(3) of the EU ABS Regulation ("any changes or updates made to a best practice for which recognition was granted");

- The call for clarification on where the declaration is to be made, if a product is placed on the market in more than one Member State, has not been specifically addressed, as the users are free to choose;

- The call to provide for a "zero option" (i.e. submitting a declaration merely stating that the Regulation does not apply to the case at hand) has not been followed, as there is no need to file the declaration in case the Regulation is not applicable – in other words, the declaration cannot cover situations which are not covered by the EU ABS Regulation;

- The call to provide a definition of "collection" has not been followed, as the definition is provided for in Article 3 of the EU ABS Regulation;

- The call to provide for inclusion of international collections or collections outside of the EU under the registered collections has not been followed, given the provisions of the EU ABS Regulation; this is a point worth looking at when the EU ABS Regulation comes up for its scheduled review (Article 16);

- The call to exclude private research funding has not been followed, given the language of the EU ABS Regulation which reflects the agreement reached on this point in the co-decision process between the co-legislators.