Doc 1.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: Re: SynBio under CBD - Zika epidemic and GM mosquitos in Latin America
Date: 05-02-2016 11:34

Dear All,

Thanks for your feedback.

In response to 10.2.e 's question "what next?": this week several colleagues on this email list happened to attend a meeting about risk assessment under the CPB in which that same question was.

The general sense was in order to have a meaningful impact on this process, it is – as 10.2.e underlined – essential that we attend the COP, MOP and SBSTTA, and preferably in good numbers of like-minded countries and organisations who can support each other. Yet, having said that, it is also important to provide input in the form of submissions and participation in the on-line fora, simply because with that those views are 'on the record' (anti biotech NGOs are very aware of this, hnce their active participation).

A second aspect is to keep providing examples of the potential of this technology to contribute to human well-being. 10.2.e 's comments about the potential of using synbio in the fight against the Zika virus, e.g. by developing – as part of a broader strategy - bio-repellants from bio materials through synbio.

A third aspect is to keep providing examples of how inadequate regulations - or inadequate implementation – can hamper finding solutions for stressing problems.

Valt buiten reikwijdte verzoek

Finally, an observation about defining synbio. I noted that some of you proposed not to have a definition of syn bio, but I assume that with that they meant is not having a regulatory type of definition, but that we all agree that if there is a discussion on Syn Bio in SBSTTA and COP about Synbio that we need some description as to what we are talking about. The debate gets very confusing if someone refers to SynBio in cases of synthethised DNA, while others refer to Bt corn as SynBio.

Regards!

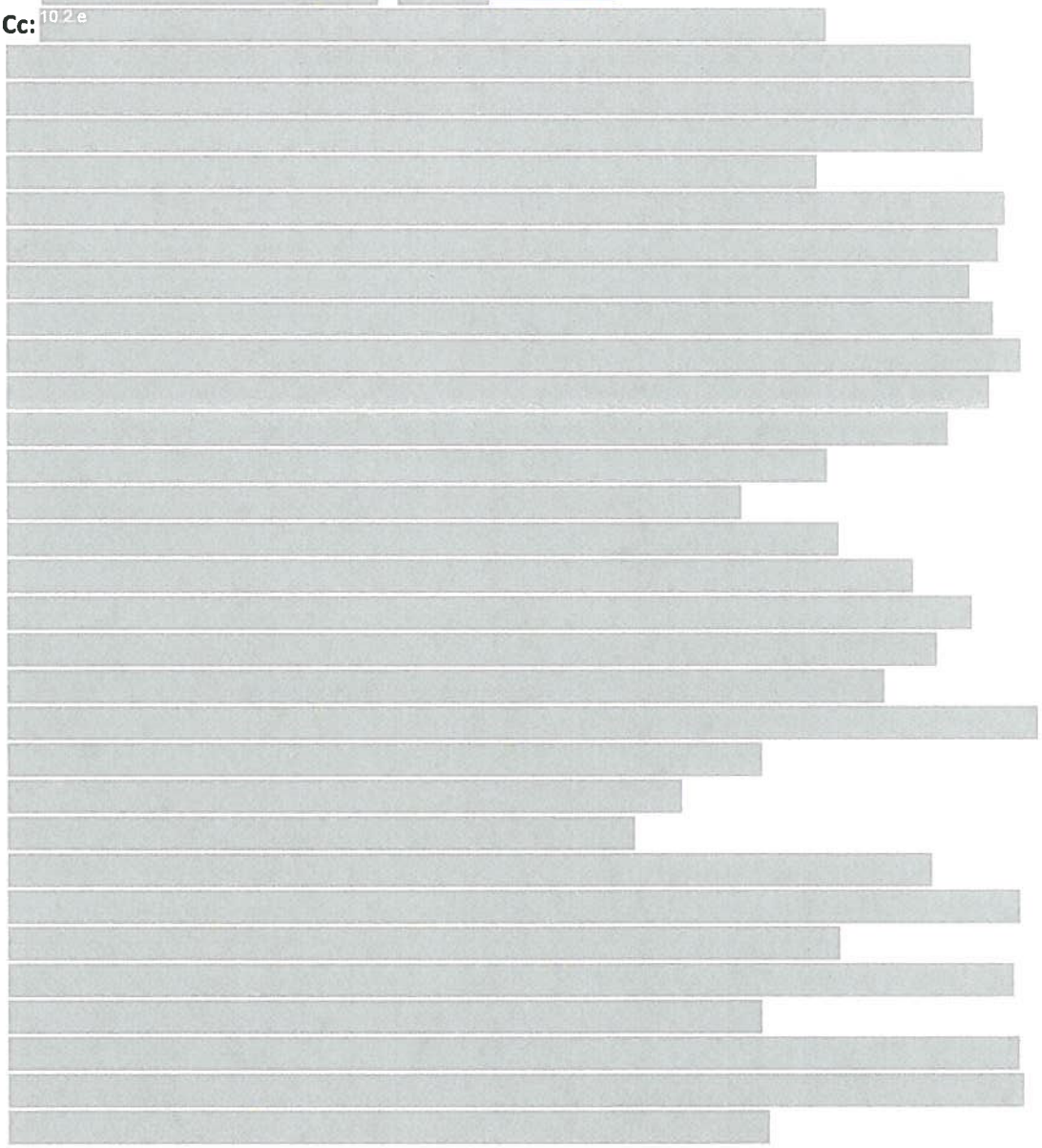
10.2.e

Doc 1.

On 5 February 2016 at 11:21, 10.2.e <10.2.e @rivm.nl> wrote:

> Dear 10.2.e and others, I wouls also be very interested in the duscission on gene drives, this relation to the environmental risk assessment. In he Netherlands we will soon publish a short report in which we
>
> Delivered to you by RIVM Mobile environment.

From: 10.2.e <10.2.e @danforthcenter.org>
Sent: 4 feb. 2016 17:09
To: 10.2.e <10.2.e @itesm.mx>
Cc: 10.2.e



Subject: Re: SynBio under CBD - Zika epidemic and GM mosquitos in Latin America

10.2.e ,

10.2.e and I are also in contact. I attended a meeting that he organized earlier this month on the topic of gene drives, with a focus on mosquitoes. I will be happy to keep sharing what I can on this topic, and likewise am interested to know

what is happening in Zika-affected areas of the world from a regulatory point of view.

10.2.e

On Thu, Feb 4, 2016 at 10:16 AM, 10.2.e <10.2.e @itesm.mx> wrote:

Dear all,

Thanks also to 10.2. and 10.2.e for their messages. As you all know, we in Latin America and the Caribbean are getting more and more concerned about the Zika, Dengue and Chingunguya epidemics, but especially Zika that may affect a wider population if it is also sexually transmitted. Regardless of the last alarm, we need to act quickly and GM mosquitos can provide solutions. The regulatory aspects are complex, but we must work on them now.

10.2.e, we are greatly interested in any new information you can give us. 10.2.e and I have already started a conversation.

Let´s keep the conversation /information flowing.

Regards to all.

10.2.e (writing from Mexico)

10.2.e
Departamento de Biotecnología y Bioingeniería
TECNOLÓGICO DE MONTERREY
CAMPUS GUADALAJARA
Espíritu emprendedor con sentido humano

10.2.e @itesm.mx
www.gda.itesm.10.2.e

Enlace intercampus: 10.2.e

Doc 1.

From: 10.2.e [mailto:10.2.e @danforthcenter.org]
Sent: Thursday, February 4, 2016 9:04 AM
To: 10.2.e <10.2.e
Cc: 10.2.e

Subject: Re: SynBio under CBD - reminders, updates and request for feedback

10.2.,

Thanks for this summary. It helped me get current on the deliberations concerning Synthetic Biology, which as I indicated when we last spoke, I am becoming more and more involved in through the Danforth Center interest in gene drives, particularly with respect to transgenic mosquitoes.

Doc 1.

Valt buiten reikwijdte verzoek

10.2.e

On Fri, Jan 29, 2016 at 7:18 AM, 10.2.e <10.2.e> wrote:

Dear All,

With my very best wishes for 2016, I follow up on our communications about the Synthetic Biology discussions under the CBD.

Below some reminders, updates and requests for your feedback.

Background: COP 12 (October 2014) decided on a process of preparation for an in depth discussion on SynBio in COP13 (December 2016):

- submission of information by governments and organisations

- a series of on-line discussions

- a discussion in the AHTEG

- Feedback on the synthesis of submissions and AHTEG report

- Peer-review in SBSTTA

SYNTHESIS OF THE SUBMISSIONS

The synthesis of the submissions can be found here.

ON LINE DISCUSSIONS (April – July 2015)

The result of the online discussions can be found here

AHTEG SYNBIO (21-25 September 2015)

The report of the AHTEG can be found here.

FEEDBACK ON THE SYNTHESIS AND AHTEG REPORT (deadline 31 January 2016)

See the invitation sent by the CBD Sec in December to peer review the outcomes of the process for consideration by the SBSTTA. The reports for peer review are available at http://bch.cbd.int/synbio/peer-review

Submissions must be sent to the Secretariat via e-mail to synbio@cbd.int no later than **31 January 2016**.

As those of you who participated in the AHTEG have already mentioned, the report is found to be fairly balanced in that it reflects the various views on the key topics.

As regards the synthesis report, as some of you said, rather than being a 'synthesis' it gives the impression of a patchwork of cherry picked bits and pieces that does not reflect what was submitted.

In particular the relationship between SynBio and Biodiversity, gives an unbalanced and a very negative impression. Attached is an example by 10.2.e on how certain views are presented.

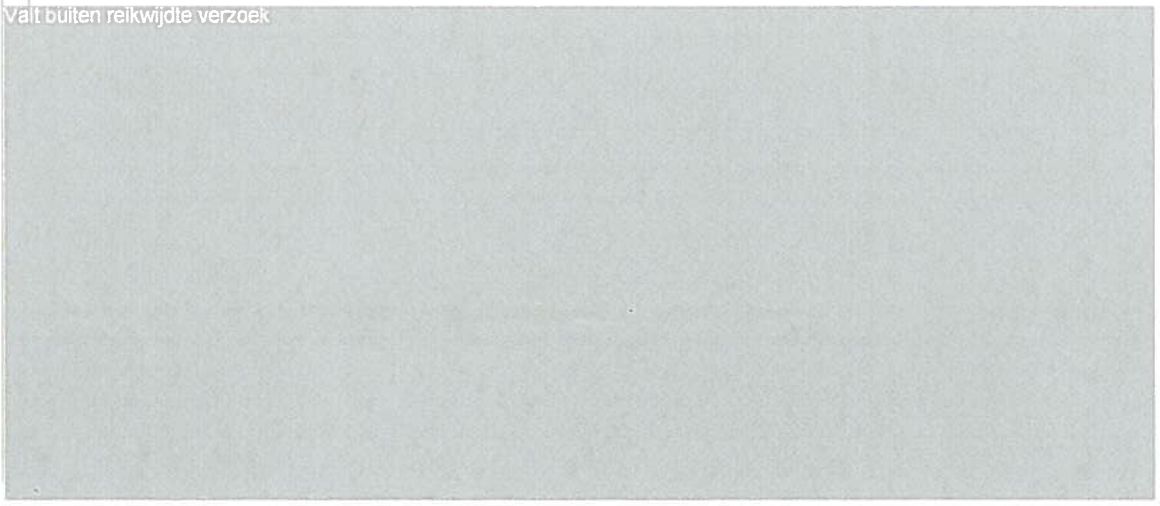
It would be good to ask the CBD how the process of synthesis was done, and what the criteria were for including or excluding views.

SBSTTA 25 to 30 April 2016

As discussed, given the key role of the Subsidiary Body on Scientific, Technical and Technological Advice in preparing documents for the COP, participation in the SBSTTA is important.

(SBSTTA 20) will be held from 25 to 30 April 2016, and the first meeting of the Subsidiary Body on Implementation (SBI 1) will be held from 2 to 6 May 2016, in Montreal, Canada. The documentation for these meetings will be made available on: https://www.cbd.int/doc/?meeting=SBSTTA-20 and https://www.cbd.int/doc/?meeting=SBI-01.

Designation of participants should be submitted to the CBD Executive Secretary through an official letter sent as a scanned e-mail attachment to: secretariat@cbd.int or by fax at +1 514-288-6588, preferably by **20 March 2016**.



Doc 1.

Valt buiten reikwijdte verzoek

COP13 (4 – 17 December)

The latest information we received is that the MOP8 (Biosafety Protocol), COP13 (CBD) and COP2 (Access and benefit Sharing) will be held sort of less simultaneously in the period 4 to 17 December.

10.2.e and I are working on the idea of getting students and some young scientists who are participating in the iGEM to COP13, to participate in the negotiations and to present their synbio work in a side event. We will keep you posted on this.

Looking forward to hearing from you

10.2.e

Some observations on
UNEP/CBD/SYNBIO/AHTEG/2015/1/2

UPDATED REPORT AND SYNTHESIS OF VIEWS IN RESPONSE TOPARAGRAPH 7(b) OFDECISION XII/24ON NEW AND EMERGING ISSUES: SYNTHETIC BIOLOGY

II.RELATIONSHIP BETWEENSYNTHETIC BIOLOGY AND BIOLOGICAL DIVERSITY

Paragraph 14 last phrases….
"The risks and potential impacts of the relationship should be assessed prior to any introduction to the environment, taking also into account risks to human health, small scale farming systems and their contribution to biological diversity and ecosystem function, food security, livelihoods and related socioeconomic considerations, indigenous peoples and local communities, including cultural aspects.

OBs. They're trying to make as onerous and time consuming as possible…. and e.g. socio economics is not a should but a "may"….

Paragraph 15. "With regard to the third objective of the CBD, it was noted in the online forum that the fair and equitable sharing of benefits arising out of the utilization of genetic resources must be considered in the light of the development of the many components of synthetic biology, their applications and possible effects on biodiversity. It was noted that the objective of fair and equitable sharing of benefits arising from the use of genetic resources may lose its purpose, as use of components, organisms and products from synthetic biology may replace the need for and use of natural genetic resources. A participant in the online forum also noted that a profit-driven approach to synthetic biology does not necessarily support the fair sharing of costs and benefits between developed and developing countries, and that this situation has been exacerbated by control over the techniques of synthetic biology by a limited number of stakeholders, most of whom are driven primarily by a profit motive rather than by ecological perspective.

OBS. -

- It's also aiming to make it more accessible for people to develop their own solutions to their needs.
- There're plenty of public research aiming to solve challenges is not limited to profit driven….
- You still start based on existing "natural" organisms

Paragraph 17
17. It was also noted that a lack of scientific underpinning to ecological and social impacts in the application of synthetic biology processes poses a key issue in the discussion on the relationship between synthetic biology and biodiversity. An increase in the complexity and range of synthetic biology tools and techniques may also lead to an increase in the uncertainty and unpredictability of their outcomes, making it harder to predict their effects on biodiversity, leading tithe need for stricter measures to prevent damage to biodiversity.

Paragraph 21
.
21. There were also participants who noted that it is premature to discuss the relationship between synthetic biology and biodiversity since an agreement has not been reached on whether or not synthetic biology is a new and emerging issue for conservation and sustainable use of biodiversity. Furthermore, some participants also noted that since no one fully understands the risks posed by synthetic organisms to the environment, there are challenges as to what kinds of information is needed to support rigorous risk assessments, or who should collect such data.

”

OBS. – one of the aims of SynBio is to decrease complexity….

- I didn’t read again the comments online, but I bet we (I mean at least someone on our like minded) posted something like that RA&M science will advance as the technology does… and that for the current or near applications it’s well covered by existing RA&M under annex III

Parts that actually have to do with RA&M also come on the next topic: **III. SIMILARITIES AND DIFFERENCES BETWEEN LIVING MODIFIED ORGANISMS (AS DEFINED IN THE CARTAGENA PROTOCOL) AND … OF SYNTHETIC BIOLOGY TECHNIQUES. In addition to paragraph 38 with a huge list examples in part V (this is about 1 page and it’s a terror….**

All these have in common that there’s lack of understanding on the RA&M process prior to release or ignores its existence, etc. In addition, some of these should be in part VI**.BEST PRACTICES REGARDINGRISK ASSESSMENT AND MONITORING REGIMES CURRENTLY USED…**

eg. Paragraph 26

(a) The differences between an LMO and an organism developed through synthetic biology **lie mainly on the higher level of complexity of the latter**. Such complexity may result from the combination of several techniques of genetic engineering to produce an organism combined with other techniques that rely on the standardization and abstraction of modular biological components. Furthermore, LMOs are organisms developed by incorporating a single or a few gene(s) of interest, whereas organisms constructed by means of synthetic biology techniques are **likely** to have larger segments of modified DNA or even complete novel genomes;

obs. It’s not true

(c) The production of living organisms through modern biotechnology and synthetic biology is similar but the genes and nucleic acid molecules transferred into the recipient organisms differ in that nucleic acids transferred through modern biotechnology **exist in nature but not those transferred through**

it makes no difference whether the DNA was taken from an organism or synthesized…..

Doc 2.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: Retry: SynBio under CBD - Zika epidemic and GM mosquitos in Latin America
Date: 05-02-2016 11:35

Dear 10.2.e, dear all,

Sorry for my earlier message, that went wrong somehow.
Again: I would be very interested to be kept updated on all yyour activities concerning gene drives.
We (in the Netherlands) have identified gene drive as an important issue from a perspective of risk assessment, that probably calls for other data to perform the risk assessment in an adequate way.
We already alerted our Ministry on this subject and I know of more colleagues who did the same.
In Europe there are plans to discuss gene drive at the international level.

Thanks for keeping me in hte loop.

Met vriendelijke groet,
10.2.e

10.2.e
GMO Office
RIVM/VSP
PO Box 1 3720 BA Bilthoven
The Netherlands

Phone number: +31 10.2.e or +31 10.2.e

Doc 3.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: Re: SynBio under CBD - Zika epidemic and GM mosquitos in Latin America
Date: 05-02-2016 11:35

Dear 10.2.e and all,
In terms of Brazil, CTNBio (commission that makes the risk assessment of GMOs) approved the transgenic mosquito from Oxitec (Aedes aegypti the same mosquito that transmits Dengue, Zika, Chigungunya....) for commercial release in 2014. But to enter the market it still needs the OK from ANVISA which is Brazilian health surveillance agency.
With the rapid increase and spread of Zika cases and newborns with microcephalie there has been new controlled releases in Piracicaba (this time southeast of Brazil). The results are again good, reduction of the mosquitoes population is slightly more than 80%. You have to keep introducing the GM mosquitoes to lower the population (no gene drive in this case).
I'm also very interested in gene drive.
Best regards, 10.2.e
Sent from my iPhone

On 05.02.2016, at 00:08, 10.2.e <10.2.e @danforthcenter.org> wrote:

> 10.2.e ,
>
> 10.2.e and I are also in contact. I attended a meeting that he organized earlier this month on the topic of gene drives, with a focus on mosquitoes. I will be happy to keep sharing what I can on this topic, and likewise am interested to know what is happening in Zika-affected areas of the world from a regulatory point of view.
>
> 10.2.e

Doc 4.

From: 10.2.e
To: 10.2.e
10.2.e

Subject: Follow up last week's ERA meeting in DC
Date: 09-02-2016 23:27

Dear All,

It was a sheer pleasure working with you last week at the ERA meeting in DC, and I thank 10.2.e once more for coming up with the idea and for carrying it forward.

As discussed, it is very important that we keep providing input on the draft AHTEG guidance in all the stages: on-line discussions, AHTEG and finally MOP.

