9 January 2014

COMMENTS

IMPLEMENTING ACTS / REGULATION (EU) NO. 511/2014 ON COMPLIANCE MEASURES FOR USERS FROM THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILISATION IN THE UNION

Introductory remarks

The above organisations, representing thousands of companies across different industry sectors, from SMEs to multinationals, fully support the objectives of the Convention on Biological Diversity ("CBD") and of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation ("Protocol") and therefore welcomes its implementation in the EU. We however believe that a number of challenges and areas of uncertainty remain and currently prevent an effective, consistent and beneficial implementation of this Regulation, including with regards to the burden and costs of such implementation. The Implementing Acts foreseen for articles 5, 7 and 8 should address some of these issues and provide the necessary legal and practical clarification in their regard.

A broad range of actors in the Union, including both non-commercial and commercial entities, utilise genetic resources, i.e. conduct research and development on the genetic and/or biochemical composition in the development of new products. It is therefore critical to set out a clear and sound framework for implementing the Regulation, which would not undermine the opportunities available and rather support the conduct of research & development activities on genetic resources in the EU. To that purpose, sufficient legal certainty must be provided to the different users as to the application in practice of the Regulation. Further, the Regulation must be implemented so as to strike an appropriate balance between the objectives of the Protocol and the burden put on users.

We therefore outline in the following paper a number of points which we consider should be addressed and/or clarified in the Implementing Acts based on the Discussion Paper circulated for the Stakeholders Meeting of 9 December 2014 as well as in its annexes so as to ensure an effective and balanced implementation of the EU Regulation.

To achieve this objective, we stand ready to continue this dialogue and to further support the Commission in developing these Implementing Acts. We urge the Commission to keep on involving stakeholders throughout the process of drafting these Acts.

We will separately provide a paper describing other aspects of the Regulation on which guidance is sought so as to enable the Regulation to achieve its objectives.

VOLUNTARY TOOLS TO ASSIST COMPLIANCE

Articles 5 and 8 of the basic Regulation provide for voluntary tools to assist users in complying with their due diligence obligation, i.e. registered collections and best practices. We overall support these concepts, which should allow users to be compliant with the Regulation requirements at a limited burden and cost.

REGISTERED COLLECTIONS (Article 5)

The concept of registered collection poses a number of legal and practical challenges, which collections are more competent to discuss. We would only flag the importance to make this option practical and meaningful for collections and for users. The requirements imposed on collections to be registered should not be so burdensome so as to dis-incentivise or even make it impossible for any collection to be registered. Furthermore, the conditions should remain attractive also for users of such collections.

BEST PRACTICES (Article 8)

We support the concept of best practices, which we believe will foster sectoral compliance. The procedure laid out for the recognition of best practices should however be accessible and flexible enough so as not to exclude any association of users of involved sectors. We note that the basic Regulation defines best practices as "a combination of procedures, tools or mechanisms" which "enables that user to comply with its obligations". To that purpose, overseeing functions should be understood as a guiding rather than monitoring function.

In this respect, we are concerned with the definition in the Regulation (Article 3.10) of 'association of users', which refers to overseeing functions and how these latter seem to be characterised in the Discussion Paper. We believe that it is likely that few associations of users have powers to oversee the activities of their members. We understand the nature and extent of these functions is not to be addressed in the Implementing Acts and should as a consequence be clarified in the Guidance document to be adopted by the Commission. In order for this Article to be effective, we therefore believe that the concept of overseeing function should be widely construed and critically should not require any in-house monitoring function from users' associations.

We suggest that the Implementing Acts precisely define the different steps of the procedure and the timelines associated with each step. In particular, the Commission should have to make its decision to grant recognition as best practice within a defined timeframe. Besides, in cases where a "Best Practice" is not recognized or withdrawn, the Implementing Act should explicitly mention that the Commission has the duty to motivate its decision and should also explicitly refer to the possibility to appeal the decision of the Commission (p. 8, l. 29).

In addition, we note that "other interested parties" are also entitled to adopt best practices, provided they have a legitimate interest in the subject matter of the basic Regulation or they access, collect, transfer or commercialise genetic resources (p. 7, l. 18-21). We are concerned that the first condition is too vague and suggest that both criteria are cumulative. In addition, any interested party should be representative of the sector for which it intends to adopt best practices.

