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

Summary of written comments submitted further to
the stakeholder meeting held on 9 December 2014

Horizontal issues

Many submissions underline stakeholders' commitment to the objectives of the Convention on Biological Diversity and its Nagoya Protocol, and to an effective implementation of the ABS Regulation. However, some are afraid that implementation of the Regulation might make biodiversity-related research – in particular if researchers from several different (including non-EU) countries are involved – more difficult, and thus run counter to relevant provisions of the Protocol itself (in particular Art. 8(a)). Some also have more general concerns that not all actors potentially concerned by implementing measures would have the necessary organisational capacities to carry them out as foreseen.

Virtually all stakeholders underline the need for legal certainty, and in particular for a clear understanding of key legal terms to be developed. This is needed also to clearly delineate the scope of application of the ABS Regulation. As regards utilisation of genetic resources outside of the EU, most stakeholders are either sceptical about or firmly opposed to this being covered by implementing measures, which in that case are seen as difficult to enforce and as lacking a legal basis in the Nagoya Protocol or the ABS Regulation.

Another horizontal concern is about the confidentiality of information requested, be it from users at the different checkpoints or from associations applying for recognition of best practices. Meanwhile other stakeholders argue for declarations of confidentiality to be accepted only under strict conditions, so as to reduce the danger that they might be abused.

Register of collections (Art. 5 ABS Regulation)

Stakeholders from both industry and public research institutions stress the need for the system of registration to be set up in a way which makes it attractive for collections. Some question that such attractiveness could be achieved in practice, in particular for smaller institutions and non-commercial collections. Many holders of collections appear to doubt that the effort necessary for meeting the criteria of registration – and the payment of fees which might be charged by national authorities in that context – would pay off for them. At the same time, for botanic gardens in particular, existing codes of conduct are identified which resemble the criteria of registration and as such should help reduce the costs for institutions applying those codes.

With regard to checks on collections to be performed by national competent authorities, there is disagreement on the extent to which those should be determined in the Commission implementing act, rather than being left at the discretion of national authorities. There is also some disagreement on the appropriate frequency of checks and on the need for defining time limits for follow-up to substantiated concerns about compliance.

Stakeholders also see a need to re-arrange the categories used to differentiate between types of collections (p. 3 of the discussion paper), to bring them closer to established scientific practice.

Due-diligence declaration on receipt of research funding (Art. 7.1)

In line with general comments on the need for conceptual clarity, stakeholders argue that the notion of "funding" needs to be further developed. Many would prefer private sources

of funding to be excluded from the application of these provisions. Alternatively, if private funding were not excluded in general, stakeholders see the need to clarify which types of funding are covered, and to exclude e.g. support from one part of a company or institution to research done in another part.

They also point out that it might not always make sense to request the declaration at the point in time when research funding is first received, for it might become clear only at a later stage whether genetic resources are actually utilised within the project funded. It is also suggested to provide for a single declaration to be made covering a number of genetic resources included in a given sample or covered by a given permit.

More fundamentally, several stakeholders argue that it should be enough for receipients of funding to declare *that* they exercise due diligence where required by the Regulation, rather than requesting them to provide information on *how* they are doing this. Alternatively, some argue that the annex requesting such information should be significantly simplified, also compared to the more extensive information requirements under Art. 7.2 of the Regulation. The need to have separate annexes for genetic resources and for traditional knowledge associated with genetic resources is questioned.

Due-diligence declaration at the stage of final development of a product (Art. 7.2)

Many stakeholders emphasise the need for sector-specific definitions or guidance on what exactly is meant by the "stage of final development". Pre-commercial trials, it is argued, should not be covered by this provision. For products which are simultaneously placed on the market in several Member States, a single declaration ought to be enough. Where Art. 7.2 refers to "a product developed via the utilisation of genetic resources", some stakeholders see a need for the necessary minimum link between the genetic resource and the product to be specified further. The notion of the "result of utilisation" is also perceived as somewhat ambiguous, and there is a proposal for addressing more comprehensively the case where users of genetic resources to do not themselves commercialise the results but transfer those results to others for commercialisation.

Best practices (Art. 8)

Comments concern, firstly, the role of associations of users in the process of identifying and maintaining best practices. Several stakeholders question whether associations can realistically be expected to fulfil monitoring or oversight functions, rather than only giving guidance to their members. Others warn that without any oversight, individual users may or may not actually follow the association's guidance. The notion of "interested parties" in this context is seen as needing further specification and more restrictive application.

Suggestions are made also on provisions regarding the process for (withdrawal of) recognition as best practice, with a view to making this process transparent, predictable and effective. There is a call for including minimum substantive criteria for recognition in the implementing act. On the other hand, several stakeholders say that information requested from associations on changes or updates to recognised best pratices should be rather limited. For some smaller or more loosely organised associations the process might generally be too burdensome, it is argued. There is also a constructive proposal on how existing industry standards and guidelines in specific sector could be tapped into for the purpose of implementing the Regulation.