As I mentioned in our meting, PRRI has been facilitating for the last couple of years various informal, 'like-minded' groups on CPB and CBD topics such as ERA, Socio-Economic Considerations, Liability, Synthetic Biology, Public Information.

These groups are entirely informal and the main aim is to inform each other of relevant developments. We used to do that in conference calls, but these groups have now become so large that we do most via email.

To give you a flavour of how we operate, I paste an email that I have sent this morning to the informal group on ERA, of which I about half of you have been a participant for a few years.

As said, the other participants of our DC meeting are warmly to have their email added to the list, if they wish so. Just send me an email.

Cheers

10.2.e

Valt buiten reikwijdte verzoek

Doc 4.

++++++++++++++++++++++++++++++++++++

Email to the informal group on CPB ERA

Dear All,

I follow up on our communications about the development of guidance for risk assessment under the CPB.

Over the last couple of weeks, many of us have met in various meetings on risk assessment where we also had an opportunity to discuss guidance for risk assessment under the CPB, and my overall sense is that many – if not all – of us are of the view that the current version is not very helpful, to put it mildly, and that it is important to keep providing input in the discussions.

There are various opportunities to provide input: the online discussions, for some of us through the AHTEG, and then of course in the MP itself.

Hereby a quick update on past and current activities and developments.

AHTEG ON RA/RM

The report of the AHTEG that was held from 16 to 20 November 2015 in Brasilia, Brazil, is avauilable here.

UPDATED VERSION OF THE DRAFT GUIDANCE

An updated version of the current draft guidance is available here.

NEW ON LINE DEBATE

Currently there is an online discussion on RA going on, which started at 1 February and will continue to 15 February 2016. You can access the discussion here.

This particular round has the objective of gathering views, relevant guidance and sources of information on:

1) "LMOs introduced in centres of origin and genetic diversity" and "LMOs intended for introduction into unmanaged ecosystems" (the two topics will be addressed together);

2) "LMOs created through use of dsRNA techniques, engineered to produce dsRNA or dsRNA" and "LMOs containing RNAi" (the two topics will be addressed together);

3) "Integrating human health into the environmental risk assessment" taking into account the topics "Nutritionally altered living modified plants" and "LMOs that produce pharmaceutical products", as appropriate;

4) "Synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs".

The purpose of this discussion is to brainstorm on the above mentioned topics, which, as agreed by the AHTEG, will be incorporated into the "Roadmap for Risk Assessment of LMOs" by, for example, adding information boxes or additional text.

From a quick scan, I think that from this email list sofar only 10.2.e has participated in the current discussions. From talking with some of you last week, I know that people are tired of the online discussions and that there is a sense that it doesn't have much impact. While I share the sense of getting tired with these discussions, and while it is true that the input in the online discussions doesn't have much direct impact, please remember that participation in the online discussions is important, because then it is "on the record", which is important because then we can refer back to that in the AHTEG and in the MOP. In short: please participate.

I will participate tonight, and despite that the moderator has asked not to debate on whether or not the topic is relevant to be further considered, I intend to address some general concerns: 1) starting to incorporate new topics in the guidance is not helpful as long as there is still no overall agreement on the guidance, 2) supporting 10.2.e 's point addressing food safety issues such as nutritional value should be done under Codex and not under the CPB, and 3) supporting 10.2.e 's point that assessment of pesticides should be done under the pesticides regimes, and not under the CPB.

As regards whether it is an appropriate moment to include new guidance: is many Parties expressed at the last MOP, it is better to first thoroughly test and finalise the guidance and th roadmap before adding even more topics.

In addition I draw your attention to some new txt that the AHTEG added to the introduction of the Guidance, starting at line 162: "The Roadmap introduces basic concepts of risk assessment rather than providing detailed guidance for individual case-specific risk assessments. In particular, the "elements for consideration" listed in Roadmap may need to be complemented by further information during an actual risk assessment."

Observations: 1) The notion that the roadmap would introduce new basic concepts is disconcerting, because the general principles are already laid down in Annex III of the CBP, and it is not up to an AHTEG to add to that, 2) the idea that this guidance is not intended to be used for individual cases seems to divert from the very reason why it was felt necessary to develop practical guidance.

VARIOUS OTHER INITIATIVES

In addition to providing input in the actual discussions, there are various other initiatives ongoing:

Testing the guidance

Several groups have been - and some still are – testing the guidance for practical use in specific cases. It is expected that the results of those activities will come available in the next couple of weeks. If anyone of you has any information on such activities, please share with this group

Alternative guidance documents

There are several groups preparing guidance documents unrelated to the CPB guidance, such as the group of 10.2.e , which is preparing a guide in Spanish for Latin America. I have seen translated drafts of that guide, which in its draft form was already far more useful than the current draft CPB guidance.

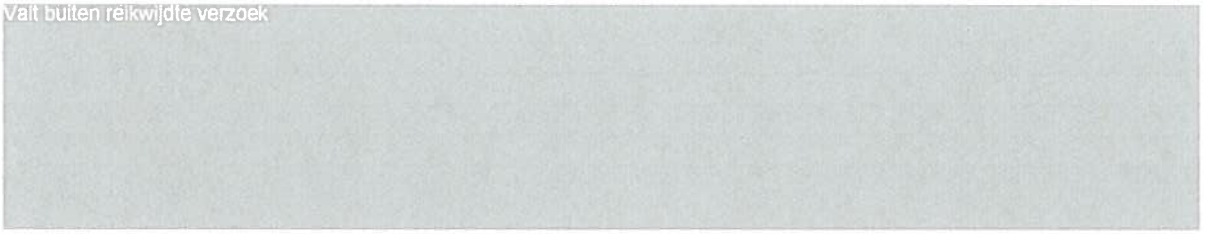
10.2.e , can you give us an update on the status of your guide?

If anyone of you has any information on similar activities, please share with this group

ERA table - Flow chart

During the previous AHTEG, we developed a simple table / flow chart of the steps of the ERA, with the main aims to 1) show the logical structure and flow of an ERA, 2) to illustrate that in those steps some points to consider are typically addressed I most cases (e.g. selective advantage /weediness) while other points are only addressed in specific cases, depending on the gene, etc. Ins hort, as 10.2.e once called it "the roadmap as it was intended to be".

Over the last couple of months I have worked with a number of colleagues to fine tune and expand that table, to incorporate a section that shows that he basic concepts for RA stem form many decades of RA under the WHO/FAO, to incorporate a similar table for food/feed safety assessment (FFFSA), and to show the commonalities and differences between ERA and FFSA. I the course of the next two weeks I will send you an update of that table. The plan is to turn the table into a paper, and whoever is interested in contributing is more than welcome.



Best regards!

Doc 4.

10.2.e

Doc 8.

From: [redacted]
To: [redacted]
Cc: [redacted]

Subject: Re: NL report on gene drive
Date: 27-03-2016 10:37

Dear All,

Valt buiten reikwijdte verzoek

Returning to daily life: thanks to [redacted] for alerting us to the Dutch statement on Gene Drives. What is also very useful is that they put out a FAQ*. For those of you who read German: a statement has also been put out by the German Biosafety Board (Link),which explains a case-by-case approach for the risk assessment, and labwork on gene drive systems is as risk level 2.

Thanks to [redacted] for offering help with a page on gene drives on the PRRI website, which we will place on http://www.prri.net/scientific-topics/. [redacted] and I will have a call about that next week. For now the page 'gene drives' is under construction, and only accessible as a password protected 'member area'.

Valt buiten reikwijdte verzoek

A few more observations:

1) [redacted] sent this email to a group discussing SynBio under the COP. Yet, I wonder whether gene drives should be considered a form of SynBio. Looking forward to your thoughts.

2) In order not to combine too many topics in email strings, we could have a separate list of people interested in gene drives. Who would be interested in joining such a list?

Wishing everyone a restful holiday break!

[redacted]

On 19 February 2016 at 15:34, [redacted]@rivm.nl> wrote:

Dear [redacted]
Thanks for your question.
What we conclude in our report is that the current (risk) assessment method for contained use in de EU is inadequate, since the assessment (and concurrent containment level) is only based on potential toxicity for humans.
So the higher the toxicity of a gm organism, the higher the containment level.
This methodology not readily applicable to organims (e.g. insects) with gene drives.
However, we do not conclude that the environmental risk assessment after intentional release in the environment is inadequate. However, we feel that case-by-case other data and other expertise is needed to perform an adequate risk assessment. This has to do with the potential quick and irreversible spread of a new trait in complete populations, espcially for insects.

Hope this helps.
Met vriendelijke groet,
[redacted]

From [redacted] @[redacted]
To [redacted] @rivm.nl>,
Cc: [redacted]

Date 19-02-2016 15:12
Subject Re: NL report on gene drive

Thanks for this, [redacted]

I would be interested to know more details if they are available, regarding the reasoning behind the conclusion that the current risk assessment method is inadequate.

I think we should start compiling a list of similar decisions be regulatory agencies, so if anyone else on this list is aware of similar decisions, please append to this thread.

[redacted] I think these would be a good start to have on the PRRI password accessible site.

[redacted]

On Fri, Feb 19, 2016 at 8:45 AM, [redacted] <[redacted]@rivm.nl> wrote:
Dear all,

Just to inform you that recently our GMO Office published a policy report on gene drive and its possible consequences for risk assessment.
Although this report is written for the European situation and for contained us of GMOs, it might still be of interest for you.

The report is available in English and is attached to this mal.

You can also follow the link to our website:
http://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsmessages/2016/Need_for_adjustment_authorisation_for_gene_drive_applications

Doc 8.

Kind regards,

[redacted]

[redacted]
GMO Office
RIVM/VSP
PO Box 1 3720 BA Bilthoven
The Netherlands

Phone number [redacted]

Proclaimer RIVM http://www.rivm.nl/Proclaimer

Doc 10.

From: [redacted]
To:
Subject: Re: NL report on gene drive
Date: 29-03-2016 16:30

Ha [redacted]
Ja, dit gaat over de risk assessment voor contained use activities. Dit geldt niet per definitie voor de ERA.
Ik sta graag op jouw mailing lijst die gaat over gene drives.

Met vriendelijke groet,
[redacted]

[redacted] —27-03-2016 10:39:23 [redacted] fully agree.

From: [redacted] @rivm.nl>,
Date: 27-03-2016 10:39
Subject: Re: NL report on gene drive

[redacted]

fully agree,

yet your FAQ gives the impression that the ERA is inadequate

" The current approach in risk assessment does not take into account the specific effects of a gene drive "

Please make clear that this si for contained use

goeie paas !

[redacted]

On 19 February 2016 at 15:34, [redacted] @rivm.nl> wrote:

Dear [redacted]
Thanks for your question.
What we conclude in our report is that the current (risk) assessment method for contained use in de EU is inadequate, since the assessment (and concurrent containment level) is only based on potential toxicity for humans.
So the higher the toxicity of a gm organism, the higher the containment level.
This methodology not readily applicable to organisms (e.g. insects) with gene drives.
However, we do not conclude that the environmental risk assessment after intentional release in the environment is inadequate. However, we feel that case-by-case other data and other expertise is needed to perform an adequate risk assessment. This has to do with the potential quick and irreversible spread of a new trait in complete populations, espcially for insects.

Hope this helps.
Met vriendelijke groet,
[redacted]

Dubbel met eerder document

Doc 11.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: RE: Synthetic Biology visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam
Date: 02-05-2016 21:01

Dear all,

I agree that all these technologies - both established and new - (Oxitec GM mosquitoes vs. gene drive mosquitoes) are essential to face the many challenges that we have, especially in tropical regions, including agricultural pests and human insect vectors such as the Zika vector.

Risk analysts, regulators and trainers of regulators need to keep u hnological developments and the nuances between them, such as synbio, gene drives vs. gene editing, vs, "conventional biotech". 10.2.e gave me a very cl xplanation on mosquitoes developed by gene drives vs. Oxitec mosquitoes and their ecological implications, in just a few minutes (thanks 10.2.e), so I can now pass it on to my students and other who need this information.

As 10.2.e and 10.2.e say, this is the right time to talk about these technologies, and maybe move away from the heat of the "GM Maize in Mexico- Mayan cosmology-Monsanto-industrial agriculture" issues that have stalled these technologies for decades. I propose we change the tune ... and use human emotions, like the "other side" does.

Mexico is host to the COP-MOPs in December and Zika has reached epidemic proportions in our region. Maybe many delegates will be worried about being bitten by mosquitoes with Zika, Dengue and Chikungunya (all "natural and organic" hahaha!), and may have a more open mind to the use of these technologies? So may the athletes and spectators going to the Olympics in Rio?

Does anybody know what the status of discussions of genome editing and gene drives is in the Synthetic Biology AHTEG ? Should these technologies be discussed in that group? There will be split opinion on this too.

Synthetic biology is one of the topics of discussion in the Risk Assessment AHTEG, but gene editing, gene drives and NBTs have not been mentioned yet. Maybe they will be discussed at the Mexico City meeting in July 2016, when the guidance is reviewed?

To change the tune, we want to take a group of young scientists to the COP-MOP (iGEM international and Mexican students) to state their position as the future generation of biotechnologists/synthetic biologists and also as the future parents of babies threatened by Zika. Some of these students studying biotechnology come from indigenous communities in Panama, Guatemala, Mexico, Bolivia, Peru, etc. This generation is inheriting both huge challenges and powerful technologies. We owe it to them not to tie their hands, for one more generation, with excessive regulation.

Best regards to all,

10.2.e

10.2.e
ogía y Bioingeniería
TECNOLÓGICO DE MONTERREY
CAMPUS GUADALAJARA
Espíritu emprendedor con sentido humano

10.2.e @itesm.mx
da.itesm.mx

10.2.e
Enlace intercampus: 80 432 2536

-----Original Message-----
10.2.e @ufpe.br]
10.2.e @ucdavis.edu>
10.2.e
10.2.e

Subject: RE: Synthetic Biology visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Além, the transgenic mosquito in Brazil is not baesd on gene drive, but on RIDL.

----- Mensagem original -----
10.2.e

Doc 11.

[redacted]

Assunto: RE: Synthetic Biology □ visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Hi,

Gene Drives need is so obvious now with successful use in Brazil for Zika virus with 90% decrease in targeted mosquitoes and now release in US. It is important to say that the gene drives target a very specific species rather than many insects like pesticides, the alternative that is used, not to mention the effects on environment and humans. BTW, California has been effectively using gene drives for controlling leaf hoppers for virus in plants and pink boll worm in cotton, such that we need very little control using BT. Ironically, we use less GM as a result. This has been done by releasing sterile insects by irradiation of males.

Arguing against this is selfish and egotistical.

A no-brainer.

best,

[redacted]

-----Original Message-----
From [redacted]
Sent: Sunday, May 1, 2016 1:46 PM
[redacted]
Subject: Re: Synthetic Biology visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Thanks to all for this thread.

It's important to be communicate that many believe that gene drives are not part of synbio. It is equally important to explain to the media, CBD, and NGOs where exactly gene drives do "belong"?

Best wishes,

[redacted]

From: [redacted]
Date: Sunday, May 1, 2016 at 1:08 AM
[redacted]@rivm.nl>>
[redacted]
Subject: Re: Synthetic Biology - visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Hi [redacted]
Tha[redacted]for the alert - we have added it to the page on SynBio on the PRRI site.
I take this opportunity to ask those who attended SBSTTA what the final outcome was on the discussion on SynBio. We heard that the discussions were quite heated at one point.
I also take this opportunity to respond to a question I received what the feedback was on whether or not people consider gene drives as a form of

Doc 11.

Synbio. We received 7 responses, all saying that they did not consider gene drives as a form of SynBio.
Wishing you all a great remainder of the Sunday!

[redacted]

On 28 April 2016 at 13:55, [redacted]@rivm.nl<mailto:[redacted]@rivm.nl>> wrote:
FYI

Kind regards,

[redacted]

RIVM/VSP
PO Box 1 3720 BA Bilthoven
The Netherlands

Phone number: [redacted]

Doc 12.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: Re: Synthetic Biology visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam
Date: 04-05-2016 20:31
Attachments: LOFSTEDT-SCHLAG - Risk-risk tradeoffs 16.pdf

Dear 10.2.e

In respons eto you question: perhaps the authors of the attached paper "Risk-risk trade offs: what should we do in Europe?"

All, I warmly recommend to read this paper.

Regards!

10.2.e

On 3 May 2016 at 18:48, 10.2.e 10.2.e @evolva.com> wrote:

> Thanks 10.2.e
>
> Now we just need a show of courage and clarity on this "no-brainer" from somebody other than the industry or the scientific community.
>
> Indeed, we need somebody from the middle weighing in on this debate—somebody whose views on synbio cannot (so easily) be disparaged by NGOs without transparent self-incrimination. Somebody whose views cannot be written off by the Secretariat, either.
>
> 10.2.e

Dubbel met eerder document

Doc 13.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: Re: Synthetic biology discussion starting within the RA AHTEG
Date: 07-05-2016 23:44

Dear 10.2.e

10.2.g en 11.1

The on-line forum within the RA AHTEG on synthetic biology starts tomorrow Sunday for two weeks. The on-line discussion on the risk assessment guide which finishes tomorrow, is not reaching consensus as opinions are polarized. It will be interesting to see what the summary reports.

Surprisingly I have been asked to moderate it with a mixed group: Japan, India and 10.2.e are also in the group (like-minded) while the rest are precautionary types like 10.2.e from China and 10.2.e (?) from New Zealand.

At least some of us are in, so let's make the most of it for damage mitigation. As I said, I am very surprised they asked us to participate.

Best regards,

10.2.e

Sent from my iPhone

On 07/05/2016, at 14:28, 10.2.e
10.2.e @agricultura.gov.br> wrote:

Dear 10.2.e

So it was exactly what happened in the SBSTTA, Brazil said very clearly that was not time for a SynBio guidance although our understanding was that an interaction between the outcome from SynBio AHTEG and RA AHTEG was necessary considering that it could be the case for future work.

In the Secretariat recomendation was written

"*Invites* the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to address synthetic biology in a coordinated manner, particularly by tapping into existing processes, such as the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management for the development of guidance dedicated to risk assessment regarding living modified organisms

developed through synthetic biology and the Ad Hoc Technical Expert Group on Socio-economic Considerations under the Cartagena Protocol, as appropriate. "

And the final recommendation was:

"*Welcomes* the recommendation of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, in its decision BS-VII/12, on a coordinated approach on the issue of synthetic biology, including its work on risk assessment and risk management [as well as socio-economic considerations, as appropriate], and *invites* the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to take into account in its future deliberations relevant information resulting from the processes under the Convention;"

I 10.2.g en en 11.1

Sincerely

10.2.e

10.2.e
Fiscal Federal Agropecuário

Ministério da Agricultura, Pecuária e Abastecimento
Unidade Técnica Regional Agropecuária em Viçosa
Tel.: 10.2.e Vila Gianetti, Casa 38 Campus da UFV | Viçosa MG BRASIL | 36.570-900

De: 10.2.e @itesm.mx>
Enviado: sexta-feira, 6 de maio de 2016 18:12
Para: 10.2.e
Cc: 10.2.e
Assunto: RE: Synthetic biology discussion starting within the RA AHTEG

Dear 10.2.e

Doc 13.

Thanks for your message for clarification. 10.2.g en 11.1

Most of the time (it seems to me), we discuss and agree on something, and the summaries and reports reflect something different.

