

January 29, 2016

Secretariats of the Convention on Biological Diversity(CBD)
413 St. Jacques Street, Suite 800
Montréal, QC, H2Y 1N9
Canada

Via E-mail to synbio@cbd.int

Re: October 7, 2015 (UNEP/CBD/SYNBIO/AHTEG/2015/1/3) "REPORT OF THE ADHOC
TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY"

Dear Secretariats of the CBD,

We are Japan Bioindustry Organization (JBA) which is a non-profit organization aiming to support industrial activities of Japanese bioindustry companies. We support modern biotechnology of this subject for its application among the Japanese industry. We thank the CBD office to give an opportunity to express our opinion on the report (AHTEG report : "UNEP/CBD/SYNBIO/AHTEG/2015/1/3") from AHTEG whether CBD to employ 'Synthetic Biology' as official agenda or not.

At first, AHTEG report indicate 'Synthetic Biology' as official agenda of COP but throughout the discussion of COP, there was never an agreement of 'Synthetic Biology' as CBD's official agenda among the parties. Such misleading statement shall not be recorded on the report.

For example, paragraph 62 (page 11) 'Fair and equitable sharing of the benefits of synthetic biology' has not yet reached to international agreement as far as we understand. It should be changed to what CBD's objective indicates 'Fair and equitable sharing of the benefits arising out of the utilization of genetic resources' or the entire paragraph 62 should be deleted.

Paragraphs 24, 29, 44, 66(a) indicate a new term 'biological systems'. To date, such the term has not been discussed. Moreover, its definition does not have clear objectives. If this 'biological systems' derive from 'Biotechnology' in the Cartagena protocol's the term 'biotechnology' refers to any technological application that uses biological system', this biotechnology as defined 'Biotechnology, in the form of traditional fermentation techniques, has been used for decades to make bread, cheese or beer' as traditional 'biotechnology'. However, 66(a)'s operational definition indicates 'synthetic biology is a further development and new dimension of modern biotechnology', therefore in disagreement to the rest. If definitions of 'modern biotechnology' or 'biotechnology' are different from that of Cartagena protocol, 66(a)'s operational definition will lose its meaning. The phrase 24, 29, 44 and 66(a)'s 'and biological system' should be deleted.

Before the above discussion, online forum has not covered enough of 'synthetic biology' would impact 'biological diversity'. The reason behind is that understandings of 'synthetic

biology' differ among the participants in the online forum and cannot come to agreement of what in the "synthetic biology" covers/cover. Reflecting this fact, AHTEG discussion decided to move forward by employment of 'operational definition' and, at this stage, submit only the temporary definition to push discussion forward. This definition has not been authorized by SBSTTA or COP yet, and the scope of 'synthetic biology' has not been determined. Therefore, 'living organism' as product of 'synthetic biology' shall have no reason why it should be in the scope of CBD's three objective.

In paragraph 66(a), 'synthetic biology' in the operative definition has been agreed as 'further development and new extension of modern biotechnology' in AHTEG. If 'modern biotechnology' is as defined in Cartagena protocol and its further developed technology is 'synthetic biology', 'synthetic biology' is applied to the definition of 'modern biotechnology'. By employment of this understanding, as Cartagena protocol subjects to 'LMO', 'synthetic biology' shall have 'living organisms arising out of synthetic biology' as its sole object. With this understanding 'Product' or 'Components' are not in the scope of subject admitted by the AHTEG members.

If Cartagena protocol's 'modern biotechnology' and this forum's definition 'modern biotechnology' are different, because the definition is not indicated and condition of 'synthetic biology' being undefined, 'synthetic biology' cannot be concluded to be in three scopes of the CBD.

'Genetic materials' therefore is out of scope due to above reason. Definition proposed by the EU Committee's 'genetic materials in living organism' may be within the definition of 'operational definition'. The wording of 'genetic material, living organisms' in Paragraphs 24 and 66(a) shall be replaced to 'genetic materials in living organisms'.

