9 Jan 2015

Comments of Japan Bioindustry Association (JBA) on "the Discussion paper for the stakeholder meeting of 9 December 2014" for implementing provisions in relation to Articles 5, 7 and 8 of Regulation (EU) No. 511/2014

Japan Bioindustry Association (JBA) greatly appreciated the opportunities for discussions at the stakeholder meeting of 9 December 2014 held in Brussels, Belgium.

As a stakeholder in relation to Regulation (EU) No. 511/2014, Japan Bioindustry Association (JBA) would like to offer our comments on the Discussion paper for the stakeholder meeting of 9 December 2014.

We would be most grateful if the European Commission would take our comments into consideration in the process of drafting the implementing acts in relation to Articles 5, 7 and 8 of Regulation (EU) No. 511/2014.

Comments on the Substance of the Discussion paper of 9 December 2014:

Comment 1:

Article 7 of the basic Regulation – monitoring user compliance

Due diligence declaration at the stage of research funding

Line 3 (page 5):

The meaning of "research funding" needs to be clearly defined to avoid confusion in an international perspective. For example, in our language, "financial investment by a large enterprise to a biotech start-up company for R&D purposes" is sometimes loosely referred to as "research funding". However, in the context of the basic Regulation, we assume that "research funding" is clearly different from "financial investment" in the above-mentioned case. In order to eliminate any ambiguity, "research funding" needs to be clearly defined in a written form.

Recommendation:

The difference between "research funding" and "financial investment" should be explicitly clarified in a written form.

Comment 2:

Article 7 of the basic Regulation – monitoring user compliance

Due diligence declaration at the stage of final development of a product

Line 2 and 18(page6)

In accordance with the Article 2 of the basic Regulation, we understand that the statement of "a product developed via the utilization of genetic resources and/or traditional knowledge associated with genetic resources" means "a product developed via the utilization of genetic resources and/or traditional knowledge associated with such resources that have been accessed within a Party to the Nagoya Protocol after the entry into force of the Nagoya Protocol for the Union." In this context, "genetic resources and/or traditional knowledge associated with such resources" to be reported in a declaration should be only "genetic resources and/or traditional knowledge associated with such resources that have been accessed within a Party to the Nagoya Protocol after the entry into force of the Nagoya Protocol for the Union," if that product have been developed via utilization of several kinds of genetic resources and/or traditional knowledge associated with such resources.

Recommendation

'Genetic resources or traditional knowledge associated with such resources' to be reported in a declaration should be explicitly clarified in a written form as 'genetic resources or traditional knowledge associated with such resources that have been accessed within a Party to the Nagoya Protocol after the entry into force of the Nagoya Protocol for the Union.'

Comment 3:

Article 7 of the basic Regulation – monitoring user compliance

Due diligence declaration at the stage of final development of a product

Lines 24 and 25 (page 6):

"Where the utilization has taken place outside the Union, the declaration is to be made to the competent authority of the Member State through which the product enters the Union", means that obligations of users based on Article 4 of the basic Regulation are to be imposed on users in countries beyond the EU jurisdiction. This would become serious international barriers to the trade of a wide range of products.

Recommendation:

This provision in lines 24-25 should be deleted.

Comment 4:

Article 7 of the basic Regulation – monitoring user compliance

Due diligence declaration at the stage of final development of a product

Lines 30 and 33 (page 6):

The intention of the statement in lines 30-33 seems to provide rigorous legal clarification. In our view, demerits of this legal clarification are greater than its merits at the current infancy stage of the Protocol implementation. We must add that, due diligence declarations to be made at the events of (c), (d) and (e) (refer to lines 16-23) are much easier said than done, particularly for those SMEs or micro-enterprises (e.g. biotech start-up companies) that are weak both financially and in manpower. The rigorous legal clarification given in lines 30-33 has legal meaning for lawyers, but, practically, it does not tell those SMEs or micro-enterprises about anything concrete as to what to do on their part. They would simply be confused, and as a result, would likely be pushed out of business. In light of the present circumstances at the infancy of the Protocol implementation, a pragmatic "step-by-step approach" will be more effective and appropriate than enforcement based on rigorous legal clarification which is too abstract for weak enterprises to comprehend and cope with.

Recommendation:

Lines 30-33 should be deleted. A pragmatic step-by-step approach (e.g. by guideline) should be given a priority, until more experiences accumulate with implementation of Nagoya Protocol in both providing and user countries.

Comment 5:

Article 8 of the basic Regulation – best practice

Application for recognition of a best practice

Line 9 and 13 (page 7):

"Other interested parties" do not represent users and, therefore, they are not legally bound by "due diligence obligations" that are stipulated by Article 4 of the basic Regulation. Testing a system of recognizing a best practice of "other interested parties" is certainly a good idea to explore a way of enabling (but not necessarily ensuring) users to comply with their obligations under Articles 4 and 7 of the basic Regulation. However, it is premature to judge whether this approach effectively works or not. Furthermore, not all the "other interested parties" will opt for a recognized best practice in the first place. We have concerns that it would be too risky to enforce a regulation on users prematurely, based on an untested assumption.