I am copying below, a message I received from 10.2.e , inviting me to moderate the synbio on-line forum and lead the development of an outline. Please read below and tell me if this is not consistent with what was agreed during SBSTTA last week. According to 10.2.e 's message, the "green light" was given. Please advice.

Warm regards,

10.2.e

10.2.e wrote:

"As you know, the SBSTTA meeting happened last week. In its recommendations, it emphasized the need for coordination with processes under the Cartagena Protocol and in particular the AHTEG on risk assessment. It also recognized that risk assessment methodologies may need to be adapted for current and future applications.

If you recall our meeting in Brasilia, the development of an outline for guidance on risk assessment of living organisms developed through synthetic biology was pending the outcomes of the SBSTTA meeting. Given that the SBSTTA has given the "green light", it is now time for the AHTEG on risk assessment to develop the outline.

In Brasilia, you volunteered to take part in the team drafting the outline. I would like to ask if you would be available to take the lead in this task and also to moderate the upcoming discussion of the online forum starting this Sunday/Monday. The discussion will last 2 weeks with the objective of gathering views, similar to a "brainstorming" session. The drafting of the outline will follow

the online discussion and the other volunteers would work together with you.

I realize it is a bit of a short notice but the online discussion is not very demanding and I would be happy to send you a draft for the opening message which you can adapt as needed.

Please let me know what you think at your earliest convenience. I hope you can accept the invitation and look forward to hearing from you.

10.2.e
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Enlace intercampus: 10.2.e

From: 10.2.e @agricultura.gov.br]
Sent: Friday, May 6, 2016 3:58 PM
To: @itesm.mx>; 10.2.e @aphis.usda.gov>; 10.2.e @jcvi.org>; ; 10.2.e @rivm.nl>
Cc: 10.2.e

Doc 13.

10.2.e

Subject: Re: Synthetic biology discussion starting within the RA AHTEG

Dear 10.2.e

I would like to say that I´m very happy with the opportunity to have someone with experience to start writing something useful but I´m also confused: I was in the SBSTTA 20 last week and in the Recommendation 8 the paragraph about RA AHTEG elaborating a guidance for SynBio was substitute with the paragraph bellow:

1. *Welcomes* the recommendation of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, in its decision BS-VII/12, on a coordinated approach on the issue of synthetic biology, including its work on risk assessment and risk management [as well as socio-economic considerations, as appropriate], and *invites* the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to take into account in its future deliberations relevant information resulting from the processes under the Convention;

We (in the brazilian delegation) presented the point that we didn´t think it was a needed for a specific guidance at this point. There was not a technical justification (nobody tested a synbio organism with the RoadMap to show which points are not covered) and the AHTEG report concluded that currently all the synbio organisms can be considered LMOs (for which the RoadMap applies).

After the deletion of the paragraph about the Guidance in the Secretariat recommendation for SBSTTA we understood that at this time the Guidance will not be elaborated.

Could you please clarify how is the AHTEG interpretation about this recommendation without a clear demand from Parties for a Guidance at this moment ?

(even the SynBio definition ended up in brackets in the final recommendation...)

Thanks.

Sincerely,

10.2.e

10.2.e
Fiscal Federal Agropecuário

Ministério da Agricultura, Pecuária e Abastecimento
Unidade Técnica Regional Agropecuária em Viçosa
Tel.: 10.2.e Vila Gianetti, Casa 38 Campus da UFV | Viçosa MG BRASIL | 36.570-900

De: 10.2.e @itesm.mx>
Enviado: sexta-feira, 6 de maio de 2016 16:45
Para: 10.2.e
Cc: 10.2.e
Assunto: Synthetic biology discussion starting within the RA AHTEG

Dear all,

The on-line forum on Synbio within the Risk Assessment (RA) AGTEG starts this Sunday for two weeks. A face-to face RA AHTEG will take place in *Mexico City in July 2016*, and guidelines on "special topics" such as LMO trees, LMO fish RNAi, and **synthetic biology** need to be ready. Since Zika is on everybody's agenda in Mexico and the region, gene drives for mosquitoes will be discussed .

Doc 13.

I have been invited to moderate the two-week on-line forum on synthetic biology and take the lead on drafting an outline within the Risk Assessment AHTEG, after I (timidly and worriedly) raised my hand during the RA AHTEG meeting in Brasilia, when the chair asked for volunteers.

Inviting – or rather accepting - someone with my background and views is rare for the Secretariat and the subgroup leading the draft of the RA guidance, so I will accept.

Just want to let you know that I think we may have a small and rare opportunity here to steer things in the right direction, before the July meeting in Mexico city and before the COP8-MOP13 in Cancun in December.

The current discussion on gene drives is extremely timely and relevant – especially for regions with Zika. I hope we can come to some consensus from this specialist group, before the on-line forum on risk assessment on synthetic biology starts and wild opinions start flying from all quarters.

Warm regards to all

10.2.e

10.2.e
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Enlace intercampus: 10.2.e

Doc 13.

From: 10.2.e @ucdavis.edu]
Sent: Friday, May 6, 2016 12:28 PM
To: 10.2.e @aphis.usda.gov>; 10.2.e @jcvi.org>; 10.2.e 10.2.e @rivm.nl>
Cc: 10.2.e

Subject: RE: Synthetic Biology – visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Doc 13.

Hi,

I agree with 10.2.e and others. I offer that any directed selection (all plant and animal breeding (and associated microbiota)) is literally a gene drive. Plant breeding has three steps. Create genetic diversity, Select for desirable alleles (gene drive) and fix it in a variety to reproduce (gene drive). It seems like the groups of people and regulators have just discovered a new word and decided that is a bad thing. It is important that we keep it simple and not fall into a trap of accepting this 'new' bad word and defending with fine details of what is in or out when there is nothing new here in the first place...with 100 years and 10,000 of breeding examples of safe use. Same for Synbio. Keep it simple and lets think of the big picture.

best,

10.2.e

From: 10.2.e @aphis.usda.gov]
Sent: Thursday, May 5, 2016 9:49 AM
To: 10.2.e
Cc: 10.2.e

Subject: RE: Synthetic Biology – visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Hi 10.2.e

Thanks very much for the link to the review and your concise description of what synthetic biology is. I, too, was surprised to hear that the seven respondents did not think gene drives were an example of synthetic biology. With the exception of the naturally occurring gene drives, the human-directed gene drives certainly seem to fit the definition of synthetic biology that includes a "large basket" of genetic manipulation techniques.

Doc 13.

I will be keeping your concise paragraphs close at hand when trying to convey to non-specialists information about gene drives and where they fit in the large basket of techniques within synthetic biology.

And lastly, let me offer another word of thanks for the free flow of ideas and information among this group over the past months. It's greatly appreciated.

10.2.e

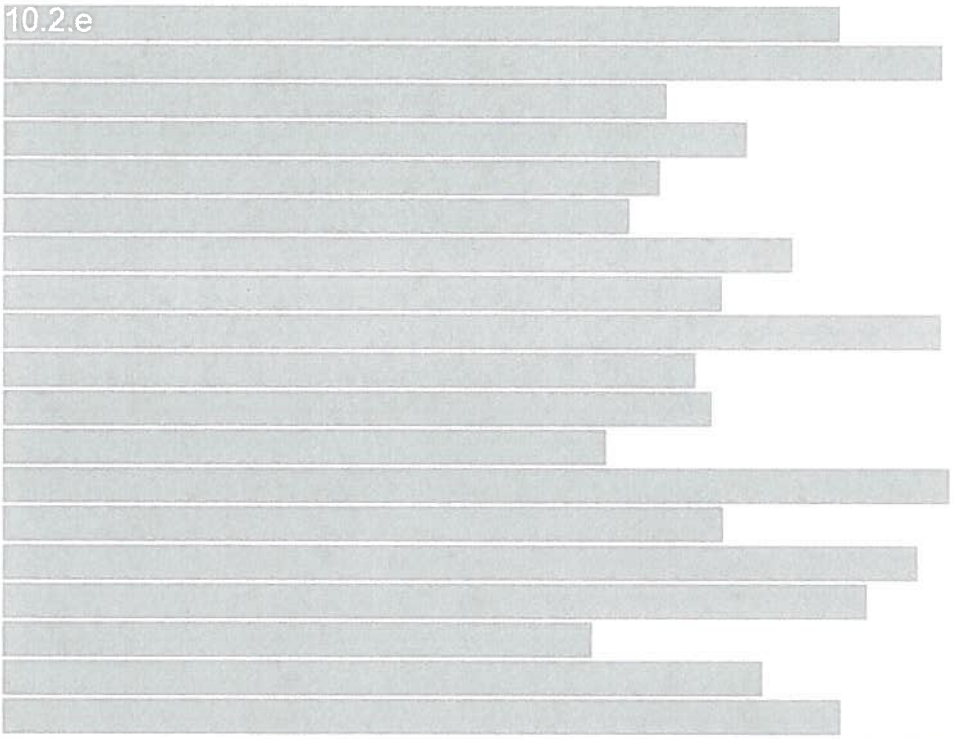
****

10.2.e
10.2.e

Biotechnology Regulatory Services
USDA-APHIS
TEL: 10.2.e
MOBILE: 10.2.e
EMAIL: 10.2.e @aphis.usda.gov

From: 10.2.e @jcvi.org]
Sent: Thursday, May 05, 2016 12:25 PM
To: 10.2.e ; B10.2.e @rivm.nl>
Cc: 10.2.e

Doc 13.



Subject: RE: Synthetic Biology – visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Hi all—

Just a quick response to the query whether gene drives are a form of synbio. I was surprised to read that all seven responders replied "no". I guess that is technically correct, but perhaps misleading. Hints of the "process vs product" debate here...

In my view, synthetic biology is a process: a group of methods that can be used to genetically modify an organism. An organism with a gene drive is the product. The drive is a trait that can be engineered into an organism (and, in fact, is sometimes found in nature).

Decades of prior gene drive research did not use what we now call synthetic biology techniques. (Nor were they particularly successful.) But in my view, the recent burst of activity to add a desired gene with the ability to drive through a population (using CRISPR or other modern systems) has relied on the synthetic biology techniques. A good review of the different types of gene drive systems is here: http://www.nature.com/nrg/journal/v17/n3/abs/nrg.2015.34.html Champer, Buchman, and Akbari, "Cheating evolution: gene drives to manipulate the fate of wild populations" Nature Reviews Genetics.

Doc 13.

10.2.e

10.2.e

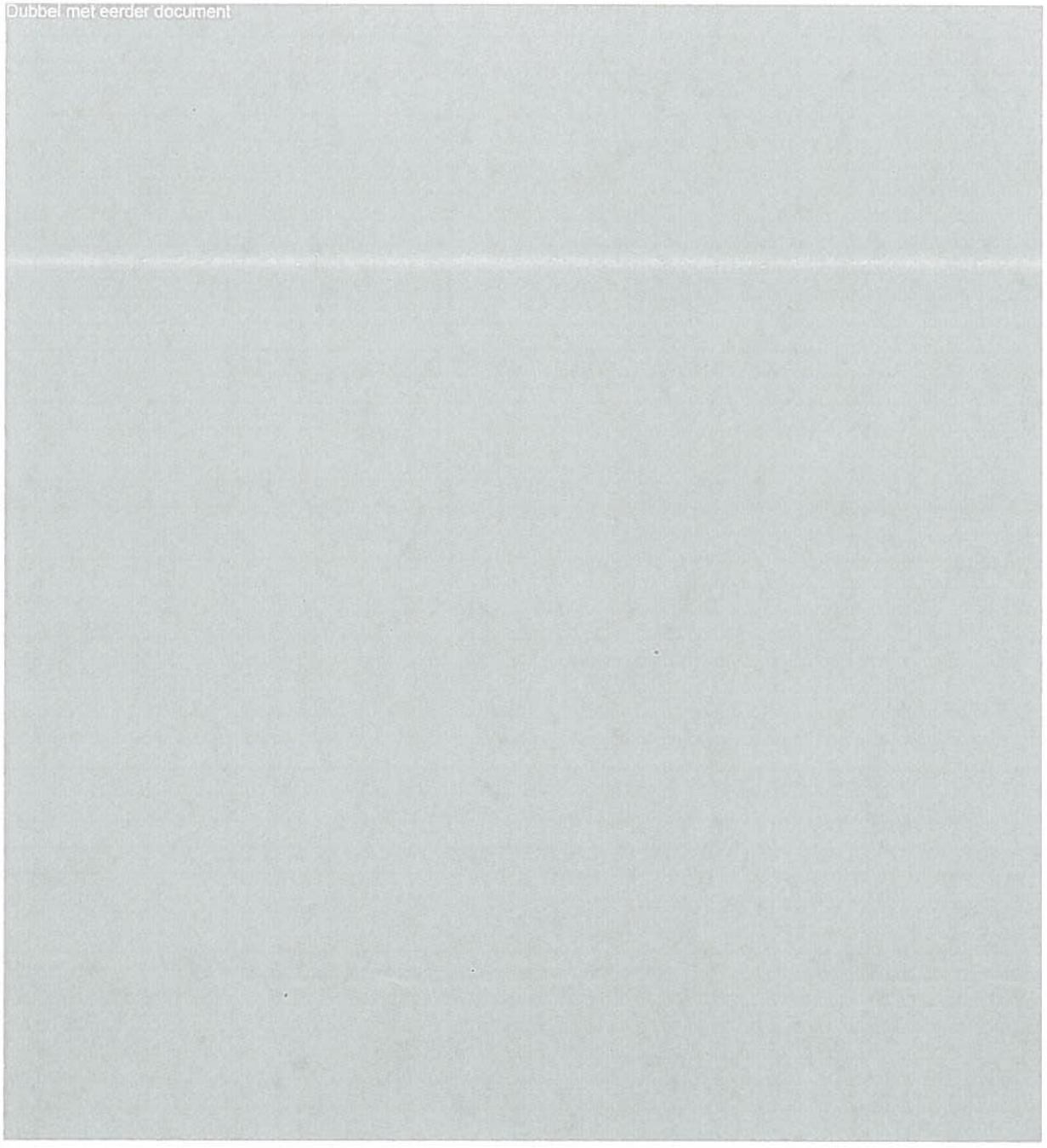
10.2.e

J. Craig Venter Institute

4120 Capricorn Lane, La Jolla, CA 92037

phone: 10.2.e

cell phone: 10.2.e



Doc 14.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: RE: Synthetic biology discussion starting within the RA AHTEG
Date: 08-05-2016 06:32

Dear 10.2.e

I was also at SBSTTA and agree with 10.2.e Apart from the paragraphs in the final document referring to a 'coordinated approach' between the AHTEGs, I do not recall an agreement about that AHTEG developing guidance/'outline' for guidance. The Secretariat did explain that the RA AHTEG has a mandate to work on synthetic biology, and that SBSTTA cannot directly request that AHTEG to do anything because it is a body under another treaty, but there is a 'line of communication' between them, and that AHTEG is waiting for the go-ahead from SBSTTA. The Secretariat also pushed for inclusion of the 'coordinated approach' language. 10.2.g en 11.1

Kind regards,

10.2.e
10.2.e

BAYER **Science For A Better Life**

Crop Science Division
Bayer CropScience Pty Ltd
10.2.e

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Web: www.bayer.com.au

Doc 15.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: [Spam] On-line forum on SB within the Risk Assessment AHTEG begins tonoight
Date: 08-05-2016 17:41

Dear 10.2.e , dear all,

10.2.g en 11.1

. Tonight at 7 pm we will open the on-line forum on synthetic biology within the RA AHTEG, and very likely, embark on an equally frustrating and futile clash of opinions, similar to all other past discussions of this kind.

The precautionary side wants to block application of products of synthetic biology by developing even more complex and convoluted RA guidelines that what already exists for LMOs, or worse, by developing completely separate RA guidelines for SB designed to block application. The emphasis here will be to define SB accordingly and regulate the process. This will very likely include gene drives and genome editing.

Maybe "we" (the like-minded group) have made progress from past times, in that opposing opinions to the precautionary ones can no longer be blatantly disregarded in official reports. As moderator of the discussion about to start, I will be rigorous in that *all views* will be reflected for the Parties to consider at MOP 8.

As humans, we must all acknowledge that we have agendas (regardless of good or bad ones) whether they are commercial, political, environmental, social, agricultural, educational (mine) or other, and try to put ourselves in the other´s shoes, to understand where they are coming from. Not at all easy to do, but essential if we are to go forward with the process before December in Cancun.

I invite those of you who would like to contribute to coach the next generation of biotechnologists/synthetic biologists to join our parallel "student on-line forum" for our young people. We are planning to take a group of international iGEM students and a group of host Mexican students to the COP13-MOP8. Those interested, please contact me directly at this email, so I can send you information of how to register in the student forum to coach the kids.

Warm regards,

10.2.e (as there are several 10.2.e in the on-line forum)

10.2.e .
Departamento de Biotecnología y Bioingeniería
TECNOLÓGICO DE MONTERREY
CAMPUS GUADALAJARA

Doc 15.

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Enlace intercampus: 10.2.e

From: 10.2.e @ufpe.br]
Sent: Sunday, May 8, 2016 8:51 AM
To: 10.2.e @bayer.com>
Cc: 10.2.e

Subject: RE: Synthetic Biology – visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

I fully agree with 10.2.e: we should not let the biotech opposition rooted at the

Doc 15.

CBD demonize Synbio and other technologies.

As stressed by most of you, a critical point in regulating "new technologies" is the loss of focus on the product: many scientists, regulators and – as expected – the biotech opposition, insist in discussing and embedding the technology in the regulatory framework. Moreover, once the right focus is regained, we still have to keep clear in our minds that regulations should be rooted on risk assessment (not on risk perception). A fundamental paper has just been published in Nature Botechnology:

Conko G, Kershen DL, Miller H, Parrott WA, 2016. A risk-based approach to the regulation of genetically engineered organisms. Nature Biotechnology 34: 493–503 doi:10.1038/nbt.3568

http://www.nature.com/nbt/journal/v34/n5/full/nbt.3568.html

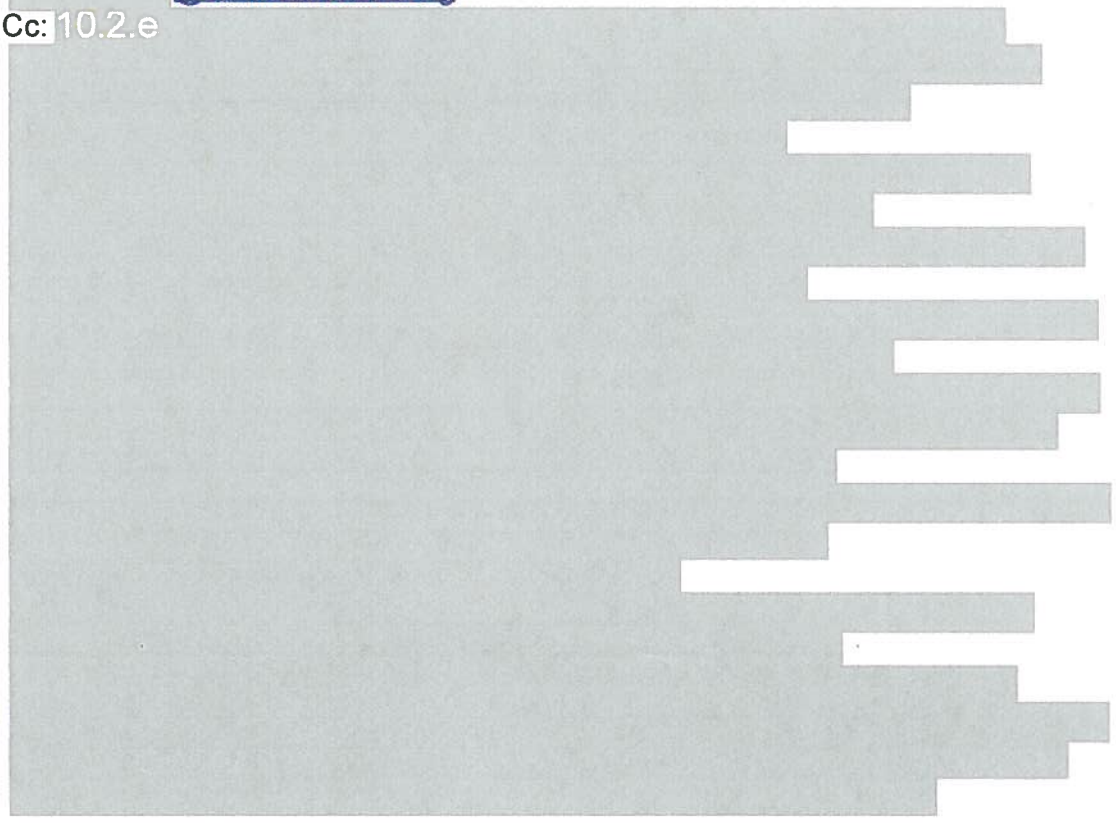
I suggest you should take some time to read it. If you don´t have access to the full paper, just send a note (10.2.e @ufpe.br).

