s.19(1)

From:
To:
Date: 2015/07/10 5:36 AM
Subject: SynBio discussions under the CBD

Dear All,

It has been a while since our last exchanges about the discussions on synthetic biology under the Biodiversity Convention (CBD).

As we discussed in our last conference call on this, given that the number of these informal discussion groups that are facilitated by PRRI keeps growing and that also the number of people participating in this groups keeps growing, PRRI will limit emails and conference calls to a 'need basis', indicated by requests from one or more of you.

After more than a month of relative - and relaxing - silence, we received the last two weeks several questions around two points: 1) what is the current situation on the on-line debates, 2) what next?

Below a quick update, but before doing so, first a welcome to some new people on this email list and a brief reminder of the objective of our exchanges: This is a group of colleagues with an interest in discussing Synthetic Biology in international fora such as OECD, CBD etc. The main aim is to exchange information and views. The exchanges in this group are informal, and not aimed at establishing common positions. Some colleagues on this list actively participate in the discussions, while others are mainly 'listeners'. PRRI participates facilitates similar groups on various CPB and CBD topics, such as environmental risk assessment, socio economic considerations in decision making, liability and redress, review and assessment. All these discussions are conducted under the Chatham House rules.

Returning to the debates under the CBD:

1. Current situation of the on-line debates.

The online discussions of are now over. For further details see: http://bch.cbd.int/synbio/calendar/.

The most recent online discussions (topics 6 and 7) focused on the following topics:

a) Which instruments exist that regulate the organisms, components or products derived from synthetic biology techniques?
b) Are these instruments adequate to address the potential impacts on the objectives of the Convention and its Protocols?

As people noted, the topics 6 and 7 overlapped quite a bit and in fact also duplicated earlier on line discussions.

In addressing topics 6 and 7, there were roughly two views: one view suggested that the current systems are not applicable and/or not adequate and that entirely new systems have to be set up for synthetic biology, while another view suggested that the current systems are applicable and adequate for now. I hold the latter view (I paste my post below).

As discussed with some of you, this debate goes beyond Synbio and takes place in many other areas such as genome editing.

As one of you noted: "the underlying question is why and how much regulation is needed, i.e. what safety problem needs to be fixed and how vulnerable is our safety?".

What we see in many of the posts in the online debate, many people have lost sight of why the original focus on GEOs/GMOs/LMOs: that focus was not because rDNA techniques were considered to confer risky characteristics per se, but based on the consideration that while conventional breeding and rDNA can both result in novel characteristics that can cause adverse effects, rDNA can make a broader range of novel combinations, with which there is limited experience. AS with food additives, societies have over the years taken the approach that it is wide ask in the case of things to which we may get exposed whether there are safety questions.

In short, the regulatory trigger in most regulatory frameworks and in the CPB is based a degree of novelty. (Notate bene: the fact that techniques are often linked to that definition of novelty is because conventionally produced organisms are by definition not considered to obtain that degree of novelty.) Once the novelty triggered scope is defined, the next step is choosing the regulatory instrument, which can range from a general condition that food should be safe (e.g. FDA), to a simple notification system, up to a full-fledged authorisation / certification system (e.g. EU, EPA, USDA). Yet, whatever the regulatory mechanism, case by case risk assessment plays a key role. As I mentioned to some of you, I plan to work with a number of colleagues from universities and research institutes the coming months to produce a number of papers that outlines the background and history of the objectives, scope (definitions), regulatory mechanisms and risk assessment in biosafety systems, so that they can use that in their discussions with their colleagues and authorities.

Will keep you posted on this.

*2. Next steps. *

The Secretariat is in the process of selecting experts to take part in the first face-to-face meeting of the AHTEG. AHTEG participants will be

s.19(1)

selected by the Secretariat, in consultation with the SBSTTA Bureau, from among those who were nominated by Parties, on the basis of their expertise and their participation in the Online Forum. A limited number of experts nominated by other Governments and organisations will be invited to take part in the AHTEG as observers. We understand that some of the people on this email have received an informal invitation checking their availability.

We will alert you once the appointed AHTEG members are published on the CBD site.

The first face to face meeting of the AHTEG is tentatively scheduled from 21 to 25 September 2015, in Montreal. Some of

We will come back with further updates early/mid September.

In the meantime we wish all the Northern Hemispherians a splendid Summer holiday.

PS: the Genetic Literacy Project has often interesting blogs on SynBio, e.g.:

http://www.geneticliteracyproject.org/2014/08/05/what-the-f-is-synthetic-biology/

http://www.geneticliteracyproject.org/2015/05/28/three-developments-that-will-help-synthetic-biology-to-live-up-to-its-promise/

Post on topics 6 and 7

Dear colleagues,

My name is