Recommendation:

Users' obligations to seek, keep and transfer information and relevant documents (as stipulated by Article 4(3)(b) of the basic Regulation) need to be explained concretely from a practical perspective. We are of the view that implementation of these provisions within the EU should be postponed until sufficient experiences of the Protocol implementation accumulate in both providing and user countries worldwide

Comment 6:

Need for guidance

Meaning of "utilization (R&D)":

The terms "research and development" are not defined in the Nagoya Protocol. According to "the Minutes of ABS Stakeholders' Meeting of 9 December 2014" that was prepared by the European Commission", the Commission informed that there will be no declaration at the time of collection of the genetic resource, as the triggering moment will be the utilization. In case of simple analysis of genetic resources without subsequent utilization, no declaration will be needed".

Therefore, we understand that "research and development" in the basic Regulation

refer to the process intended to create new products. Accordingly, meaning of "utilization" becomes quite clear.

Recommendation:

Meaning of "research and development" and "utilization" in the context of in the basic Regulation should be elaborated in a guidance document, based on the information provided by the Commission at the Stakeholder meeting of 9 December 2014.

Comment 7:

Need for guidance

Elaboration of "commodity trades"

The term "commodity" is referred to neither in the Nagoya Protocol nor in the basic Regulation. According to a presentation that was made by a Commission official at the Workshop entitled "Working Out ABS" organized by ICC in Paris on 24-25 November 2014, the EU ABS Regulation concerns "utilization" of genetic resources, but not commodity trade. It was a useful clarification.

Recommendation:

Treatment of "commodity trade" in the context of the basic Regulation should be elaborated in a guidance document.

Comments on Annexes

Annex A

Comment 8:

(1) Pages 1-2, Part A, 3

The current template assumes a case where only one kind of genetic resource is utilized in one funded project. However, in actual situations, there are cases where multiple kinds of genetic resources are used on a funded project. Therefore, the template's wording should be modified to accommodate such cases by a single declaration in a cost-effective manner.

Recommendation:

For example, it would be useful if "Part A, 3. Information on exercise of due diligence" is annotated by, e.g. footnote saying "attach a list of genetic resources and their relevant information for each item if a multiple number of different genetic resources are used on a single funded project".

Comment 9:

(2) Page 2, Part A, 3 (d)

The statements in this section (given below) are not consistent with the principles of protecting confidentiality as stipulated in the Nagoya Protocol, and therefore should be changed.

Reason: the principles of protecting confidential information are stipulated in Nagoya Protocol (e.g. Art. 14(2), 17(1) (a) (iii) and 17(4)). Caution must therefore be exercised to prevent any chances of disclosing confidential information without the applicant's consent. The EU authority should not transmit confidential information, without the applicant's consent, to the process where it cannot directly control.

Recommended changes:

a) Lines 1-2,

The statement: "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" should be changed to the following statement: "Please provide information under items given below."

b) (i) through (viii)

Delete all the ticking boxes and accompanying words "confidentiality".

c) (viii) line 3

The statement "If 'Yes' was selected, please indicate the name of the subsequent user:" should be changed to "If 'Yes' was selected and the information is non-confidential, please indicate the name of the subsequent user"

Annex B

Comment 10:

(1) Page 5, Part A, 3(b)

The statements in this section (given below) are not consistent with the principles of protecting confidentiality as stipulated in the Nagoya Protocol, and therefore should be changed. Reason: the same as that given above for Annex A, Part A, 3(d).

Recommended changes:

a) lines 2-3,

The statement: "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" should be changed to "Please provide information under items given below."

b) (i) through (viii)

Delete all the ticking boxes and accompanying words "confidentiality".

c) (viii) Line 3

The statement "If 'Yes' was selected, please indicate the name of the subsequent user:" should be changed to "If 'Yes' was selected and the information is non-confidential, please indicate the name of the subsequent user".

Annex C

Comment 11:

(1) Pages 7-8, Part A, 4

The current template assumes a case where only one kind of genetic resource is utilized in one product. However, in actual situations, there are cases where multiple kinds of genetic resources are used in a single product. Therefore, the template's wording should be modified to accommodate such cases by a single declaration in a cost-effective manner.

Recommendation:

For example, it would be useful if "Part A, 4. Information on exercise of due diligence" is annotated by, e.g., footnote saying "attach a list of genetic resources and their relevant information for each item if a multiple number of different genetic resources are used on a single product".

Comment 12:

(2) Pages 8-9, Part A, 4(d)

The statements in this section (given below) are not consistent with the principles of protecting confidentiality as stipulated in the Nagoya Protocol, and therefore should be changed. Reason: the same as that given above for Annex A, Part A, 3 (d).

Recommended changes:

a) Page 8, (d), lines 2-3

The statement: "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" should be changed to "Please provide information under items given below."

b) 4(d), (i) through (viii)

Delete all the ticking boxes and accompanying words "confidentiality".

c) Page 9, line 3

The statement: "If 'Yes' was selected, please indicate the name of the subsequent user" should be deleted and replaced by the following statement: "If 'Yes' was selected and the information is non-confidential, please indicate the name of the subsequent user".

Annex D

Comment 13:

(1) Pages 12-13, Part A, 4(b)

The statements in this section are not consistent with the principles of protecting confidentiality as stipulated in the Nagoya Protocol, and therefore should be changed. Reason: the same as that given above for Annex A, Part A, 3 (d).

Recommended changes:

a) 4(b), lines 2-3

The statement: "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" should be changed to the following statement: "Please provide information under items given below."

b) 4(b), (i) through (viii)

Delete all the ticking boxes and accompanying words "confidentiality".

c) Page 13, lines 2-5

The statement: "If 'Yes' was selected, please indicate the name of the subsequent user" should be deleted and replaced by the following statement: "If 'Yes' was selected and the information is non-confidential, please indicate the name of the subsequent user".