Kindly

10.2.e

Department of Genetics/ Federal University of Pernambuco RECIFE Brazil

----- Mensagem original -----
De: 10.2.e @bayer.com>
Para: 10.2.e 10.2.e
@danforthcenter.org>
Cc: 10.2.e



Doc 15.

Enviadas: Sun, 08 May 2016 02:12:48 -0300 (BRT)
Assunto: RE: Synthetic Biology – visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

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Hi all,

I have been reading your messages and would like to weigh in on the gene drive and related gene/genome editing discussion. I am coming from the perspective of someone who has long battled with the very difficult, complex, unpredictable, long and enormously costly process of global regulatory clearance for the commercialisation of biotech crops. Very generally speaking, this process is based on the risk assessment framework set out by the Cartagena Protocol ([redacted]). This process has become so difficult it affects decisions about funding new biotech projects.

The SB discussions under the Convention on Biological Diversity have been driven by certain interest groups – they have pushed SB as a 'new and emerging' issue and they are seeking the development of a new international regulatory framework for SB that would fill all the 'gaps' that they believe exist in the current framework. According to them, these gaps include gene drives and gene/genome editing. [redacted]

In regard to gene/genome editing, we (green biotech industry) have long followed the new breeding technique (NBT) discussion globally, and there have been many opinions published

that some applications of gene/genome editing, including CRISPR, do not result in GMOs/LMOs and should not be regulated at all – this is often based on the resulting organism being the same as that which could be created using conventional breeding techniques.
Often people claim gene/genome editing is SB based on its inclusion in the 'opinion' documents of the three European scientific committees. [redacted] . In our view, [redacted]

Kind regards,

[redacted]
cid:C15DEDD5-288E-4312-857A-B6E1A5E2692F
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E-mail: [redacted]r@bayer.com
Web: www.bayer.com.au

From: [redacted]

Sent: Friday, 6 May 2016 4:57 PM
To: [redacted]
Cc: [redacted]

Subject: Re: Synthetic Biology – visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Dear All,

First of all my thanks to [redacted] for sharing his observations with the whole group, and for the thoughtful feedback from the others.

FYI: After the last updates I sent out, I received feedback from various colleagues, sometimes copied to few people on this list, and yesterday I realised that this resulted in 10 very interesting exchanges in small groups that would probably benefit the entire group. I will try highlight those discussions in this and next emails.

Doc 15.

Here my two cents contribution to this exchange on GD and SB.

Whether GD falls under SB depends on what we mean by GD and on the definition of SB.

Like 10.2.e, I dread the idea on yet another exhausting discussion on definitions, but given that 'falling under SB' may have policy and perhaps even regulatory implications, I think that we are well advised to give it a try, just to be prepared. Although we may not have to aim for a water tight regulatory definition, I believe that it will be important to identify the main characteristic(s) of SB.

NB: remember the debate on rDNA/GMO. From Asilomar 1975 to the Blue book in 1986 scientists managed to come to substantial consensus on the safety aspects, without having to resort to detailed discussions on definitions. However, when as of the mid-80s rDNA/GMO became regulated in more and more countries, definitions on rDNA/GMO did become necessary. The current discussion about the status of organisms developed through genome editing shows us that we would have benefited tremendously today if - in addition to the definitions -we would have some authoritative statements on the main characteristics of rDNA/GMO to help us figure out in which cases genome editing results in rDNA/GMO. For me, that main characteristic is the question whether the resulting organism possesses a novel genetic combination that goes overcomes natural physiological reproductive or recombination barriers (see the definition of the Cartagena Protocol).

Turning to the main characteristic(s) of SynBio: I very much share the observation of 10.2.e that we should first get clear how SB is different from for example genetically engineering.

As far as I have distilled from the earlier discussions, what sets SB apart are in any case the - interrelated - terms: "design" and "new systems/pathways". In this sense, introducing a Bt gene in corn would not be SB, while designing and implementing a pathway for the production of certain compounds in plants would be.

Looking with that perspective at GD: as 10.2.e said, a GD as such is not much more than a transgene that is inherited dominantly. Yet on the other hand GD can also be used to engineer entirely new systems (see her example), in which case it could fall under SB.

In short, i believe that it depends on the case at hand whether GD falls under SB.

Finally, there were several references to natural gene-drives: please send me some examples, preferably with documents or links, so that we can include that on the PRRI website.

Wishing everyone a great weekend!

10.2.e

On 5 May 2016 at 20:44, 10.2.e @danforthcenter.org> wrote:

I would like to understand this more fully myself, and the recent responses have prompted me to weigh in to try to gain that understanding from the group on this email thread. As I have mentioned previously in past conference calls, I struggle to see that what we are doing under

the activities we now call Synthetic Biology is qualitatively any different from what we were doing when we were genetically engineering things. We now have more sophisticated
and powerful tools, but to use an analogy, whether we are using a hand saw and hammer or a power saw and nail gun, we would be still doing carpentry. And if we say we are using engineering principles, what do we mean exactly, and are we saying we were not
doing so when were doing genetic engineering? What type of thinking were we not doing then that we are doing now? So with respect to gene drive, those constructs that drive through a population seem to me to be just newer implementations of the knowledge
and capabilities that have been developed in the fields of molecular biology and genetics, which have underpinned genetic engineering from the beginning. Whether transgene insertions that drive through a population (a characteristic of the gene combinations
inserted into a genome through genetic engineering techniques) are or are not a part of Synthetic Biology depends on what we agree Synthetic Biology is or even if it is an area of scientific endeavor that deserves a new name at all. Right now, I am reminded
of the fable about the blind men and the elephant.

10.2.e

On Thu, May 5, 2016 at 1:37 PM, 10.2.e (TGAC) 10.2.e @tgac.ac.uk> wrote:

I loathe to get into the defining Synthetic Biology argument and I very much fear that I might regret the contribution,
but the lack of clear definition is clearly problematic in this conversation. The question of whether gene drives are synthetic biology does not have a simple answer - a synthetic gene drive is a tool that is a product of synthetic biology. It's like many
tools that are the product of an engineering process: it can be used to engineer a new system or it can simply be used.

The logic behind this answer is that synthetic biology is defined as the application of engineering principles (e.g. standardisation, modularisation, modelling, predictive design and abstraction hierarchies etc.) to biology and biotechnology. Synthetic biology
is not limited to making changes to genomes since you can apply engineering principles to building with biological materials
in vitro as well as in a cell. The insertion into, or modification of DNA in living cells is, however, where most of the community is working at present. Since we are not yet advanced to a stage where we can consider ourselves as true engineers, synthetic
biology practitioners are mainly aiming to advance the science and technologies to enable the engineering of biology to be as predictable (and as easy/cheap/reliable/repeatable etc.) as possible.

While the successful invention of synthetic gene drive systems (and many other new biotechnolgies) may have required the application of engineering principles, it does not mean that the use of these tools in any other process is synthetic biology by default:
Synthetic gene drives can be used in, for example, classical biology experiments 'to observe what might happen. In most cases being discussed in this group, the aim is to use them to use them to

engineer a biological system as predictably as possible with predictive modelling done in advance to make a specific, desired outcome as certain possible. It's very hard to argue that this does not fall into the above definition of synthetic biology.

10.2.e

10.2.e

10.2.e

The Genome Analysis Centre

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Norfolk, NR4 7UH, UK

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Doc 16.

From: 10.2.e @bayer.com]
Sent: Sunday, May 8, 2016 4:23 AM
To: 10.2.e @itesm.mx>; 10.2.e @bayer.com>; 10.2.e @agricultura.gov.br>; 10.2.e @aphis.usda.gov>; 10.2.e @jcvi.org>; 10.2.e 10.2.e @rivm.nl>
Cc: 10.2.e
Subject: RE: Synthetic biology discussion starting within the RA AHTEG

Dear 10.2.e

In the AHTEG in Brazilia they had already decided that the RA AHTEG would write an outline for SB guidance, I said that we should wait for the outcome of SBSTTA and they accepted to postpone it till then. 10.2.g en 11.1 It will be finally up to the Parties at COP-MOP to decide if they want a guidance developed. 10.2.g en 11.1 10.2.g en 11.1

I urge all to contribute to the brainstorming online session on SB

Best regards / Cordialement / Saludos cordiales

10.2.e
10.2.e

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Web: http://www.bayer.be

From: 10.2.e @itesm.mx]
Sent: Sunday, May 08, 2016 6:50 AM
To: 10.2.e
Cc: 10.2.e

Doc 16.

Subject: RE: Synthetic biology discussion starting within the RA AHTEG

Dear 10.2.e

I agree with what you say. 10.2.g en 11.1 I agreed to moderate the synthetic biology on-line forum within the risk assessment AHTEG, because if I say no, they will appoint somebody else and continue anyway.

Maybe those able to participate in the Synbio on-line forum starting tomorrow can state so strongly and we (the moderating group) will make sure your opinions are recorded on the outline document.

Regards,

10.2.e

10.2.e
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Enlace intercampus: 80 432 2536

From: 10.2.e @bayer.com]
Sent: Saturday, May 7, 2016 11:31 PM
To: 10.2.e @agricultura.gov.br>; 10.2.e @itesm.mx>; 10.2.e @aphis.usda.gov>; 10.2.e @jcvi.org>; 10.2.e 10.2.e @rivm.nl>
Cc: 10.2.e
Subject: RE: Synthetic biology discussion starting within the RA AHTEG

Dear 10.2.e

I was also at SBSTTA and agree with 10.2.e. Apart from the paragraphs in the final document referring

to a 'coordinated approach' between the AHTEGs, I do not recall an agreement about that AHTEG developing guidance/'outline' for guidance. The Secretariat did explain that the RA AHTEG has a mandate to work on synthetic biology, and that SBSTTA cannot directly request that AHTEG to do anything because it is a body under another treaty, but there is a 'line of communication' between them, and that AHTEG is waiting for the go-ahead from SBSTTA. The Secretariat also pushed for inclusion of the 'coordinated approach' language. 10.2.g:en 11.1

Kind regards,

10.2.e
10.2.e

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Doc 17.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: RE: Synthetic Biology - current online discussion
Date: 18-05-2016 15:41

I echo 10.2.e 's words and gently invite everyone to participate. We have 4 days left. So far there is almost unanimous agreement, except for one intervention, of what the RA & RM AHTEG should do (or not do) regarding synthetic biology.

The outline we need to prepare needs to reflect the opinion of experts. You are those experts.

Kind regards to all,

10.2.e

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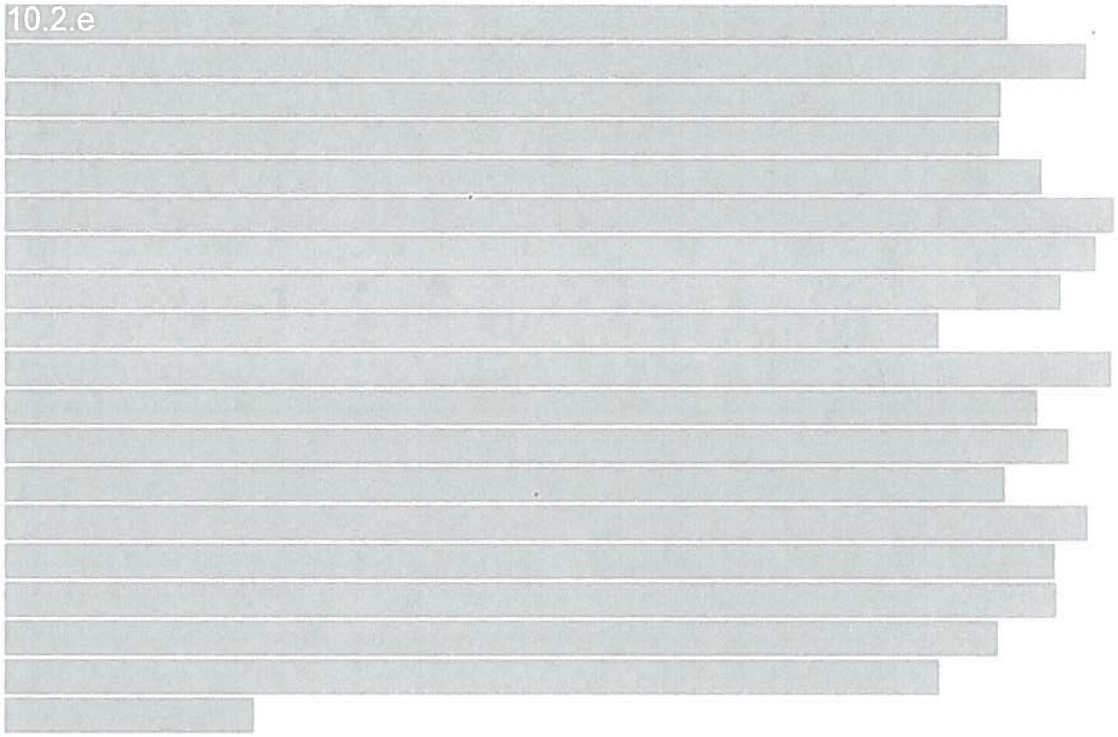
From: 10.2.e @bayer.com]
Sent: Tuesday, May 17, 2016 10:00 PM
To: 10.2.e
Cc: 10.2.e

Doc 17.



Subject: Synthetic Biology - current online discussion

Dear 10.2.e and all,

I would just like to repeat 10.2.e's encouragement to everyone in this group to participate in the current online forum in the Risk Assessment and Risk Management Forum (not the Synthetic Biology Forum – make sense?!).

The discussion will end this weekend and the thread can be found here: http://bch.cbd.int/onlineconferences/onlineconferences/forum_ra/discussion.shtml?forumid=17465&threadid=7834#7860

Even if you are not a registered participant yourself, you may have a colleague that is. This list is here: http://bch.cbd.int/onlineconferences/participants_ra.shtml

As noted in 10.2.e's first message (as moderator), the AHTEG on Risk Assessment and Risk Management intends to develop an "outline for guidance" on "risk assessment of organisms produced through synthetic biology". The ultimate intention is to develop SB-specific "guidance" that will form part of the "Guidance on Risk Assessment of LMOs" (also known as the "Roadmap"). [This Guidance was the subject of the online discussion held immediately prior to the current one on synthetic biology and you can find the latest version of it attached to that discussion ("Feedback on the Proposed Revisions to the Guidance" http://bch.cbd.int/onlineconferences/onlineconferences/forum_ra/discussion.shtml)]

There have been some good posts in the discussion so far, especially from Brazil (#7861) and the UK (#7866). In particular, the UK provided an example of a risk assessment that was conducted for an LMO that some assessors considered to be SB, and their existing approaches to risk assessment were adequate.

Kind Regards,

10.2.e
10.2.e

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Change of address from ***3rd June 2016****:* 10.2.e

From: 10.2.e
Sent: Thursday, 12 May 2016 10:19 PM
To: 10.2.e
Cc: 10.2.e

Subject: Re: Synthetic Biology – visions of the future SYNENERGENE Forum 24-25th June 2016 Amsterdam

Dear All,

Going through all these emails on Synthetic Biology, I realise again how fortunate it is to have such a variety of experts exchanging insights and articles.

I concur with 10.2.e's observation that the SB discussions under the CBD have been driven by certain interest groups that have pushed SB as a 'new and emerging' (i.e. 'threatening') issue and that they are seeking the development of a new international regulatory framework for SB that would fill the 'gaps'. I believe that for the foreseeable future SB applications make at one stage or another use of GMOs, and that consequently the current national biosafety systems and the Biosafety Protocol are sufficient to assess case by case whether there are risk concerns.

I could therefore not agree more with 10.2.e's call that we best take care in the language

we use, since this can unintentionally have the effect of separating these technologies/applications from what the existing framework covers.

We can in this respect learn important lessons from the current discussions about NBTs in relation to the definitions of LMOs, GMOs, GEOs, etc, which is being discussed in quite a number of articles.

My thanks to 10.2.e for alerting us to the article of Conko et al "A risk-based approach to the regulation of genetically engineered organisms", which also touches on many of the questions in relation to NBT and GMO.

Thinking about 10.2.e's call to be precise with language, I take this opportunity to summarise some general thoughts that I shared in a similar discussion about the EU regulations for GMOs:

1) It is very important distinguish between what is taken into consideration in **risk assessment** and what is taken into consideration for the '**regulatory trigger**' (i.e. which organisms fall under the regulations and therefore require prior risk assessment), because those are two very different notions.

2) As to the regulatory trigger, it is very important to distinguish between the regulatory trigger of the **current regulations** and what **future regulations** might ideally look like.

The **current regulatory triggers** vary from system to system, but in most cases focus on organisms with inheritable novel traits, whereby in many cases the focus is on novel genetic combinations that overcome natural physiological reproductive or recombination barriers.

The way in which the definition of LMO in the Biosafety Protocol is designed means that the technique is a 'trigger' to check whether novel genetic combinations are obtained, yet the use of the technique in itself does not necessarily lead to an LMO.

I interpret the EU regulatory trigger in the same way, and am very pleased that an increasing number of authorities is following a similar interpretation, which means for example that some uses of ZFN or CRISPR would result in GMOs and other uses would not.

With regard to the question what **future regulations** might ideally look like, it is encouraging that many governments are reviewing and evaluating their regulatory approaches, as it seems that the original objectives of the regulations are not being fulfilled (in general, the objectives include using the technology in a safe manner while fostering innovation). For me, key questions in preparing amendments or new regulations are: the scope and regulatory trigger, the regulatory mechanism (e.g. with our without authorisation systems), mechanisms for simplified procedures and exemptions.

After this I will go through the exchanges about the current online Forum on RA of Synbio organisms, which is being moderated by 10.2.e. I very much hope that everybody will find time to contribute to that debate (http://bch.cbd.int/onlineconferences/onlineconferences/forum_ra/discussion.shtml?forumid=17465&threadid=7834#7860).

NB: Please note that this is an online debate in the context of Risk Assessment under the Cartagena protocol.

Regards to all!

Doc 17.

Doc 18.

