Forum Umwelt und Entwicklung

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To whom it may concern,

Please find attached our comments concerning the proposed Implementing Act on Regulation (EU) No 511/2014.

Yours sincerely,

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Comments on the proposed Implementing Act on Regulation (EU) No 511/2014

1) MONITORING USER COMPLIANCE

The Regulation (EU) No 511/2014 of the European Parliament and of the Council (hereafter referred to as 'the Regulation') in its Article 3.4 defines the 'user' of genetic resources (GR) and traditional knowledge associated with genetic resources (ATK) as any natural or legal person that utilizes GR and ATK. Furthermore the Regulation in its Article 3.5 defines utilization of GR as 'conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.'

Article 7 of the Regulation deals with 'Monitoring User Compliance' and in Article 7.2 the Regulation details the nature of compliance obligations of users of GR and ATK as:

> At the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4 and shall simultaneously submit:
> (a) the relevant information from the internationally-recognised certificate of compliance; or
> (b) the related information as referred to in Article 4(3)(b)(i)-(v) and Article 4(5), including information that mutually agreed terms were established, where applicable.

Users shall further provide evidence to the competent authority upon request.

On a reading of Articles 3.4 and 3.5 along with Article 7.2, it is clear that the obligation of 'declaration of compliance' rests prima facie upon those who utilize GR and ATK (utilization as defined under Article 3.5) and not on those who would commercialize or profit from the results of the utilization of GR and ATK (hereafter referred to as commercializers) if they happen to be different from the users. This obligation to declare compliance exclusively on users and not extending it to commercializers causes certain challenges in establishing checkpoints for compliance with the Regulation since in many cases the users and commercializers will not be the same natural or legal person or entity.

The proposed Implementing Act on the Regulation (hereafter referred to as the Implementing Act) seeks to address this difficulty not altogether successfully. In this comment we will show how this difficulty is addressed in the Implementing Act, its limitations and propose specific solutions to overcome this difficulty effectively.

The Discussion Paper on the proposed Implementing Act identifies specific events on the occurrence of which declarations of compliance with the Regulation would have to be made to the Competent Authorities by users. These specific events act as checkpoints and occur when any of the following activities are undertaken for the first time by users:

(a) market approval is sought for a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources;
(b) a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources;
(c) placing for the first time on the Union market a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources, for which no market approval or notification is required;

Now the need for the user to make a declaration of compliance to the Competent Authority on the first occurrence of events (a), (b) or (c) are significant steps to ensure compliance in the Union. However they beg the question regarding what happens in a very likely situation where the user is not the commercializer, but merely transfers the results of the utilization to the latter in the Union who introduces the product into markets in the Union. In order to address this situation, the proposed Implementing Act includes event (d)

(d) the result of the utilisation is sold or in any other form transferred to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

However, unlike events like (a), (b) and (c) which are materially verifiable and hence useful checkpoints, event (d) is nearly impossible to monitor as they are not regulatory requirements or publicly visible events and hence leaves a significant gap in the Union's ability to monitor compliance under the Regulations.

Another significant gap in monitoring compliance occurs when both the user and the commercializer are not within the Union. Instead a natural or a legal person within the Union sources the product based on a result of utilization from a commercializer outside the Union. This begs the question regarding how the Union will monitor compliance of natural and legal persons operating in the Union who trade or transfer results of utilization of GR and ATK sourced from commercializers outside the Union.

Solution:

The solution we would propose to address both these gaps is a rewording of (d) to state:

(d) *A declaration of compliance with Article 4 of the Regulation should be provided by the user* when the result of the utilisation is sold or in any other form transferred to a natural or legal person ~~within the Union~~ in order for that person to carry out one of the activities referred to in points (a), (b) and (c). *At the first occurrence of any of the activities referred to in points (a), (b) or (c), the aforementioned natural or legal person will submit the declaration by the user to the Competent Authority.* (Sentence in italics is our addition)

Additional compliance gap:

Important ways in which products based on GR and ATK are commercialized are through sales via Internet. These products would be placed in the Union market, albeit virtually, for direct purchase by consumers within the Union. This loophole not only circumvents efforts to ensure compliance with the Regulation in the Union, but also disadvantages and thereby creates perverse incentives for users and commercializers who comply with the Regulation.

Lines 24 and 25 of page 6 of the Discussion Paper on the draft Implementing Act state: "Where the utilisation has taken place outside of the Union, the declaration is to be made to the competent authority of the Member State through which the product enters the Union."

We understand these lines as a possible effort to address the aforementioned challenge of monitoring compliance of products based on utilization of GR and ATK, which enter the Union via Internet sales. We however would suggest greater clarity in the draft Implementing Act regarding the natural or legal entity tasked with presenting the declaration to the competent authority of the Member State through which the product enters the Union. Would this entity be for e.g. the utilizer, the vendor or the postal service or courier company?

2) CONFIDENTIALITY

The Annexes to the draft Implementing Act provide templates for the declarations to be made to the Competent Authority by recipients of funding or at the final stage of development of products based on GR or ATK. Where the GR or ATK has an internationally recognized certificate of compliance or the GR is a non Annex 1 PGRFA under an SMTA or the GR is secured via registered collection, relevant information for identification should be provided. However when neither of the aforementioned three situations exist, then the following information should be provided: i) Date of access ii) Place of access iii) Person or entity granting PIC iv) Unique identifier of access permit where available v) Description of GR or ATK or unique identifier vi) Source from where the GR or ATK was obtained and vii) Subsequent users.

