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European Federation of Pharmaceutical Industries and Associations

EFPIA COMMENTS ON THE DRAFT IMPLEMENTING REGULATION LAYING DOWN RULES FOR THE IMPLEMENTATION OF REGULATION (EU) NO. 511/2014

Introductory Remarks

EFPIA fully supports the objectives of the Convention on Biological Diversity and of the Nagoya Protocol, which determines how and according to which terms users should access and use genetic resources. We are however extremely concerned that EU Regulation No. 511/2014, designed to implement the Nagoya Protocol, may have unforeseen negative effects, including onerous, excessive and disproportionate administrative and transaction costs placed on innovators. The number of challenges the Regulation poses and the significant uncertainty it creates could prevent its effective implementation and thereby impede European innovation and legitimate trade.

A more flexible, low-cost concept of due diligence is urgently needed to support implementation of the Regulation. Specifically, Recital 9 of the Implementing Regulation must be redrafted to reflect the complexities of GR utilisation in the EU.

As a broad range of actors in the Union, including commercial and non-commercial entities, conduct research and development (R&D) on genetic resources, the concerns set out in this paper will undoubtedly be broadly shared by the innovative community.

The Promise of a Low Cost & Flexible Approach

The primary obligation for users of genetic resources under the Regulation is to conduct "due diligence". The Commission Q&A provides that "*The flexibility of the due diligence concept should allow users to tailor due diligence measures to existing best practices, thereby lowering costs*."

It was clearly intended that the due diligence process would be flexible and low-cost, a concept which as users, we support. We assume that the legislator knew that genetic resources used within the EU are obtained from many different countries, many of which are outside of the EU. They are rarely obtained directly by the users utilising them from the country in which they originated. The person who initially accesses them may not know or intend that they will ultimately be used in the EU. They will often have been traded through various parties and various countries before the user wishing to utilise them in the EU acquires it. The Regulation was presumably intended to address the commercial reality reflected in these complex transactions chains in an appropriately flexible and low cost way.

The Reality on Offer – A burdensome and costly approach

However, the draft Implementing Regulation (Recitals 6-9) indicates that the Commission sees the Regulation very differently. In its view, unless a user obtains a genetic resource from registered collections (which do not exist) or has an internationally-recognised certificate of compliance (which does not exist), he must obtain all the information described in Art 4.3. If he does not do so, he must obtain an access permit and establish mutually agreed terms.

However, in many cases the information described in Art 4.3 will not exist. Unless the person who initially accesses the genetic resource knows that it will be utilised in the EU, he is unlikely to have or be able to obtain all the documentation that a person ultimately utilising in the EU will need in order to satisfy the due diligence obligation of the Regulation.

Any person utilising a GR without this information will be liable to effective, proportionate and dissuasive penalties.

Any person wishing to conduct R&D on a genetic resource, for example a piece of fruit purchased from a supermarket, will have to determine first whether the Regulation applies and, if it does, comply with the due diligence obligation. This means that a user must consider each of the questions described in Annex 1**.**

Far from being a low cost, flexible approach, the view the Commission appears to take of due diligence means the Regulation imposes inflexible and burdensome requirements which may be impossible to satisfy in many cases. It is clearly disproportionate to the objectives the Regulation seeks to achieve.

Further, if this approach is correct, the Regulation will seriously impede lawful trade in genetic resources, even where they are traded as commodities, as well as investments in R&D and ultimately, innovation in the EU.

Recital 9 of the Implementing Regulation should be amended along the following lines to more accurately reflect the flexible, low-cost concept of due diligence clearly intended by the Regulation.

> (9) Accordingly, only users who have not obtained genetic resources from registered collections, or who do not possess an internationally-recognised certificate of compliance, or a standard material transfer agreement, should be required to provide the detailed information referred to in Article 4(3)(b) of Regulation (EU) No511/2014 in their due diligence declaration. ***In the event that such users are unable to provide all the information referred to in Article 4(3)(b), they will be considered by the Competent Authority to have exercised due diligence under Article 4(1) if they can demonstrate they have taken reasonable steps to verify that the genetic resources do not fall within the Regulation or that, if they do, they are not illegally accessed genetic resources and that their use complies with any applicable mutually agreed terms.***

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ANNEX 1

PROCESS REQUIRED TO ENSURE COMPLIANCE WITH THE REGULATION

As per the Impact Assessment conducted, it was intended that the due diligence process would be flexible and low-cost. However, the legislation appears not to have achieved this objective and to impose burdensome and disproportionate requirements upon users.

It is our understanding that any person wishing to conduct R&D on the genetic or biochemical composition of a genetic resource must follow these steps:

1. STEPS TO DETERMINE WHETHER THE REGULATION APPLIES TO THE GR

Check whether the GR was accessed from the country of origin or at some point in case of a complex transaction chain before 12 October 2014 (this information may not be available)?

- If yes, free of Regulation obligations
- If no or if not clear (i.e. no certainty as to whether Regulation applies) , go to next step

Check from which country of origin was the GR accessed (this information may not be available)?

- A non-Party to the Protocol at the time of access - freedom to use free of Regulation obligations
- A Party to the Protocol at the time of access or if information not available (i.e. no certainty as to whether Regulation applies) , go to next step

Check whether the Party had applicable ABS legislation or regulatory requirements at the time of access?

- If no, freedom to use free of Regulation obligations (but if it not clear, assume Regulation applies or risk penalties if it turns out that it does)
- If yes[1], Art of the Regulation applies - go to next step

2. STEPS TO ENSURE COMPLIANCE WITH THE OBLIGATION OF ARTICLE 4?[2]

Check whether there is an internationally recognised certificate of compliance? This does not exist at present so the obligation of Article 4 cannot be met by having one

Check whether the GR obtained from a registered collection?[3] If yes, obligation satisfied. If no, see next bullet

Check whether there is information and relevant documentation on the 6 items listed on Art 4.3(b)?[4]

- If no, obtain access permit and establish mutually agreed terms (MAT) or discontinue utilisation
- If yes, is it “insufficient” or do any uncertainties as to legality of access and utilisation persist
    - If no, proceed/continue utilisation in accordance with permit and/or MAT
    - If yes, obtain access permit and establish MAT or discontinue utilisation.

[1] Under the Protocol, any such legislation or regulation should be available in the ABS clearing house. However, if it is not, that does not mean the Regulation is not applied

[2] This does not include steps needed to determine whether Art 4.8 applies.

[3] As registered collections are all in the EU, this will not apply to any GR accessed outside the EU

[4] In order to satisfy the general due diligence obligation of Art 4.1, it appears that having this information and documentation is required in all cases other than where there is no international certificate of compliance or the GR was not obtained from a registered collection.