From: 10.2.e
To: 10.2.e [redacted]

Subject: Discussions on SynBio and RA under CBD and CPB
Date: 07-07-2016 21:05
Attachments: bsrarm-ahteg-2016-01-01-add1-en.doc

Dear All,

I follow up on our earlier communications on the Synthetic Biology (SB) and risk assessment (RA) discussions under the CBD and CPB.

As you will see, in the meantime several more people have been added to this email-list. In fact, given that recent discussions were both about RA and SB, I have combined the two email lists this time.

Interestingly, what started as a general discussion among the people on this list two months ago, gradually developed into many parallel subdiscussions in smaller groups. At any one moment, there were at least 3 discussion threads in small groups on a whole range of topics.

Given that much of what was shared in those discussions may be of use in preparing for the COP and the MOP, I have tried to briefly summarise those comments below.

1For an **effective participation in the CBD and CPB process**, it is best to participate in the intersessional activities **as well as** in the MOPs and COPS.

2) Despite an understandable fatigue about the on line discussions and AHTEGs, **continued participation remains important**, because that way the contributions are 'on the record', and one gets a taste of the type of discussions at COP and MOP.

3) The last rounds of on line discussions on RA and SB

+ Great appreciation that 10.2.e agreed to moderate despite her busy schedule and for the way she moderated, which helped clarify some procedural issues.

+ There was a division between those who advocate additional guidance for RA of SB and those who believe that a decision on additional guidance is best taken on the basis of concrete examples of releases of organisms developed through SB. The arguments of those who advocate additional guidance for RA of SB are mostly related to aspects that are not specific to SB (e.g. comparators).

+ Interesting was that sometimes it seemed that the discussion had shifted from the need for additional guidance based on Annex III to modifying Annex III itself. Some parts of the Secretariat's background document "Doc 1 Secretariat Synbio RARM", give a similar impression, e.g.: " that risk assessment methodologies may need to be updated and adapted for LMOs developed through synthetic biology".

+ As in earlier on-line discussions, comments were made related to a particular interpretation of the definition of LMO. For example, reference was made to difficulties to detect single nucleotide changes obtained through genome editing. Apart from technically incorrect (as 10.2.e nicely illustrated), the underlying assumption of the comment is that such organisms fall under the definition of LMO. Several of us discussed that this incorrect, because a single nucleotide change is not a novel combination of genetic material that "overcomes natural physiological reproductive or recombination barriers". In short, the mere use of a certain technique in itself does not per se result in a LMO/GMO. This issue relates to the broader discussion on NBTs that is ongoing in many countries. It is not unlikely that this topic also comes up in MOP and/or COP.

+ These last also showed again that there is still confusion about the procedures of on-line discussions and AHTEG. For example, while on the one hand the AHTEG is a 'Party driven process', meaning that in the case of voting only the representatives of Parties can vote, while on the other hand participants participate in the 'personal capacity'. A new procedural aspect that came up was the question whether in the online discussions the participants actually 'vote', for example on whether or not additional guidance is needed. As some of us discussed, voting is not consistent with the nature of online discussions which are supposed to be an 'innovative way of collecting data and views'.

4) The AHTEG on Risk Assessment and Risk Management, 25 - 29 July 2016 - Mexico City, Mexico.

Attached is the annotated provisional agenda. Some key elements:

Introduction:

COP7 invited Parties, other Governments etc to test or use, as appropriate, the Guidance in actual cases of risk assessment, and a mechanism for revising and improving the Guidance on the basis of the testing, and to produce an improved version at **COP8**.

- Further, COP7 instructed that an attempt should be made to take into account the topics prioritized by the AHTEG for the development of further guidance.

Substantive issues to be addressed by the July AHTEG

a) Review draft changes in response to the outstanding issues and remaining comments provided through the testing and the Online Forum.

b) Development of an outline on RA of LM fish

c) Development of an outline on RA of LMOs produced through SB.

Note: despite that the majority of contributions in the on-line discussions suggested that developing additional guidance for SB was premature, this document refers to the

development of an outline on RA of LMOs produced through SB, as if the conclusion was already drawn that additional guidance is needed, which is a conclusion that can only be drawn by the MOP.

5) MOP8, COP13, MOP2, - 4 to 17 December 2016.

It is time to start looking ahead to the upcoming meetings: MOP8 (Biosafety Protocol on Biosafety), COP13 (Biodiversity Convention), MOP2 (ABS Protocol), which will be held in parallel from 4 to 17 December 2016, in Cancun.

The fact that these meetings are held in parallel for 2 weeks draws heavily on travel budgets and the ability to get people to participate that long, but it also offers opportunity to connect the dots between these three, related processes.

PRRI is preparing for its members an 'extended annotated agenda', which gives for the substantive agenda items some background and history, key elements of discussion, and where relevant, linkages with similar topics under the other two fora.

In collaborating with like mined organisations, PRRI will organise a preparatory meeting the weekend before the three meetings, probably on the Saturday.

10.2.e is the driving force behind the initiative to bring young scientists and students (e.g. iGem participants) to the COP and MOPs.

Hoping that this summary of discussions is helpful, I wish you all a good end of the week and a good weekend!

10.2.e

Doc 20.

From: 10.2.e
To: 10.2.e
Subject: Re: COP MOP 8 and position of other parties
Date: 19-10-2016 19:37

Thanks –

Yes, please send the Council conclusions so that I can have a look at those before the KL workshop.

FYI I attach a PRRI MOP8 background that give some context and background to the CPB, MOPs and MOP8 agenda items. Not for distribution.

This first version aims to help PRRI members to find their way around in the topics and documents. The next version will have more detail and positions on each of the topics.

Cheers

10.2.e

On 19 October 2016 at 17:59, 10.2.e @rivm.nl> wrote:

> Dear 10.2.e
>
> Great, thanks for the information! We would really appreciate feed back from the regional meetings.
> For the EU the main discussion sofar was on a) the endorsing and b) on further guidance.
> I made an inventory among the experts and it seems that 10.2.g en 11.1
>
> 10.2.g en 11.1
>
> I will send you the Council Conclusion, which were adopted last Monday. I assume they are public.
>
> Met vriendelijke groet,
> 10.2.e
>
> -----10.2.e schreef: -----
> Aan: 10.2.e @rivm.nl>
> Van: 10.2.e
> Datum: 10/19/2016 05:24PM
> cc: 10.2.e
> Onderwerp: Re: COP MOP 8 and position of other parties
>
> Hi 10.2.e
>
> Thanks – very reassuring to know you are in the lead of the EU position on RA.

You can probably guess the PRRI position on endorsing the guidance and attached is the GIC position on RA. I am not certain whether you can distribute this version, but I trust GIC is fien with you having this.

As regards positions of Parties, in the next three weeks there will be 4 regional prep meetings, after which we should be able to tell you more:

- 24-26 Oct: Asia (see attached programme)

- 26-27 Oct: Africa

- 7-10 Nov: CEE / Central Asia

- 10-11 Nov: Grulac

I will attend the one in Asia and the one in CEE/Central Asia, 10.2.e will attend the one in Africa and I hope that 10.2.e will attend the one in Costa Rica. I can send you an update from KL.

What do you expect the EU position to be on a) endorsing, b) more guidance, c) the suggestion of the CBD Sec to become some sort of capacity building agency?

Cheers

On 19 October 2016 at 15:44, 10.2.e @rivm.nl> wrote:

> Dear all,
>
> I hope you are all doing fine!
>
> I have a question to all of you, hope you help me out.
> As you know I am the 'lead' for the EU position on risk assessment and risk management for COP MOP 8. My co-leads are 10.2.e from UK and 10.2.e from Sweden.
> As usual, the EU and its member states are quite divided when it comes to this topic, especially about the endorsement of the guidance and on further guidance on organisms obtained by synbio.
> Therefore we (lead and co-leads) like to get an indication of the positions of the other parties in order to come to a realistic position of the EU.
> 10.2.g en 1.1.1
>
> I know that 10.2.e already discussed with 10.2.e, so this info I already have.
>
> Since you are all involved in testing and working with other Parties on risk assessment, you are the ones who are best informed and are most experienced in this area.
> So our question is if you already have an indication of positions from other Parties on the two main topics (endorsement of guidance and further guidance on synbio) to be discussed?
> If not, can you advice me on which parties to contact to get a good view of other positions?
> Any suggestions are welcome!
>
> Thansk a lot,
>
> Kind regards,
> 10.2.e

10.2.e
GMO Office
RIVM/VSP
PO Box 1 3720 BA Bilthoven
The Netherlands

Phone number: 10.2.e or 10.2.e

Doc 21.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: Re: COP MOP 8 and position of other parties
Date: 20-10-2016 10:00

Thank you, 10.2.e
This is really helpful. 10.2.g en 11.1
Let's keep in touch.

10.2.g en 11.1 I am part of the Netherlands-Slowakia-Malta trio presidency, meaning I can only facilitate the process. 10.2.g en 11.1

10.2.g en 11.1 Having positions of other parties, based on good reasons, helps a lot.

Met vriendelijke groet,
10.2.e

10.2.e ---19-10-2016 19:34:15---Hi 10.2.e (and 10.2.e), Good to hear from you!!

From: 10.2.e @umn.edu>
To: 10.2.e @rivm.nl>,
Cc: 10.2.e 10.2.e @estelconsult.com>
Date: 19-10-2016 19:34
Subject: Re: COP MOP 8 and position of other parties

Hi 10.2.e (and 10.2.e),

Good to hear from you!!

At the moment, Brazil is one 'party' that I know has been working on these questions. Although I'm not exactly sure what their 'official' positions will be, I think they are generally opposed to the guidance and definitely opposed to further guidance on synbio. I've had a couple messages from 10.2.e , who was with us at the February meeting in DC, and I know she is working on these issues in Brazil. I encourage you to get in touch with her, if you haven't already been. 10.2.e email: 10.2.e @agricultura.gov.br.

I think it might also be good to check in with 10.2.e in Mexico, although I am sure Mexico has mixed opinions about the guidance similar to the EU. 10.2.e email: 10.2.e @conacyt.mx

If you want to explore the situation in India, you could also try 10.2.e , who was at our meeting. 10.2.e is a good person to give you an informal update. I think she will know what is going on there.
10.2.e @nic.in

I want to say it would also be good to know Japan's position, but I'm not

sure who you could talk to. If you recall, [redacted] presented for Japan at our meeting. Maybe [redacted] knows someone you could talk to there, at least to get a feel.

I am curious for updates from all of these places as well.

As [redacted] mentioned, I will be attending the Africa regional meeting. (Keeping a low profile, but I will be there.) I do not know where Africa as a group is going to fall on these issues. I am hopeful that they will concede that it is not useful pr practical and should not be endorsed, but there are mixed feelings there as well, for sure. It would be HUGE if they would reject it, but I am not holding my breath.

At the last RA&RM AHTEG meeting in July in Mexico City, there were a number of AHTEG 'party' members, including from South Africa, Kenya, India, and Croatia, who expressed the opinion to me personally that they do not like the guidance and do not intend to use it, but they are tired of working on it and think it should just be endorsed and move on. I was sad to hear this. I belive the gentleman from Japan is opposed, but he is painfully quiet.

Among those is favor, [redacted] from Finland and [redacted] from Mexico and [redacted] from Maldova and [redacted] from China are all staunch supporters of the guidance, and these were the people in the subgroup which led the process for revisions. But these people's opinions are not necessarily the opinion of their party (as you know). [redacted] strongly influenced the revision process, as the de facto 'leader' of that subgroup.

No surprise, my own opinion is that the guidance should absolutely NOT be endorsed. I think if it is endorsed by the MOP, it will become a serious 'roadblock' for parties who do not have experience, rather than a 'roadmap'. This will be an utter shame. I am soooo hoping that the EU will somehow decide not to endorse it. It would make all the difference.

I have been working on an 'opinion' about this, which I will share (for what it is worth) with all of the participants from the February meeting sometime soon.

You might have noticed that I still have not produced any sort of publication from our meeting... yet. The real reason is that I just haven't had time. But I do still intend to, and if the guidance DOES get endorsed (and I have a terrible feeling that it might), then I think a publication describing its deficiencies might be more important than ever.

More coming soon.
Cheers,
[redacted]

Doc 22.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: Re: COP MOP 8 and position of other parties
Date: 21-10-2016 08:26

Hi 10.2.e

True - question is indeed how to get those messages across.

In fact, it is largely for that purpose that we organise the regional MOP preparatory meetings, i.e. to have time to alert people to what is actually in the MOP documents (e.g. the Guidance) and what the draft decisions (e.g. endorsing the Guidance) would imply.

As regards what is actually in the guidance: as mentioned, I believe we should get some quotes of the guidance to illustrate how it sends (novel) risk assessors in endless circles, and quotes that are simply entirely unclear. I am working on that but love to get the input of you three on that. In addition, I very much hope that you can still before the KL meeting get to me the key flaws we identified in our DC meeting in January.

As to the proposed endorsement, we should discuss what this means in legal terms but above all what it will mean in reality:

- the to be expected push to incorporate this guidance in national guidance or regulations,

- the endorsement making it inevitable that there will be even more guidance, and

- as 10.2.e said, the troubling notion of this Guidance being used by the Secretariat in training and capacity building.

As we have seen with MOP7, if we discuss this well in the MOP prep meetings, this certainly has a positive effect on the discussions in MOP itself.

Cheers

10.2.e

On 20 October 2016 at 15:24, 10.2.e @umn.edu> wrote:

> What 10.2.e said here is what I absolutely think:
>
> there seems indeed be with some folks a fatigue and a wish to simply get rid of this. What we need to explain is that by endorsing we are not getting rid of it, on the contrary. What we also need to explain what endorsing would mean in practice: i.e. governments being pressured to incorporate it in their legislation.
>
> Just don't know how to get this message across.
> 10.2.e
>
> On Thu, Oct 20, 2016 at 2:00 AM, 10.2.e 10.2.e wrote:
>
> > Hi 10.2.e,

Regret that you cannot be in person in the Costa Rica meeting, but good that you can at least participate via video. We hope that 10.2.e will be able to participate.

The Council conclusion is indeed depressing, and there seems indeed be with some folks a fatigue and a wish to simply get rid of this. What we need to explain is that by endorsing we are not getting rid of it, on the contrary. What we also need to explain what endorsing would mean in practice: i.e. governments being pressured to incorporate it in their legislation.

Cheers

10.2.e

On 20 October 2016 at 08:49, 10.2.e <10.2.e @estelconsult.com> wrote:

> Dear 10.2.e
>
> Yes, I will be participating in the Costa Rica meeting by videoconference. I am a bit concerned that this time round some countries appear to be tired and we will end up with endorsement of the guidance. However, there are still many countries that are very concerned about the impact that an endorsement may have on their regulatory system, these are mainly Japan, Brazil, Colombia, Honduras, Philippines, Paraguay and India. I believe these countries will oppose endorsement, but they have not yet finalised their country positions. I can put you in contact with representatives in these countries if you wish to liaise directly with them.
>
> I was quite concerned when I saw the council decision on this, it looks like you have a difficult task ahead. I am happy to help you wherever you think I can.
>
> Best regards
>
> 10.2.e
>
> 10.2.e
>
> Estel Consult Ltd
>
> Tel: 10.2.e
> Mobile: +10.2.e
> Skype: 10.2.e
>
> www. Estelconsult.com

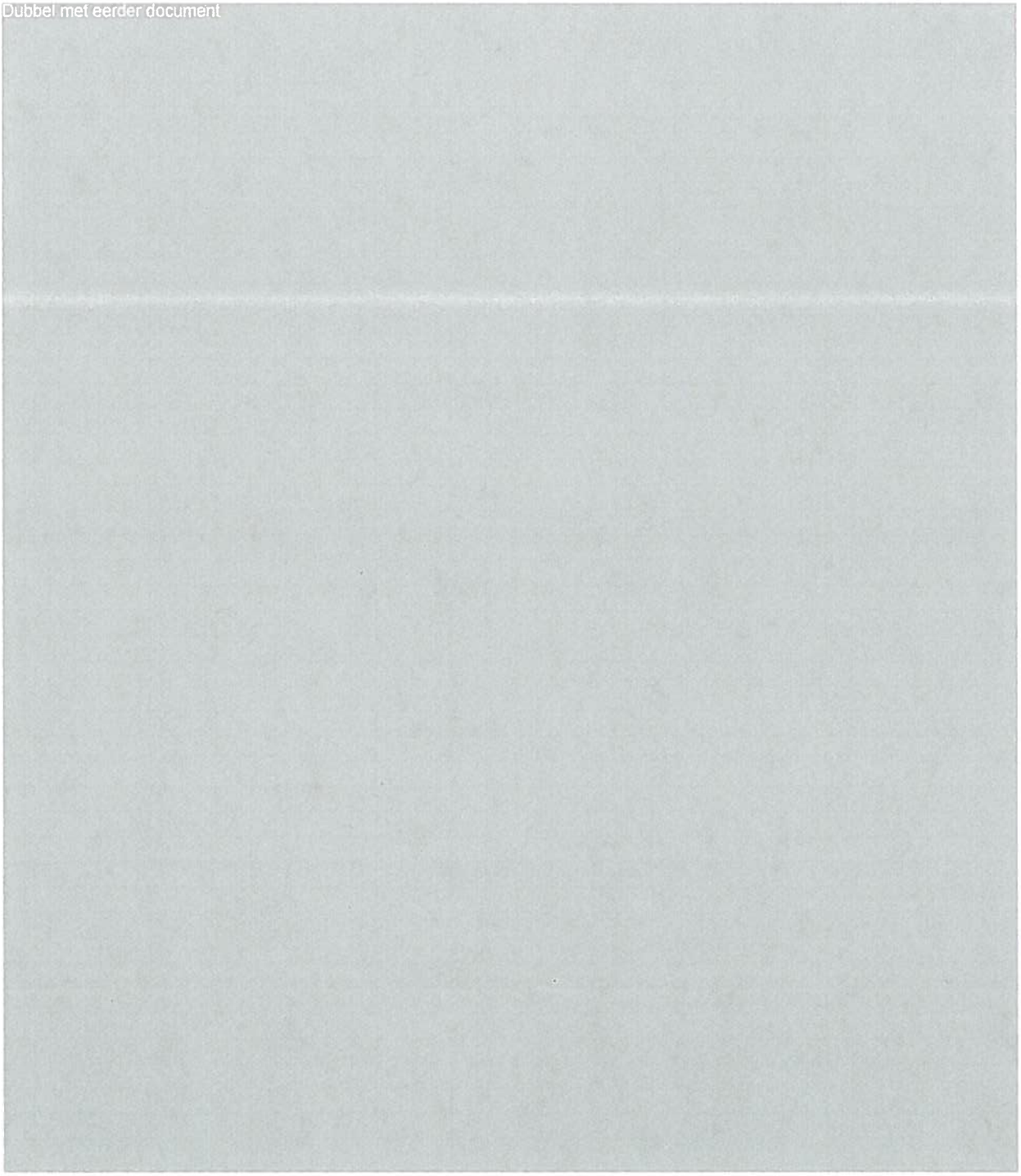
Doc 23.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: Re: COP MOP 8 and position of other parties
Date: 21-10-2016 08:41

Dear 10.2.e,
Thanks you for your anwer. 10.2.g en 11.1

I understand the message and try to get it along in the position paper that I am writing.

Met vriendelijke groet,
10.2.e



Doc 24.

