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European Federation of Pharmaceutical Industries and Associations

NEED FOR URGENT GUIDANCE RELATING TO 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 EU

Introductory Remarks

There are many important aspects of the Regulation that are unclear including the scope of its fundamental due diligence obligation. These create uncertainty for EU users as to what they may and may not do in their efforts to innovate through R&D. In cases of failure to comply with the unclear obligations in the Regulation, Member States shall ensure that apply "*effective, proportionate and dissuasive*" penalties are applied. It is a fundamental principle of justice that, before being exposed to such penalties, the underlying obligations to be met should be clear. However, without clarification of the Regulation's fundamental obligations, users affected by this Regulation are not afforded the necessary legal certainty to conduct research and business in the EU. Inevitably, the lack of guidance will have a chilling effect on innovation in the EU in areas involving natural products.

Though the need for clarification is admittedly acknowledged in the Q&A[1] published by the Commission – "*The issues for which guidance is needed will be discussed in the Consultation Forum, which will be convened in the third quarter of 2015, once the Implementing Regulation is adopted*." – these timelines are neither appropriate nor acceptable. The Regulation applies to genetic resources that are being acquired now and the obligations of Article 4, which are among the most important requiring clarification, will apply from October 2015. Meanwhile, Member States are in the process of implementing the Regulation in national laws and will have obligations to enforce the Regulation from October 2015.

It is therefore imperative that a clear and sound framework is established for implementing the Regulation, which supports – and does not inadvertently undermine – the conduct of R&D activities on genetic resources in the EU, and that well in advance of the imminent October deadline in order to make the necessary preparations.

This paper sets out a number of related issues that should be considered and clarified, either by the Commission or by Member States.

➢ ISSUES TO BE CLARIFIED BY THE EUROPEAN COMMISSION

• ON SCOPE (Article 2)

1. In cases where the genetic resource is acquired in the country of origin and transits through different countries and is accessed by various parties in the transaction chain in some or all of them, under the Regulation do the laws of each of these countries or only of the country of origin have to be complied with?
2. If a human being or an animal is infected with a pathogen in one country (the country of origin) and moves to another where the pathogen is extracted for research, under the Regulation does the user have any obligations, whether of due diligence or otherwise, in respect of the law of the country of origin and which country this would be?
3. Some have argued that if someone publishes information concerning the genetic or biochemical composition of a genetic resource to which the Regulation applies, a third party who wishes to use that information but does not have physical access to the

[1] Available at http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Q_As_on_ABS.pdf.

genetic resource has obligations under the Regulation. This would mean controlling use of information that is in the public domain and would have ramifications which stretch far beyond the Nagoya Protocol. The Commission should confirm that the Regulation does not control use of, or create any obligations relating to, such information.

4. Does the Regulation apply to genetic resources used as research tools and if yes, why?
5. Does the Regulation apply if only the manufacturing, but no R&D, takes place in the EU? If so, which Articles apply and please explain why?
6. Does the Regulation apply to material isolated from a genetic resource without any research efforts but on the basis of known procedures?

- **ON THE FRAMEWORK FOR PATHOGENS (ARTICLE 4.8)**

1. Who makes the decision whether a situation described in Article 4.8 exists? Is it an EU institution, the authorities of the Member State(s) in which utilisation occurs, the user or someone else?
2. Please clarify the meaning of the words "no exclusive rights of any kind will be claimed by such user to any developments made via the use of such pathogens" in Article 4.8. Please confirm that this prohibition does not apply where pathogens are used in a situation other than that described in Article 4.8.

➢ ISSUES TO BE CONSIDERED BY MEMBER STATES

Besides the areas where clarification and guidance from the Commission are critically needed, our organisations would further urge Member States to consider a number of issues while adopting the necessary implementing measures at national level.

- **COMPETENT AUTHORITIES AND FOCAL POINT (Article 6)**

In order to establish a simple and efficient system, we suggest Member States designate only one competent authority to deal with the requirements under the Regulation. In addition, where the utilisation takes place in several EU Member States, only one authority should be competent. The Commission should establish criteria to determine which authority that should be.

- **CHECKS ON USER COMPLIANCE (Article 9)**

Member States should provide detailed procedures on how they will perform checks on user compliance. For instance, on-the-spot checks should generally be subject to judicial control. If compliance authorities are to be granted rights of entry with notice to the user, the circumstances when this may be permitted should be precisely defined and advance permission from the court should be required. Users should have rights to challenge the grant of such permission.

- **PENALTIES (Article 11)**

Member States shall also decide on penalties applicable to infringements of Articles 4 and 7: these shall be effective, proportionate and dissuasive. Insofar as many of the obligations identified in the Regulation are unclear, we suggest penalties should be progressive and flexible enough to foster corrective actions by users and ultimately, compliance. For that same reason, we also urge Member States to clearly limit criminal sanctions, if considered at all, to cases of intentional failure to comply with all the obligations provided for in the Regulation. Finally, detailed procedures for ordering penalties, including appeal procedures, should be provided for by Member States.

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