At the online forum discussion, the 'LMO' in the Cartagena Protocol and 'living organisms arising out of synthetic biology' cannot be differentiated to existing or what to arise in near future and should be considered the same as major argument. Also, unknown 'organisms' which can potentially appear in the future cannot be evaluated with no product of such are in existence. Even if such outcome arise is considered as progressed form of 'synthetic biology' or 'modern biotechnology', as Ambrozevicius (Brazil): [#7062] mentioned in the online forum that employment of definition of 'LMO' in the 3rd paragraph of the Cartagena Protocol works for 'living organisms' arising from 'synthetic biology' and carries out the risk evaluation. Currently, nothing has been indicated that cannot be covered by Cartagena protocol's 'LMO', 66(b)'s 'are similar to' should be change to 'are'.

Paragraph 52 and 66(c) discusses on 'potential benefits and potential adverse events', 'positive impact' or 'negative impact' indicating dual use of 'LMO' outcomes depending on kind, object and who to use. There shall have no conclusion on this matter and 66(c)'s 'review new information regarding the positive and negative impacts of synthetic biology' should be deleted.

Paragraph 66(d) indicates 'AHTEG on Risk Assessment and Risk Management' and 'AHTEG

on Socio-economic Considerations' as possible place for discussion of 'synthetic biology', they are designed to consider different matters and employment after COP-MOP8 as subject shall be a discussing matter of SBSTTA or COP-MOP8. It therefore means continuation of AHTEG extension should not be indicated and 66(d)'s 'such as the AHTEG on Risk Assessment and Risk Management and AHTEG on Socio-economic Considerations under the Cartagena Protocol' should be deleted, and limit the following sentence, such as '(d) Urge Parties to address synthetic biology in a coordinated manner within the context of the objectives of the Convention and its Protocols, particularly by tapping into existing appropriate processes in the CBD.'

Paragraph 66(e) should add 'the Global Network of Science Academies,' to the list of international organization to consider about this current discussing issue in CBD, and reflect the views of not only the synthetic biologists but also the renowned academic bodies of respective nations. Otherwise, it shall not be accepted by international academic scenes.

Paragraph 66(f) and (g) do not have to be separated and new BCH establishment is not needed. Existing information sharing system can do the same as below.

"Promote the use of online tools to facilitate work on synthetic biology in the context of the Convention and its Protocols;"

Paragraph 66(i), 'digital genetic information' is an issue of intellectual property unless it is derived from the living organisms of certain countries of origin and is not a matter of biological diversity. It is not a matter of CBD and therefore this paragraph should be deleted. Also page 9 'potential adverse effect' (n) indicates 'Patent-driven and open-source approaches to synthetic biology may have different implications in the context of access and benefit sharing;' but ABS has no relation to intellectual property matter. In order to avoid potential harm, 'synthetic biology' shall have no reason to mention about 'patent-driven and open-source approaches', this paragraph should be deleted.

Paragraph 66(j), as our above statements, so long as 'synthetic biology' is what has been indicated in Cartagena protocol's 'modern biology's improved form and if the technology is in the same line, 'products' or 'Components' discussion are unnecessary. Paragraph 66(j) should be deleted. As online forum or AHTEG comments indicate, if the 'Products' or 'Components' are of food, CODEX Alimentarius, drug or cosmetics approval system of respective nations, if chemicals bodies such as REACH regulation in EU should be the responsible bodies. CBD is not a responsible body to change their rules or in responsible position.

CBD's article 1 indicates objective of CBD to be 'Fair and equitable sharing of the benefits arising out of the utilization of genetic resources.' But the AHTEG report indicates 'Fair and equitable sharing of the benefits arising from the utilization of genetic resources' together with above statement. It should be unified as 'out of'.

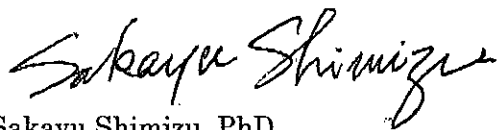
Also, page 8 lower part 'Objective 3' indicates 'Fair and equitable sharing of the benefits of biological diversity' but it should be corrected to 'Fair and equitable sharing of the benefits arising out of the utilization of genetic resources'.

Above is all from us on online forum and AHTEG report and look forward to our opinion to be reflected to future decision of CBD office. We thank you again for giving us a chance to give our opinion.

Respectfully submitted

Date: January 29th, 2016.

Japan Bioindustry Association
Chairman

A handwritten signature in black ink, appearing to read 'Sakayu Shimizu', written in a cursive style.

Sakayu Shimizu, PhD.