From: 10.2.e
To: 10.2.e
Subject: RES: COPMOP8
Date: 01-11-2016 08:04

Dear 10.2.e
Thanks a lot for you opinion and the reasoning behind it. And I understand this may not be the final Brasil position.
For me, this is very useful for the discussion with the EU member states. 10.2.g en 11.1

Next Friday we will have our first discussion on the position paper on risk assessment, and I can indicate to them (without naming Parties) that there are a number of Parties who are not ready to endorse the Guidance and -more important- why this is the case.
Yesterday I heard form 10.2.e that also the African and Asian countries (at their recent their regional meetings) were not happy at all with the Guidance. They thought the word 'Guidance'was actually too strong.

Thanks again!

Met vriendelijke groet,
10.2.e

10.2.e @agricultura.gov.br> schreef: -----
Aan: 10.2.e @rivm.nl>
Van: 10.2.e @agricultura.gov.br>
Datum: 10/31/2016 08:44PM
Onderwerp: RES: COPMOP8

Dear 10.2.e

Thank you for your message.

I can imagine how difficult it is to find a common position with so many member states. Here in Brasil we are already having problems only dealing with different ministries....

I can tell you our position as Ministry of Agriculture but not as Brasil because we will have our preparatory meetings with other ministries on November. For us at MoA:

- we do not agree with the endorsement of the RA/RM Guidance: mainly because we think the RA AHTEG concentrated their activities in adding other topics (boxes) in the Guidance and proposing other guidances (fish and SynBio) instead of fixing the RoadMap. We basically have the same document we had two years ago, ´improved´ with boxes, this is the feeling of some here. We think the mandate was clear that the main RA AHTEG task was to review the RoadMap and this was not done accordingly. Also the review process was not really shared with the on line forum as it should be. The on line forum is the opportunity of more experts from more countries to colaborate with the document and only 2 rounds were dedicate to the Guidance revision and not in the most productive way.

- we do not agree with SynBio Guidance at this moment: there is not one technical justification for this Guidance, for example the RoadMap was never tested with a SynBio organism to show that is not applicable. The decision about SynBio Guidance was taken by the RA AHTEG before the Parties answer the Secretariat notificiation about new topics and that is contrary to the last COP-MOP decision. The coordinate approach between RA and SynBio AHTEG (as written in the SBSTTA Recommendation) is not happening as the SynBio draft guidance was made entirely by the RA AHTEG. The opinions in the on line forum about the lack of necessity of a SynBio Guidance and the topics in the draft doc were completely disconsidered at the RA AHTEG face-to-face meeting.

At the end I think at MoA our feeling is that the lack of transparence and the decisions taken by a small group are jeopardizing the entire process for too long.

When I have our final Brasil decision I will let you know.

Sincerely,
10.2.e

Auditora Fiscal Federal Agropecuária
Unidade Técnica Regional Agropecuária em Viçosa - UTRA-VIÇOSA/SFA-MG
Ministério da Agricultura, Pecuária e Abastecimento - MAPA
Tel.: 10.2.e

De: 10.2.e @rivm.nl]
Enviado: quinta-feira, 27 de outubro de 2016 10:04
Para: 10.2.e
Assunto: COPMOP8

Dear 10.2.e

I hope you are well!
I would like to bother you with a question, if you don't mind.

As you may know, I am -as the 'lead'- responsible for drafting the EU position on agenda item 11, risk assessment and risk management. As you may also know, the member states of the EU are quite divided on the topic of RA/RM.
10.2.g en 11.1

About our position: it seems that 10.2.g en 11.1

The EU is very divided on further guidance on synthetic biology

To come to a final EU position, it is important to know the position of other Parties and the underlying reason why they came to this position.
My question is: can you give an indication of the position of Brazil on endorsement of the guidance RA/RM and on further guidance on synthetic biology?
This would help me a lot.

Thanks in advance and hope to see you in Cancun.

Kind regards
10.2.e

10.2.e
GMO Office
RIVM/VSP
PO Box 1 3720 BA Bilthoven
The Netherlands

Phone number: 10.2.e or 10.2.e

Doc 26.

From: 10.2.e
To: 10.2.e
Subject: Re: Risk assessment and management COPMOP8
Date: 06-11-2016 16:06

Dear 10.2.e
I am very grateful for your extensive answer which includes very good arguments not to endorse the Guidance. 10.2.g en 11.1

10.2.g en 11.1

Last Friday we had an EU coordination meeting and for sure the EU will go for endorsement. Even though I included in our draft position paper the very valid reasons of other Parties not to endorse. 10.2.g en 11.1 . As you know we have our own Guidance of EFSA, so we do not have to use the Guidance. 10.2.g en 11.1

As I indicated before, reasons for endorsing are that we want to give a 'positive' signal, it has been 'much work', and we have to 'move on', it is a living document and some member states think the guidance is improved. We are still collecting arguments why we are so positive :).

I will not use your information about Mexico, but it is good to know to put things into context. I am in contact with 10.2.e from Mexico, and with 10.2.e from Brazil and receive information from them directly.

I also will arrive December 2 and looking forward to meet you there.
Also good for you to know that I am in regular (informal) contact with 10.2.e .

Thanks again and have a good weekend Valt buiten reikwijdte verzoek

Met vriendelijke groet,
10.2.e

10.2.e
GMO Office
RIVM/VSP
PO Box 1 3720 BA Bilthoven
The Netherlands

Phone number: 10.2.e or +10.2.e

-----10.2.e schreef: -----
Aan: 10.2.e @rivm.nl>
Van: 10.2.e
Datum: 11/04/2016 03:42PM
Onderwerp: Re: Risk assessment and management COPMOP8

Dear 10.2.e

I understand totally about being swamped by meetings and many commitments. Let's try then to communicate by email. Here are some points you may want to consider, to understand the Latin American context:

1. We are aware about split positions in the EU regarding endorsing the guidance, that mirrors what is happening in countries with economies in transition like Mexico and Brazil. Heads of delegations of Brazil and Mexico will be diplomats that will try to keep a "middle road" and everyone happy (scientists and experiences risk assessors and environmental advocates).

2. As delegates from a small developing country (Honduras) we are aware of the need for countries that need to adopt new and more sustainable technologies, to have coherent biosafety systems. For countries that have little expertise in biotech/synbio risk assessment and biosafety in general, the Guidance in its current state is "not useful or practical" and very dense to understand and implement by inexperienced risk assessors. This will be even more so when the guidance gets translated into Spanish and terms like "risk"are translated as "danger" (as it has been in official documents in the past)

3. Adopting the Guidance for countries that are still developing their biosafety systems and have never approved an LMO, will achieve the important purpose of "advancing" with an issue, and it will give parties the impression (on paper) that they are moving forward. Thus politically, it is important to show "progress" and parties will likely follow the lead from the Secretariat to endorse the Guidance. I fear most countries will vote in favor of endorsing the Guidance.

4. However, in real situations of having to assess a risk assessment dossier, adopting the methodology of the Guidance will be difficult and cumbersome for inexperienced regulators, because the risk assessment approach used by the developers in preparing the dossier, and that used by regulators to assess it, will be different.

Regulators (afraid to make mistakes) will probably stop applications if they don't find a coherent and fluid way to evaluate risk assessment dossiers presented by industry or small companies that will follow a different approach. This is what we found during the "testing of the guidance" in Honduras. The end result will be that useful technologies (like adopting GM maize for managing drought or insect pests in tropical areas) will be stopped at the stage of evaluating the risk assessment dossiers.

5. Countries like Mexico that may endorse the Guidance will never have to use it, as they have more robust methods to assess risk already in place, that follow international standards and are similar to approaches used by the developers who present dossiers to the Government.

Please note that I currently live in Mexico and I am very familiar with the Mexican biosafety system, as I participate actively in several groups and committees. Mexico, like the EU is also split between scientists and experienced regulators who reject the Secretariat;s Guidance and those from environmental agencies who promote it (10.2.e , 10.2.e). Mexico is host to the COP-MOP and being "politically correct" will probably have to endorse the Guidance to maintain a good "green image". Many other countries will follow Mexico's lead, without having robust alternative systems in place.

6. The Guidance may become part of many small countries biosafety legislation in the future, and will have to be implemented by the successors (next generation officials) of those who voted to adopt it in the first place in 2016. In other words, taking decisions is easy; living with the consequences of bad decisions is hard.

Please keep this comments about Mexico to yourself, as they are a little volatile and the reason I would have preferred to make comments verbally on the phone.

When do you arrive in Cancun? I am helping 10.2.e and the PRRI delegation with logistical aspects and will be in Cancun on Dec. 2. We will have a preparatory wrokshop for PRRI and ISAAA delegates on Saturday 3 that will also be attended by the student group (about 20)

Doc 26.

I am organizing.

I hope this gives you some idea where we are.

Best regards,

10.2.e

(P.S.I am not using my institutional university address for now, as I
am on sabbatical to concentrate on other issues like the COP-MOP)

On Fri, Nov 4, 2016 at 12:57 AM, 10.2.e @rivm.nl> wrote:
> Dear 10.2.e, Thanks a lot! I hope I have not spammed you with email, because
> I received an error message when sendinfg my mail to you regular email
> adress.
> I am sorry to say that I do not have time to call, because today there is an
> EU coordination meeting, saturday is fully booked and next week I am in
> Parma for an EFSA meeting.
> Maybe we find some time the week after that., than I also have some more
> info about the position of the EU and other Parties, since I am contacting a
> number of them?
>
> Thanks again,
> Kind regards,
> 10.2.e
>
> Delivered to you by RIVM Mobile environment.
>
> _____
> From: 10.2.e
> Sent: 4 nov. 2016 06:35
> To: 10.2.e @rivm.nl>
> Subject: Re: Risk assessment and management COPMOP8
>
> Dear 10.2.e
>
> Thanks for your message. I have been busy all day, so apologies for not
> replying earlier.
>
> May I suggest we have a conference call and speak this over the phone? I
> travel to IICA's preparatory meeting for Latin America on Tuesday 8 , so I
> wonder if you are free tomorrow or Saturday.
>
> Hondura's position is not to endorse the guidance, as we feel is still very
> deficient for inexperienced risk assessors and the testing of the guidance
> we did a few years ago showed this. Furthermore, there are other ERA guides
> available that we find more useful than the one developed by the AHTEG.
> Honduras has been invited to lead some of the sessions on this topic during
> the IICA meeting next week and share our position with other Latin American
> countries.
>
> Risk assessors in Honduras have been trained by USDA and other experts from
> Argentina, Brazil and Mexico and not by Genok like other regulators
> frommany countries have, thus, we have different views on what we look for
> in an ERA.
>
> My sense is that Mexico may endorse the Guidance as they are hosts for this
> MOP and expected to do so. The Mexican delegation is also split on the
> decision and "political correctness" other than technical sense or
> scientific rigour may prevail.
>
> Please let me know if you are available to speak tomorrow.

> My phone is 10.2.e . We can also skype.
>
> Best regards,
>
> 10.2.e
>
>
>
>
>
> On Thu, Nov 3, 2016 at 4:16 AM, 10.2.e @rivm.nl> wrote:
>>
>> Dear 10.2.e
>>
>> I was suggested to contact you by 10.2.e , who I know very
>> well.
>> I hope you don't mind if I bother you with a question?
>>
>> I do not think I introduced myslef to you before: I work as a senior risk
>> assessor and governmental expert in the GMO Office at a governmental
>> institute in the Netherlands. 10.2.e was my former colleague.
>> I am also active at the European and international level with respect to
>> GM plants and their environmental risk assessment.
>> At the moment I am -as the 'lead'- responsible for drafting the EU
>> position on agenda item 11, risk assessment and risk management. As you may
>> also know, the member states of the EU are quite divided on the topic of
>> RA/RM.
>> 10.2.g en 11.1
>>
>> About our position: 10.2.g en 11.1
>> The EU is very divided on further guidance on synthetic biology
>>
>> To come to a final EU position, it is important to know the position of
>> other Parties and the underlying reason why they came to this position.
>> My question is: can you give an indication of the position of Honduras on
>> endorsement of the guidance RA/RM and on further guidance on synthetic
>> biology?
>> This would help me a lot.
>>
>> Thanks in advance and hope to see you in Cancun!
>>
>>
>> Met vriendelijke groet,
>> 10.2.e
>>
>> _____
>> 10.2.e
>> GMO Office
>> RIVM/VSP
>> PO Box 1 3720 BA Bilthoven
>> The Netherlands
>>
>> Phone number: +31 10.2.e or +31 10.2.e
>> DENK AAN HET MILIEU VOORDAT U DIT BERICHT PRINT
>> Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u
>> niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden,
>> wordt u verzocht dat aan de afzender te melden en het bericht te

Doc 27.

From: 10.2.e
To: 10.2.e
Subject: EU experts die naar Cancun gaan
Date: 06-11-2016 16:17

Ha 10.2.e

In antwoord op je vorige vraag: de experts waarvan ik weet dat ze gaan voor RA/RM, zijn:

-10.2.e (Oostenrijk)
-10.2.e (Slovenie)
-10.2.e (Finland)
-10.2.e (Verenigd Koningrijk)
-10.2.e (Frankrijk)
-10.2.e (Belgie) niet zeker
-10.2.e (Bulgarije)
-10.2.e (Zweden)
-Ikzelf

Verder weet ik het niet zeker, ik heb wel namen van experts, maar ik weet nog niet of ze zelf gaan of dat een ander gaat in hun plaats.
Laat maar weten als je meer info nodig hebt.

Met vriendelijke groet,
10.2.e

10.2.e
GMO Office
RIVM/VSP
PO Box 1 3720 BA Bilthoven
The Netherlands

Phone number: 10.2.e or 10.2.e

-----10.2.e schreef: -----
Aan: 10.2.e @rivm.nl>
Van: 10.2.e
Datum: 11/04/2016 12:14PM
Onderwerp: Re: wanneer reis je af naar Brussel? vanavond of morgen vroeg?

Dit is de openbare versie

On 4 November 2016 at 11:00, 10.2.e @rivm.nl> wrote:

> Dank!
>
> Delivered to you by RIVM Mobile environment.
>
> ---
>
> **From:** 10.2.e
> **Sent:** 4 nov. 2016 08:12
> **To:** 10.2.e @rivm.nl>
> **Subject:** Re: wanneer reis je af naar Brussel? vanavond of morgen vroeg?
>
> PS: er waren in Asie en africa twee lijnen van discussie:
>
> 1) niet endorsen
>
> 2) andere titel, i.e. "roadmap" or "reference document" (see also under Objectives)

Doc 28.

From: 10.2.e
To: 10.2.e
Subject: Re: [Spam] Re: Upcoming CBD meeting
Date: 15-11-2016 09:04

Thanks for the info, 10.2.e !

Met vriendelijke groet,
10.2.e

▼ 10.2.e ---14-11-2016 21:23:57---Dear all, Thanks 10.2.e for sharing this letter. It is from a German activist

From: 10.2.e
To: 10.2.e @danforthcenter.org>,
Cc: 10.2.e

Date: 14-11-2016 21:23
Subject: [Spam] Re: Upcoming CBD meeting

Dear all,

Thanks 10.2.e for sharing this letter. It is from a German activist group? is some food for thought for our side events, and for our student coaching efforts, as we will be greatly outnumbered by 7 anti gene-drive, synbio and gene editing side events, vs, only 3 from us.

Best,

10.2.e

I am taking the liberty of adding 3 of our student group coordinators to this message, so we discuss this issue further on the student on-line forum. I also invite all of you scientists and experienced regulators to contribute to the coaching of our young people and to join our on-line discussion. The students will be attending many of the side-events and need to be well informed on technical issues.

Real-life case -study:

To put the type of activism of the German letter in perspective for you in the US, who are relatively free from a lot of the ideological currents on policy imposed by activists groups from Europe in our developing countries, I will share a current task of mine:

I am currently advising the Undersecretary of Agriculture from a Andean country (she is an agronomist and was my student at Zamorano) who needs to rebate a colleague from the Ministry of Environment on policy for GM crops in her country this week, before they report to the President, on the "technical decision" they were asked to study.

This country has been discussing GMO policy for more than two decades and they have a prohibition in their Constitution. The team is young and new in government. They are all learning and deciding if they keep or change the old policy. There is a rather uninformed official at the Ministry of Environment, t who is citing an article on the lack of benefits of GM crops published on a European newspaper that misreports the findings of the National Academy of Science report on GE crops. The colleague is now "citing " the NAS report as stating that GM cops bring no increases in yield and no benefits. The article claims Europe (France and Germany) is doing very well without GM crops and thus, the world does not need this technology. The official from the Ministry of Environment echoes the sentiments of the European journalist, who is shaping her views on GMOs. She feels her country should not lift the ban on GM crops and is keen to tell her President so.

The Undersecretary of Agriculture on the other hand, wanted to know if what the article stated about the NAS report was true or not, as she had no time to read the long NAS report and was not aware there was a brief (I sent her the link last night). She is being a conscientious policy maker and trying to verify sources of information and consulting specialists. Most policy makers don't have the time or the interest to do the same and have to trust their advisers and technical people. President -elect Trump in the US may be in that same category now (so says my American husband!)

Allow me a provocative statement in this closed group and for the benefit of starting a discussion with the student group :

"what is the cost of inaction and the risk of maintaining the status quo and not using gene drives for GM mosquitoes?" Not much for the Germans... but much is at stake for us in tropical developing countries.

If the Germans and other Europeans like the Finish opr Norwegians (that populate the CBD and the Cartagena Protocol had to have their homes regularly sprayed with chemical insecticides to "eradicate" vectors of Malaria, Dengue, Zika and Chingungunya, or had to take their children and pets away from their homes for a whole day and return home in the evening only to see less mosquitoes, but also no fireflies or other insects, and their natural ecosystem threatened, they may think differently. And this is the sentiment from someone who has not experienced malaria or the other diseases except dengue which is miserable!, Malaria kills millions. I have yet to see a baby with micrcephaly because of Zika. I hope that day never comes... but I think it will unless we intervene now.

ov 14, 2016 at 8:41 AM, 10.2.e
10.2.e @danforthcenter.org> wrote:

> I am also happy to know you will attend. As you might have noticed, the
> Danforth Center side event on gene drives is on Monday December 5, and am
> hoping you will all attend, as I am sure there will be people there from the

Doc 28.