What is surprising is that the entity providing this information has the blanket option to require that this information is kept confidential after providing reasons for such confidentiality. The sentence in the Annex referring to this states:

> If the information provided is confidential, please provide the information nonetheless, but tick the respective box to mark it, and provide the justification for confidentiality.

While the entity providing this information may have several reasons to require confidentiality, its power to withhold critical information regarding the legitimacy of access from public scrutiny by providing a subjective justification is highly problematic. Article 7.5 of the Regulation is clear that the only justification for withholding such information is when a Union or national law to secure a legitimate economic interest provides for such a right to confidentiality. Arbitrary or subjective reasons based on which the public scrutiny of

access information is stymied will in the long run undermine compliance with the Regulation. This is because the Competent Authority by itself will not have the capacity to judge the veracity of every declaration.

It is highly likely that fraudulent declarations would be brought to the attention of Competent Authorities in the Union by vigilant and concerned groups or individuals or by those directly affected by the fraud. Blanket confidentiality based on subjective reasons that have nothing to do with protecting legitimate economic interests will deny access to information for concerned and affected groups and individuals. We submit that such blanket provisions will adversely affect the Regulation's ability to create a transparent and efficient compliance system and will stand in violation of Article 7.5 of the Regulation.

Solution:

We propose that the following changes in the Annex templates to the draft Implementing Act-

The sentence:

"If the information provided is confidential, please provide the information nonetheless, but tick the respective box to mark it, and provide the justification for confidentiality."

Has to be changed to:

"If the information provided is confidential, please provide the information nonetheless, but tick the respective box to mark it. *Please note that it is only possible to justify confidentiality where Union or national law to protect a legitimate economic interest provides for such confidentiality. If this is the case please reference the corresponding law."*

The sentence:

"If you have declared above, that some information is confidential, please state the reasons for each piece of information for which you have declared confidentiality applies."

Has to be changed to:

"If you have declared above, that some information is confidential, please state the reasons for each piece of information for which you have declared confidentiality applies. *Please note that it is only possible to justify confidentiality where Union or national law to protect a legitimate economic interest provides for such confidentiality. If this is the case please also reference in each case the corresponding law*."

3) REGISTER OF COLLECTIONS

The draft Implementing Act lists the documentation to be submitted by a collection seeking to become a registered collection. These documents detail information about the collection including the type of collection, contact information including information that enable the Competent Authority to verify whether the collection is capable of meeting the requirements of Article 5.3 of the Regulation.

Suggestions:

i) We urge that these documents demonstrating the capacity of a collection to comply with the requirements of Article 5.3 are published and are publicly accessible in the internet-based register. This would not only enable public scrutiny and transparency but also enable providers and users of GR to choose the collection meets their standards of excellence among registered collections that meet the basic requirements of Article 5.3. We hope that this would in the long run encourage greater efforts towards best practice and quality service among registered collections rather than the collections limiting themselves to just complying with the basic requirements of the Regulation and Implementing Act.

ii) The draft Implementing Act requires Competent Authorities to carry out the verification of compliance by registered collections with Article 5(4) of the Regulation at least once every three years. Where there are substantiated concerns that a registered collection does not meet the criteria set out in Article 5(3) of the basic Regulation, the competent authority will have to carry out additional verification. While the once every three years verification is infrequent to say the least, we would urge that once it is clear that there are substantiated concerns of non-compliance, the additional verification has to be performed *immediately* without any further delay to prevent possible on-going violation of the Regulation. We would go so far as to suggest that the Implementing Act include a specific timeframe for additional verification (e.g. 2 months), since both users and providers would need to know at the earliest whether they could still trust the collection.

iii) For the additional verification to be effective, proportionate and capable of detecting cases of non-compliance with Article 5(3) of the Regulation, the draft Implementing Act suggests a list of measures. We suggest that a verification of the MTAs with provider countries is also included in this additional verification along with where relevant interviews with the providers of GR.

iv) An important but open question is what happens with the utilization of GR, which was based on an access through a trusted collection that has finally (after concerns raised and an additional verification) been declared as non-compliant with Article 5.3 of the Regulation. Has the user still fulfilled it's due diligence requirement? What kind of remedy does the provider have? We suggest that the draft Implementing Act detail out remedial steps for both the subsequent user who has accessed GR from the registered collection that is now declared non-compliant and for the provider who has provided the GR to the said collection.

4) BEST PRACTICES

Regarding the recognition of best practices we make the following suggestions for the sake of public scrutiny and in the interests of providers of GR and ATK who would like to make an independent assessment about whether or not enter into an agreement with entities claiming best practice:

i) The information submitted that enables the recognition of combination of procedures, tools or mechanisms developed, and how they will ensure compliance should be published in the internet-based register of recognized best practices;

ii) The footnote in the Discussion paper mentions that the oversight of the procedures could include a "record keeping system or control system". We suggest that it should include both: record keeping and control;
iii) In cases where there is either recognition or withdrawal of recognition as best practice we suggest it would be important that not only the decision is published, but also the information provided to the Commission, which lead to the decision.

An important but open question is what are the remedial measures that would need to be undertaken with regard to the utilization of GR and ATK based on an access via a best practice which was later deemed not to have complied with the requirements for best practice. We suggest that the Implementing Act detail out remedial steps to safeguard the rights of the providers therein.

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