Finally, we believe that what constitutes "any changes or updates" to a best practice needs to be clarified, so as not to create a notification burden for both users' associations and nor a flow of irrelevant notifications to the Commission. Similarly, with regard to potential deficiencies in best practices (p.9, l. 11), we think it is of key importance that the Commission only act upon information if it is '*substantiated*' information. If any type of information can trigger revisions, whether or not substantiated or supported by evidence, the concept of best practices would be undermined and the administration for Competent Authorities, the Commission and applicants would become very burdensome.

MONITORING USER COMPLIANCE (Article 7)

Article 7 provides for two different checkpoints in time at which the declaration of due diligence should be submitted: at the stage of research funding (§1) and at the stage of final development (§2).
We would like to flag a few areas where clarification of the implementing acts would be needed.

Due diligence declaration at the stage of research funding (para. 1)

The Commission's Proposal did only refer to public research funding and therefore implied that each user would only be likely to make one declaration depending on the academic or commercial nature of its activities: either at the stage of research funding or at the stage of commercialisation. The consequences of the current Regulation are relatively unclear, as any entity – be it a public institution or a private company – may be considered as a "recipient of research funding". To ensure the scope of paragraph 1 is fully understood by users, we believe that the concept of "research funding" should be further clarified.

The Discussion Paper assumes that private funding is within the scope of Article 7, rather than only public funding. The Implementing Acts explicitly acknowledge the burden represented by the filing of a declaration and provide that it should only have to be done once. Extending the scope of the requirement to private funding significantly increases the regulatory burden imposed by the Regulation. We believe that the Implementing Acts should restrict the applicability of paragraph 1 to recipients of public research funding.

Should the Commission however decide otherwise, we believe that the Implementing Act should clarify the nature of private funding which is to be captured in the scope of this paragraph, especially to clarify that intra-company financing schemes are not meant to be included.

We welcome the precision as to which national authority should receive the declaration and that such declarations only concern funding for research activities involving genetic resources.

Due diligence declaration at the stage of final development of a product (para. 2)

Competent authorities monitor users' compliance relying on the provision by the latter of a declaration of compliance "at the stage of final development of a product developed via the utilization of genetic resources" as far as commercial entities are concerned, which stage shall be defined by the Commission for different sectors in the Implementing Acts to be adopted as explicitly provided by Article 7.6 of the Regulation.

First, a declaration should only be made for products developed by utilising genetic resources within the scope of the Regulation. The burden of proving that the Regulation applies to a particular genetic resource should lie with the enforcing authority; it is not for any party utilising the genetic resource to prove that it does not apply.
.

The Implementing Acts should also define which authority is competent in different scenarios. For cases where the declaration is to be filed upon application for a marketing authorization, the Implementing Acts should also foresee simplified declaration procedures depending on the different sectorial regulatory procedures, for instance when a centralised marketing authorisation is sought for a product or where a product is to be placed on several markets. A criterion to designate only one competent authority in such situations should be identified. (p.6, l.3-4)

We appreciate the Commission's intention to clarify the definition of "placing on the Union market" but we think this notion requires further clarification by the Commission, especially since different sectors all face very different situations. Various cases in every sector should therefore be carefully assessed.

Finally, the basic Regulation alternatively uses "product deriving from the utilisation of a genetic resource" or "product developed via the utilisation of genetic resources". It is therefore critical that guidance is provided to establish a common understanding and define the exact nexus required between the final product and the genetic resource. We suggest that the minimum link required between a genetic resource and a product to justify a declaration needs to be clarified, as well as the difference between "product deriving from the utilisation of a genetic resource" or "product developed via the utilisation of genetic resources".

Signatories:

AESGP - Association of the European Self-Medication Industry
Cosmetics Europe – The Personal Care Association
EFPIA – European Federation of Pharmaceutical Industries and Associations
EuropaBio – The European Association for Bioindustries
ESA – European Seeds Association
Zentralverband Gartenbau e.V.- German Horticultural Association