> opposing side. I am especially happy to know you will be focusing on CBD
> issues, since the majority of people I am in contact with are focusing on
> Cartagena, and I am concerned that a move to propose a ban on gene drive
> research might surface at the CBD level, foreshadowed by this letter:
> https://www.testbiotech.org/sites/default/files/Offener%20Brief%20CBD%20COP%2013.pdf
> (translation below)
>
>
> Open Letter to the Biodiversity Conference (CBD COP 13) and the danger of
> Gene Drives
>
> Ladies and Gentlemen,
>
> In December 2016, the 13th meeting of the States Parties to the Convention
> on the Biodiversity (CBD). With this letter we would like to ask you to
> visit the Conference on measures to combat the uncontrolled spread of
> genetically modified organisms. This topic will be discussed at the COP13
> conference, both under the item Synthetic Biology, as well as within the 8th
> Meeting of the Contracting States of the Cartagena Protocol, in which, among
> other things, to the report of an expert group on the opportunities and
> risks associated with organisms produced by synthetic biology.
>
> Already today, various examples of uncontrolled propagation are genetic
> modified plants in the environment: cotton in Mexico, rape in North America,
> Japan, Australia and Switzerland as well as grasses in the USA. In addition,
> were repeated Transgenes found in regional or original varieties, such as in
> Mexican Maize and rice from China.
>
> This development gives particular cause for concern regarding planned
> releases of genetically altered trees, fish and insects as well as the new
> challenges posed by the Synthetic biology and so-called gene editing. It is
> likely that in the close future many of these organisms are to be released.
> This also increases the probability of uncontrolled spread of genetically
> modified organisms in the environment.
>
> Our concern is given the utmost urgency by discussing the use of so - called
> Gene Drives. These change not only the genetic information, but also the
> frequency of the genetic information heredity, so that the DNA incorporated
> in the laboratory significantly faster in affected populations than would be
> the case. The use of Gene Drives currently. For the purpose of genetic
> modification of natural populations or of the eradication of certain
> species. A sufficiently effective control over these releases there is not
> any.
>
> While hitherto crop plants or farm animals have been at the center of
> genetic engineering applications are now about to change natural populations
> genetically. Releases Genetically modified organisms, which lead to their
> genes being expressed in natural populations cannot be held responsible. If
> we allow and even strive to make genetically modified organisms their
> genetic material in natural populations is similar to an intervention in the
> "germline" of biological diversity, whose Impact on all future generations
> and their ecosystems.
>
> Even under existing laws, such releases are extremely high problematic:
> · Spatial and temporal control of the spread of genetically modified
> organisms is an indispensable prerequisite for any serious risk assessment:
> it is not possible, reliable statements on the consequences of the release
> of genetically modified organisms when they spread in the environment and
> become more evolutionary processes.
> · The precautionary principle can only be implemented if genetically
> modified organisms can also be removed from the environment in an emergency.
> But this is often impossible, as soon as the organisms are e.g. In natural
> populations.
> · By signing the Cartagena Protocol, Germany has committed itself to
> the Biological diversity before a transnational, uncontrolled spread of
> genetically modified organisms. The increasing number of cases uncontrolled
> spread of genetically modified organisms increases the risk of transboundary
> spread.
>
> In order to ensure a sufficient level of protection for man and the
> environment, we demand In particular a ban on the release, import and
> commercial cultivation of genetically modified organisms when these are
> selected in natural populations and spread.
>
> Ladies and gentlemen, we are very concerned about the imminent loss of
> control over the spread of genetically modified organisms and the emerging
> challenges. We therefore expect you to be on the Conference of the States
> Parties to the Convention for the application of genetic engineering with
> regard to the possible uncontrolled spread of genetically modified organisms
> clear limits. We hope that you support and ask for our demands You for an
> early opinion.
>
> We are also available for an interview with you and your employees
>
>
>
>
> 10.2.e
>
> I arrive on December 2, around 1 pm. I assume the prep meeting you are
> referring to is on Saturday December 3, not December 2? If so I will
> definitely attend, and would like to bring along a few colleagues as well.
>
>
>
>
> 10.2.e
>
> On Sun, Nov 13, 2016 at 10:33 PM, 10.2.e
10.2.e

>> Dear [redacted], dear all,
>>
10.2.e you must have read my mind, as I was wondering what you were
>> doing and planned to write to you to encourage you to come to Cancun.
ighted to hear that you will participate. Great move by
10.2.e to invite you as a speaker.

10.2.e when are you planing to arrive in Cancun ?

10.2.e and I will be in Cancun for the duration of the COP-MOP (2 - 17
>> December). If you have any flexibility it would be excellent if you
>> could also attend the preparatory session we are planning for the
>> PRRI, ISAAA delegates, student biotech/synbio/iGEM group and
>> like-minded delegations on Saturday 2 from 1-5 pm, followed by a
>> social event to network with the party delegates and to meet everyone.
>>
>> I am aware you would have to sacrifice your weekend, but it would be
>> worth it. Everybody copied in this message is welcome to attend our
>> social event. Meeting all of you will be especially useful for the
>> students. The students (about 20 so far from the PRRI group) will
>> also be able to attend the side events and interact with party
>> delegates,

10.2.e if you have a credential as part of an observer group delegation
>> (say CropLife), yes, you would be able to attend the technical
>> sessions. I will keep you posted on dates for the key sessions on
>> substantive issues of the MOP (risk assessment guidance) and
>> transversely issues of the COP (synbio). The first week will be
>> devoted to starting negotiations, so they are important.
>>

10.2.e did alert us on the 7 other side events on synbio, gene
>> drives, etc organized by 5 activist groups working coordinately. Our
>> side events are only 3 by comparison.
>>
>> A good thing for this COP-MOP, unlike previous ones, is that we will
>> have a greater crtical mass ot scientists and biotech students
>> attending the side events and meeting party delegates, especially
>> those from their own countries. I am also happy to report that more
>> parties, at least in Latin America, are becoming less precautionary
>> than what they have been in the past, especially with the issues of
>> synthetic biology, which we agree, should come under the umbrella of
>> biotechnology if synbio passes from the COP to the MOP.
>>
>> Let's all keep in touch to coordinate efforts in the next couple of
>> weeks. It will be great to see you all in Cancun.
>>
>> Best regards,
>>
>> 10.2.e
>>
>>
>>
>>
>>
>> ,
>>
>>
>>
>> On Sun, Nov 13, 2016 at 7:50 PM, 10.2.e @jcvi.org>
>> wrote
>> > Hi 10.2.e
>> >
>> >
>> >
>> > I hope all is well with both of you. I have a few questions for you,
>> > given
>> > your prior experience attending these meetings.
>> >
>> >
>> >
>> > If you have not looked at the side events devoted to synthetic biology,
>> > please take a look. ETC Group, Third World Network, and Friends of the
>> > Earth dominate, with a session by Crop Life International (CLI) and
>> > another
>> > by North Carolina State. Rather one-sided line-up.
>> >
>> >

10.2.e has invited me to speak at the CLI, thus I plan to do
>> > so. I
>> > look forward to seeing both of you in Cancun.
>> >
>> >
>> >
>> > I have a question about which sessions observers can attend. The
>> > proposed
>> > organization of work lists the synthetic biology discussion Tuesday
>> > morning,
>> > Dec. 6. (Working group II.) Am I allowed to observe that discussion or
>> > is
>> > that for delegates only?
>> >
>> >
>> >
>> > ETC has a side event Tuesday afternoon, as well, thus I am thinking
>> > about
>> > flying Monday to observe the discussion and the perhaps be able to
>> > respond
>> > to the misinformation by ETC group. The CLI session is Thursday and I
>> > would
>> > probably fly back to San Diego Friday.
>> >
>> >
>> >
>> > But other than the Thursday CLI session, my schedule is flexible. Does
>> > the
>> > trip as I proposed make sense? 10.2.e, if are attending that week, I
>> > would enjoy meeting you in persc And 10.2.e, if you will be there that
>> > week, lets plan to get together at some during those days.
>> >
>> >
>> >
>> > Regards,
>> >
>> > 10.2.e
>> >
>> >
>> >
>> > 10.2.e
>> >
>> > 10.2.e
>> >
>> > J. Craig Venter Institute
>> >
>> > 4120 Capricorn Lane, La Jolla, CA 92037
>> >
>> > phone: 10.2.e
>> >
>> > cell phone: 10.2.e
>> >
>> >
>> >
>
>

Doc 29.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: Student group and social even Cancun
Date: 18-11-2016 20:38

Dear all,

Greetings from Mexico. There are many things pending on many fronts in preparation for the COP-MOP and we have less than two weeks before Cancun.

To all in this email message: If you are in Cancun on Saturday 3, you are invited to our pool-side /beach networking social event at the Carisa and Palma building (near the Cancun convention center) from 6 pm onwards after the PRRI workshop (1-5 pm).

All our students and PPPR and ISAAA delegates are invited. I will also invite like-minded party delegations and "undecided" parties from GRULAC to the social event. If you have contacts from African and Asian delegations, please let me know.

This relaxed low-key social event ("with the kids") has three main objectives:

1). Give the "Biotech at the UN" student group the chance to interact with the scientists, party and non-party delegates and observers from industry. The students come from many countries and will enjoy meeting their country delegates.

2) Give the chance to party delegates to interact with scientists and students and feel they are being mentors and coaches to the new generation. Most adults like that and show their generous side. We are academics and students and don´t have a political agenda like governments or a commercial agenda like the industry. This is a powerful message to spread.

3. Have fun! The COP-MOP sessions will be dense and intense and we will have a grueling schedule, so let´s have some enjoyable time together and become friends, before we start the COP-MOP.

The students and scientists can use this time do their work in sharing the science perspective on many issues with country delegates: the AHTEG RA guide, GM crops (the Zamorano students know a lot about this), synbio(the IGEM students are very knowledgeable), gene drives for Zika and malaria, genome editing, GM crops, etc. There are also many PPRI members who are very well vesrsed on CBD, CPB issues.

My students are preparing short informative ppt ppt on gene drives, CRISPR CAS9, GM crops, etc, to share with delegates (on their cell phones from facebook pages and other social media) who are not familiar with these technical issues. This is training for students in science coommunication and an important skill to learn and practice ("learning by doing").

I believe this social event will be as effective (and much longer and relaxed) and can complement other side events that will be competing for time and people with the technical COP and MOP sessions and the many other side events. It will also be a great experience for the students. Please give us a hand and come and support us !

Valt buiten reikwijdte verzoek

Good weekend to all,

10.2.e

Doc 30.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: Re: GRULAC position on guidance??
Date: 19-11-2016 01:06

Dear 10.2.e, dear all,

10.2.e asked me if the there is a position from GRULAC for the AHTEG RA guidance.

I can only offer my very personal opinion on how I saw the country dynamics (or rather individuals representing countries) during the IICA meeting in Costa Rica organized by Pedro. IICA may give a different perspective to mine. I speak from my rather unencumbered platform as an academic.

The short answer is : There is no common GRULAC position on the guidance or other substantive issues, or even a common Central American, Andean or "Cono Sur" position.

However, here is my personal perspective of the "geopolitical dynamics" in the region. Please note this is similar to a political analyst predicting who was going to win the US elections and why -- I could be wrong!

!, Like - minded non-parties and parties (science-based approach): Canada, USA, Argentina, Honduras, Paraguay and possibly now Ecuador

2. Parties with precautionary and science-based official representatives: Brazil, Mexico, Colombia

3. Precautionary parties (official representatives): Peru (and Bolivia (from the distance) .

4. "Silent" parties: Chile, Uruguay, Antigua, Dominican Republic, Panama, Costa Rica, Guatemala

5. Absent parties from IICA meeting: Bolivia (very precautionary), Venezuela, Nicaragua, El Salvador, Belize, most Caribbean countries (mostly silent).

Regarding the guidance, we discussed the verb "endorse" and how this may be interpreted by different audiences. The general consensus was that "endorse" is not a good word for the official text. Monica gave a great presentation on the deficiencies of the AHTEG guidance.

A better term that may be a good compromise between endorsing and rejecting the guidance maybe " We Welcome the AHTEG RA guidance as another RA document, or, " We Take Note that there is the AHTEG RA document as another resource for ERA...."

10.2.e and I are trying (against the clock) to finish the second edition in English to the ERA Guide for Genetically Modified Organisms" whio will include an introductory section (in the preface) on the current discussions on synthetic biology, gene drives, genome editing, NBTs etc and stress that it is no different from modern biotechnology and that the basic principles of RA also apply.

On Synthetic biology (which somehow groups ous like gene drives, genome editing, CRISPR CAS), 10.2.e gave a superb summary on where the CBD is and how handle this. It would be very useful to get input from other groups like PPRI, the US, Canada, etc for a good strategy for the like-minded parties.

I feel the dialogue on synbio in GRULAC is very immature still, as party delegates still grapple with the complex technicalities of molecular biology and genetic engineering terms and processes and don´t feel they can give an opinion.

I am asking the student group "(Biotech students at the UN") to help prepare technical information for the science communication efforts for COP-MOP with party delegates. If we don´t do this ourselves with side.events and other activities, the activist NGOs will be the only source of information for these party delegates. The NGO efforts will surely influence "undecided or silent" party opinion and later policy for those countries. The countries most at risk are small least developed countries in Latin America and the Caribbean, Africa and South East Asia.

Here is my humble opinion of the dangers of what will be decided at COP-MOP:

Strong industrialized parties like the EU or economies in transition like Mexico or Brazil won´t be that affected by endorsing or rejecting the guidance or deciding what to do with synbio, as they already have different approaches to RA and synbio in place, and will disregard what the CBD and the CBP says if it doesn´t suit them in the end.

Small developing countries, on the other hand, will have nothing in place and will adopt whatever they see coming from the CBD and CPB by default. These may become part of their legislation in the future. This could halt science and innovation in their countries and the adoption of useful technology. We have seen ample examples of this with GM crops in countries that adopted the precautionary direction dictated by the CPB. Ecuador for example, has a prohibition for

"transgénicos" in their constitution and Peru a moratorium. Activists are asking for a similar moratorium on gene drives.

I feel much is at stake for this COP-MOP. Again, these are only personal opinions. Feel free to disregard them or indeed challenge them if you also attended the IICA meeting last week.

Best regards,

10.2.e

On Fri, Nov 18, 2016 at 2:36 PM, 10.2.e @umn.edu> wrote:
> Thanks!
look for your reply later.
10.2.e
>
2:25 PM, 10.2.e
10.2.e @gmail.com> wrote:

>> Hi 10.2.e,
>>
>> I am rushing but will answer your questions later with some details of
>> my reading of things (geopolitics) in GRULAC, after the meeting in
>> IICA.
>>
>> More later...
>>
>> 10.2.e
>>
>>
>>
>> On Thu, Nov 5 PM, 10.2.e @umn.edu> wrote:
>> > Greetings 10.2.e
>> >
>> > I hope this message finds you well!
>> >
>> > Would you be able to tell me whether there is a position for the GRULAC
>> > region the Guidance Document - endorse or not endorse??
>> >
>> > How about Honduras?
>> >
>> > I heard from a colleague in Brazil that Brazil is planning to 'take
>> > note
>> > of' the Guidance, not endorse. I'm sure that they will endorse or not
>> > endorse based on what others say.
>> >
>> > Mexico will endorse.
>> >
>> > I was at a MOP prep meeting for the African Group a couple weeks ago,
>> > and
>> > they are actually leaning toward 'not endorsing', but 'welcoming' it as
>> > reference document rather than a guidance, to just be done with it. I
>> > can't
>> > say for sure that they will stick with this position, but this is what
>> > they
>> > were discussing. They will be swayed by the position of others as well.
>> >
>> > A colleague from the EU was asking me if I know about other 'regional'
>> > positions, like GRULAC. The EU is likely to endorse, but my colleague
>> > is
>> > still hoping to change this.
>> >
>> > Any info you have will be good to hear.
>> >
s,
10.2.e

>> >

10.2.e
>> > Stakman Borlaug Center for Sustainable Plant Health
>> > Universi ota, St. Paul, MN 55108
>> > Mobile:
>> > E-mail:
>
>
>

Doc 31.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: [Spam] Re: Upcoming CBD meeting
Date: 19-11-2016 09:45

Hi 10.2.e

Thanks for your note and apologies for this belated reply; am a bit swamped with preparations of PRRI's participation in MOP8 and COP13.

We are having many ongoing discussions on the topics of the agendas of MOP and COP. Update to the wider group like-minded group will follow soon.

Am pleased to report that, as a result of 10.2.e's tieless work, over 35 students (many of whom Synbio students), will participate under the wings of PRRI in MOP8 and COP13. The total PRRI delegation will probably be between 45 and 50.

Below is a quick response to your email and the follow up from others, but I **urge everyone on this email not to react to the below, but to hold your substantive reactions in reply to my update this weekend** to the larger like-minded group, just to avoid too many parallel discussions.

1) 10.2.e, I am delighted that you will attend COP/MOP and I look forward to finally meeting you. I will be there from 2 – 17 December. Hope that you have already registered and booked a hotel, or will do so soon, because apparently Cancun is running out of affordable accommodation. I recommend that you register as CJVI, so that we have one more voice bringing the same message, but if you prefer I can also register you as PRRI. Make sure you register for all three meetings, i..e MOP8, COP!3 and MOP2. See: http://www.prri.net/meetings/upcoming-meetings/. As 10.2.e said, some discussions may move from one forum to the other.

2) Anyone can participate as an observer in any session of the plenary and working groups, as well as in contact groups, if the chair allows. To what extent observers are allowed to speak in the various groups will depend on the chair and available time.

3) On Saturday 3 December, PRRI will organise in collaboration with like-minded organisations a – by now tradition- MOP/COP preparatory meeting in which we will explain how the MOPs and all these negotiation groups function, and go through the topics on the agenda. Details about the 3 December meeting will follow to the larger like-minded group. Anyone welcome, but we need to know names to keep track of numbers and logistics and to arrange access. The same goes for the social event that 10.2.e mentioned, for which details will also follow.

3) Side events: there is indeed a multitude of side events, some of which pretty disconcerting. On 3 December we will take stock of which side events we should attend and who will go where.

4) 10.2.e: a side event on the last day may not sound very attractive, but it may offer an opportunity to discuss the – by then emerging - outcome of the MOP and COP, and how to deal with that on the home front.

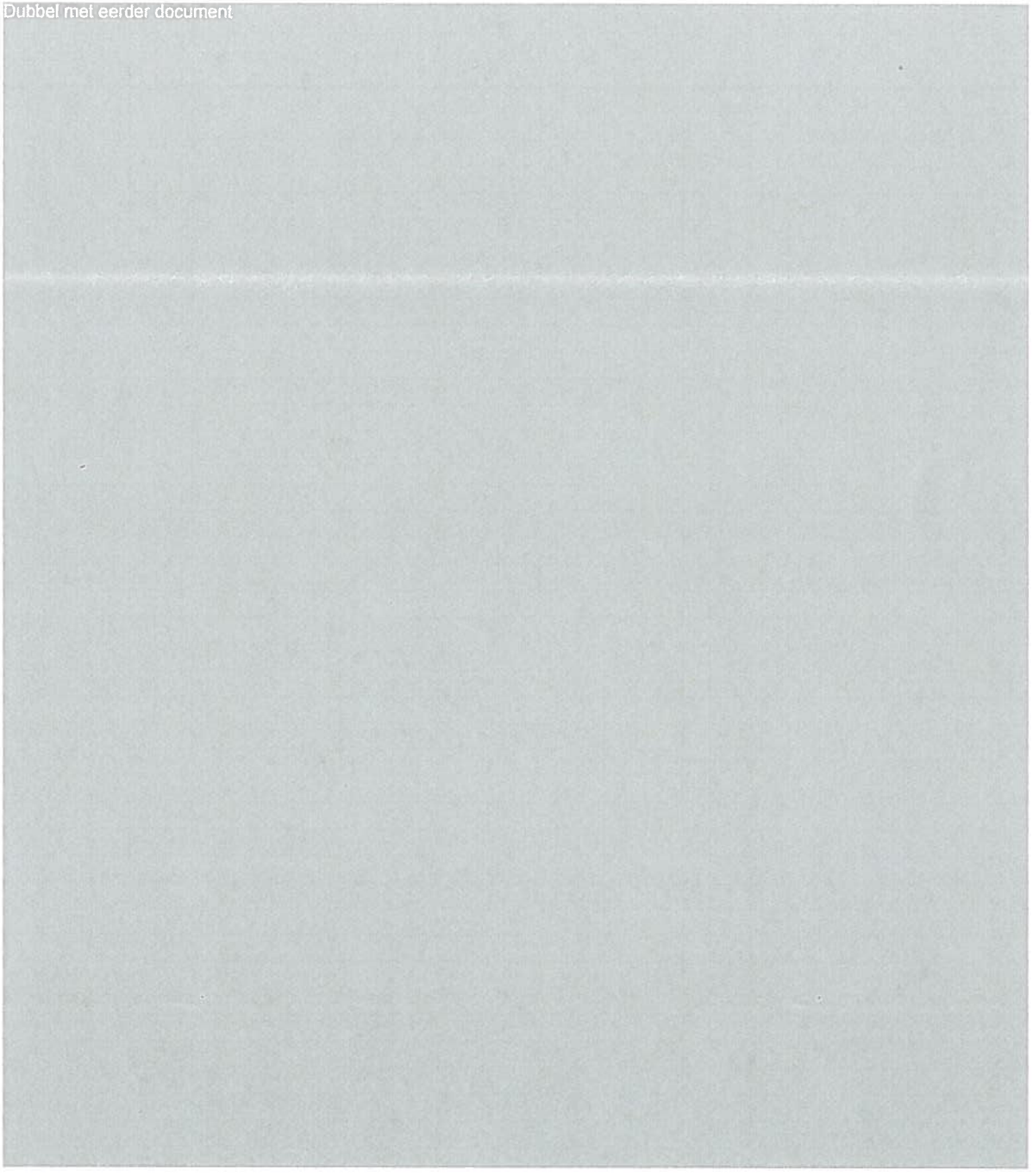
5) NGO advocated bans on Synbio and Gene Drives: there are unfortunately several calls for unjustified, blanket bans on SB and GD, similar to the German letter 10.2.e distributed. There are several initiatives of colleagues to send letters

to their Governments and open letters to all Parties to the COP and MOP, not support any ban, but in fact to increase R&D on GD and SB. Once finalised, we will circulate these letters. NB: One important thing that keeps coming up is not to mix SB and GD, because those are different things and mixing the two only confounds the debate. About GD: I think that 10.2.e 's comment at the end of her email below hits the nail on the head.

6) Please make it a habit of copying 10.2.e on any information you have about countries' positions on the various topics. 10.2.e is involved in coordinating the EU positions and any information you can share will help her in her task.

Good weekend !

10.2.e



Doc 32.

From: 10.2.e
To: 10.2.e
Subject: Betr: Meeting you in Cancun
Date: 20-11-2016 13:32

Dear 10.2.e
It would be great to be introduced to your students and to coach and mentor the group as far as possible!
I am not sure how much time I will have between coordination meetings, contact groups and plenary meetings on RA and synbio, but I will try.
Valt buiten reikwijdte verzoek

Kind regards,
10.2.e

Phone number: 10.2.e or 10.2.e

-----10.2.e schreef: -----
Aan: 10.2.e @rivm.nl>
Van: 10.2.e
Datum: 11/19/2016 03:54PM
Onderwerp: Meeting you in Cancun

Dear 10.2.e

I am very glad I will have the chance to meet you in Cancun. It will be a pleasure and an honor to introduce you to our student group. We have some German and UK students in our group who would greatly benefit from interacting with European scientists and get first hand experience on how policy is shaped. If you are so inclined, I would like to invite you to be a coach and mentor to our student group.

Valt buiten reikwijdte verzoek

I look forward to meeting you in person soon Valt buiten reikwijdte verzoek,

Best regards,

10.2.e

Doc 33.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: Re: postion EU COPMOP8
Date: 30-11-2016 12:39

You'll need a roadmap to get through MOP ...

On 30 November 2016 at 12:38, 10.2.e estelconsult.com> wrote:

> Dear 10.2.e
>
> Thanks for the update. I agree with 10.2.e that this is depressing indeed, a lot of countries do look at what the EU does. I wish you good luck in Cancun!
>
> I will be travelling there on the 7th. Hopefully you will all know your way around and can guide me through!
>
> Regards
>
> 10.2.e
>
> 10.2.e
>
> Estel Consult Ltd
>
> Tel: 10.2.e
> Mobile: 10.2.e
> Skype: 10.2.e
>
> www. Estelconsult.com
>
> ---
>
> **From:** 10.2.e
> **Date:** Wednesday, 30 November 2016 at 11:30
> **To:** 10.2.e @rivm.nl>
> **Cc:** 10.2.e @umn.edu" 10.2.e @umn.edu>, 10.2.e
> <10.2.e @estelconsult.com>, 10.2.e
> **Subject:** Re: postion EU COPMOP8
>
> Hi 10.2.e

Thanks for this – indeed depressing – update. When one us spoke with the EC today, they said that the EU positions were not yet available, and will only be finalised in Cancun.

Your approach on Fish and SynBio is at least better.

Later today I will copy you all on an email that I will send to the large like minded group , with an update of the various discussions we have had in various groups people over the last couple of weeks and months

Cheers

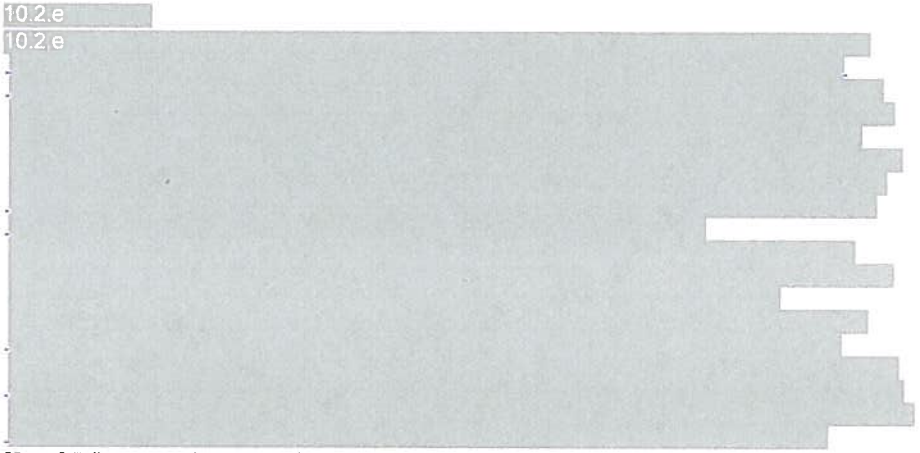
10.2.e

On 30 November 2016 at 08:52, 10.2.e @rivm.nl> wrote:

> Dear all,
>
> Thank you all for keeping me up-to-date on positions of other Parties. We finalised our position and, as indicated before, the EU and its 28 member states will endorse the Guidance. There was not too much room for me to move on this topic. The only adjustment that we managed to get into the adjusted text of the CBD secretariate was to indicate that for capacity building 'inter alia' the Guidance could be used. Otherwise the text could be read that the Guidanee would be the only document for capacity building in risk assessment.
>
> We were we more successfull in the subject of further guidance on fish and LMOs obtained by synthetic biology. Our position is that the AHTEG should establish a process to in which cases further guidance would be necessary. So the focus is now more on the proces than on the further guidance. We already have been thinking about how this process would look like.
>
> Hava a good trip to Cacun and see you soon!!
>
> Kind regards,
> 10.2.e
>
> Phone number: 10.2.e or 10.2.e
>
> DENK AAN HET MILIEU VOORDAT U DIT BERICHT PRINT
> Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te

Doc 34.

From: 10.2.e
To: 10.2.e



Subject: [Spam] Follow up on discussions about MOP8, COP13 and MOP2.
Date: 30-11-2016 23:55

Dear All,

I follow up on the various discussions that we have had the last couple of weeks and months about topics on the agendas of MOP8, COP13 and MOP2.

Given that quite a number of you were involved in the discussions on multiple topics, I have merged the various email lists into one.

Below a partial update and request for additions and reactions from your side. (I write 'partial' as it is midnight and I prefer to send this out now and add the rest tomorrow).

Best regards and safe travels to those who are travelling to Cancun!

10.2.e

General

'Cancun' seems to become a massive event, with three meetings running in parallel and whereby each of the meetings will be attended by more people than before.

PRRI will participate with 30 - 40 delegates, of which 10 delegates with substantial COP/MOP experience and 20-30 biotechnology/SynBio students. PRRI is teaming up with likeminded organisations such as ISAAA, the Cornell Alliance for Science,

the Danforth Centre and several other student groups

Likewise, a very large number of 'biotech-critical' NGOs will participate and organise events.

Frequently quoted recent article: Hawking: Humans at risk of lethal 'own goal'

https://www.biosafety-info.net/.

Documents

On the PRRI site there is a page dedicated to MOP8 (http://www.prri.net/cartagena-protocol-biosafety/cpb-mops/cpb-mop8/), with:

- a link to the official documents on the CBD website

- a zipped folder with the key MOP8 documents (with the titles of the documents pasted in the filenames)

- a password protected PRRI 'Member area' with further background documents and space for internal discussions.

During the COP and MOPs, communication experts of PRRI and the Cornell Alliance for Science

will use Twitter and other social media to frequently report on what is happening during MOP and COP.

Request to all: please share websites with positions on MOP and COP topics, such as: http://croplife.org/plant-biotechnology/cartagena-protocol-on-biosafety/.

Preparatory meetings

Over the last months there have been several MOP/COP topic-focused preparatory meetings, as well as regional preparatory meetings where MOP/COP topics were discussed, such as:

- Asia: 24 - 26 October, Kuala Lumpur, Malaysia. Ain organisers: ISAAA and PRRI (Chair's notes)

- Africa: 26 - 27 October, Accra, Ghana, main organiser: ABNE

- Latin America: 10 - 11 November, San Jose, Costa Rica. Main organiser: IICA.

PRRI-ISAAA COP/MOP preparatory workshop, 3 December, 13.00 -17.00 Cancun.

As with previous MOPs, PRRI and ISAAA will organise a preparatory workshop for ISAAA and PRRI delegates in the weekend before MOP/COP. The workshop aims to 1) give the newcomers an introduction to the CBD, CPB and MOP procedures, and 2) to discuss topics on the agenda of MOP and COP.

In this workshop we will also take identify contact persons for each agenda item, and for side events, media contacts, social media, etc. If other groups have similar contact persons, please share names.

Although the workshop is intended for ISAAA and PRRI delegates, others are welcome to participate as observer. Requests can be sent to:
10.2.e

The workshop will be held on 3 Deember from 13.00 – 15.00. The workshop will be held in a venue in the 'zona hotellera'. Details of the exact venue will be forwarded to registered participants.

Side events

An large number of side events has been registered. (https://www.cbd.int/side-events/).

PRRI and ISAAA will identify contact persons who will keep track of past and upcoming the side events. If your delegation has similar side event contact persons, please share contacts.

SUBSTANTIVE TOPICS

General

As with earlier COPS and MOPS, most of the discussions circle around agricultural

topics. This is also the case in the draft Cancun Declaration.

General feedback from public researchers during the preparatory discussions:

1) the Cancun Declaration has an encouraging flavour of innovation, but that the text is still ambiguous at places.

2) Some general thoughts for the international debate: the future of agriculture does not lie in a choice for a particular technique, but in combining the best available techniques, tailored to local needs. In the interest of food security, the toolbox of farmers should be expanded, and no form of agriculture should be excluded.

Interesting recent publications and articles:

- 2016 FAO annual State of Food and Agriculture

- 2016 the OECD Green Growth Studies.

- http://www.sundaymail.co.zw/zim-scientists-seek-approval-for-gm-crop-trials/

Risk Assessment.

Background: Proposed elements for a MOP decision include: endorsing the draft guidance, deciding to develop further guidance on specific topics, and asking the CBD Secretariat to conduct capacity building.

Discussions in the preparatory meetings focused on:

- the original MOP4 decision, which asked for a 'roadmap' to help risk assessors applying existing guidance documents in a way that is consistent with Annex III;

- whether the current draft guidance is useful, in particular for novel risk assessors,

- what the consequences are of 'endorsing',

- whether a term as 'noting' would be more appropriate given that there are many other specialised guidance documents available;

- whether the document would better be called 'reference' document, given the explanation given in the introduction,

- whether the system of AHTEGs is best mechanism for developing new guidance for highly scientific topics

- the need for criteria to decide for which areas new guidance needs to be developed;

- whether capacity building is best left to specialised agencies, such as FAO;

- the 'package deal' nature of the draft elements of MOP decision, linking endorsement to producing more guidance to capacity building activities

Genome editing – New Breeding Techniques

Background: the topic of NBTs as such is not on agenda of MOP or COP, but various groups are advocating with their governments that the use of any NBT results by definition in an LMO.

Important to explaining that 'NBTs' is a collection of many different techniques, and that the resulting organism is only an LMO of it possesses a novel genetic combination.

Gene drives.

Background: the topic of gene drives as such is not on agenda of MOP or COP, but various groups are advocating with their governments a ban on gene drives.

Several groups, including a group of German students, have prepared letters to governments emphasising that a blanket ban on gene drive would have no scientific justification and would in fact be an irresponsible course of action.

The organisation Target Malaria has produced an open letter: - http://targetmalaria.org/gene-drive-open-letter/ . Anyone wishing to add his/her signature to the open letter, please send name and affiliation to 10.2.e @danforthcenter.org.

The Danforth Center will also hold a side event on gene drives: http://targetmalaria.org/eblasts/gene-drive-invite/.

Synthetic Biology

Background: Synthetic Biology is on the agenda of COP13 under the heading of 'emerging issues' and on the agenda of MOP8 under the question whether additional guidance for risk assessment is necessary. Various groups have advocated with their governments that current biosafety systems are not sufficnet for SynBio, and that a separate system is needed

Main points in the preparatory discussions:

- as with NBTs, Synbio is not a particular technique, but more an approach based on 'design', which may involve many different techniques. (Or – as one of the students said - "Synbio is not a method but a mind-set").

- current and foreseeable Synbio applications all involve LMOs and therefore the current system of case by case assessment applies;

- there has been no discussion under COP whether SynBio is an emerging issue

There are several side events on SynBio.

Unintended and Illegal transboundary movement.

Background: The proposed MOP decision is to endorse the operational definitions of "illegal transboundary movements" and "unintentional transboundary movements" as proposed by the Compliance Committee;

Main points in the preparatory discussions:

The proposed definitions seem to step over the fact that

- article 17 (unintended transboundary movement) deals with cases of LMOs that are likely to have significant adverse effects

- article 25 (illegal transboundary movement) is aimed at the domestic situation

- What terms as 'adopt' and 'endorse' mean

Socio-Economic Considerations

To be continued tomorrow

Doc 35.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: Re: postion EU COPMOP8
Date: 01-12-2016 07:21

Dear 10.2.e

Good to keep in contact in this way, also with [illegible] and 10.2.e. And thanks again for your feed back. I really hope to be able to attend the workshop and the social event afterwards, but I have been invited to attend other (formal) meetings at the same time. However, I hope skip these other meetings as much as possible.
Have a good trip everybody and see you in Cancun!

Kind regards,
10.2.e

Phone number: 10.2.e or 10.2.e

-----10.2.e schreef: -----
Aan: 10.2.e @rivm.nl>
Van: 10.2.e
Datum: 11/30/2016 05:21PM
cc: 10.2.e

Onderwerp: Re: postion EU COPMOP8

Dear 10.2.e

Many thanks for you message and for sharing this information.

I am copying [illegible] and 10.2.e from the Mexican delegation and 10.2.e from the Brazilian delegation.

So it seems the EU and Mexico will "*Endorse*" the guide. Honduras will "*Take note*" that the guide will be one of other RA resources, to use by parties and for capacity building purposes.

The Latin American ERA guide in its second English edition (useful for other regions too) will be also available and it includes sections on how to address synthetic biology, genome editing by CRISPR Cas9, gene drives and other related technologies.

If you are in Cancun on Saturday 3, please come to the PRRI workshop at the Convention Center (1- 5 pm, venue to be confirmed) , followed by a social event at the Carisa & Palma pool área (6 pm onwards).

Everybody on this list is welcomed to both the PRRI workshop and social event, where you will have the chance to meet oir student group "Biotech Students at the UN"

Best regards and see you in Cancun.

10.2.e

On Wed, Nov 30, 2016 at 1:52 AM, 10.2.e 10.2.e @rivm.nl> wrote:
Dear all,

Thank you all for keeping me up-to-date on positions of other Parties. We finalised our position and, as indicated before, the EU and its 28 member states will endorse the Guidance. There was not too much room for me to move on this topic. The only adjustment that we managed to get into the adjusted text of the CBD secretariate was to indicate that for capacity building 'inter alia'

the Guidance could be used. Otherwise the text could be read that the Guidanee would be the only document for capacity building in risk assessment.
We were we more successfull in the subject of further guidance on fish and LMOs obtained by synthetic biology. Our position is that the AHTEG should establish a process to in which cases further guidance would be necessary. So the focus is now more on the proces than on the further guidance. We already have been thinking about how this process would look like.

Hava a good trip to Cacun and see you soon!!
Kind regards,
10.2.e

Phone number: +10.2.e or 10.2.e

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Doc 36.

From: 10.2.e
Reply To:
To: 10.2.e @jcvi.org
Subject: Re: Gene drive workshop report
Date: 06-12-2016 21:04

Thanks, 10.2.e !
Kind regards, 10.2.e

Delivered to you by RIVM Mobile environment.

From: 10.2.e jcvi.org>
Sent: 6 dec. 2016 14:17
To: 10.2.e @rivm.nl>
Subject: Gene drive workshop report

Hi 10.2.e

The workshop report I mentioned this morning. I also have submitted a paper (co-authored by most of the participants) to Nature Biotechnology focusing specifically on guidance (what is available now, what needs to be updated). Take a look at suggestions for researchers (especially design for multiple objectives, pp. 7-8).

Regards,
10.2.e

10.2.e
10.2.e
J. Craig Venter Institute
4120 Capricorn Lane, La Jolla, CA 92037
phone: 10.2.e
cell phone: 10.2.e

Doc 38.

From: 10.2.e
To: 10.2.e

Subject: [Spam] Summary analysis participation in COP/MOP
Date: 24-01-2017 16:53

Dear All,

I hope that you had a restful holiday period after COP/MOP 2016, and I send you my best wishes for this year!

Overall feedback from the delegates of PRRI and of like-minded organisations with whom PRRI teamed up in COP/MOP 2016, is that there seems to be some light at the end of the tunnel in the form of a 'counter force' that puts the need for science, research and evidence central again. Coupled with that, there is a general feeling that it is important to keep the momentum.

With that in mind I have produced for the delegates of PRRI, ISAAA, and like-minded organisations a summary of how COPS and MOPs developed over the years and an overview of their feedback on:

- the signs of change in MOP8 and COP13,

- experiences with holding COP13, MOP8 and MOP2 in parallel, and

- suggested activities to keep the momentum in 2017 and 2018.

I paste that overview below for your information, with the request not to distribute it but with the request to share your personal impression/analysis of COP/MOP 2016.

Regards!

10.2.e

++

Copy of email to COP13/MOP8 delegates of PRRI, ISAAA and other like-minded organisations with summary of feedback on:

- how COPS and MOPs developed over the years

- the signs of change in MOP8 and COP13,

- experiences with holding COP13, MOP8 and MOP2 in parallel, and

- suggested activities to keep the momentum in 2017 and 2018.

1) How COPS and MOPs developed over the years.

The negotiations have not always been like what we experienced in Cancun. In the negotiations to establish the CBD in the late 80s, protection of diversity and science were leading principles, and there was clear recognition that modern biotechnology can contribute significantly to the conservation of biodiversity (hence articles 16 and 19 of the CBD).

Somewhere between COP1 and COP2 (1995), things changed, around the same time when in Europe the attitude towards biotechnology changed. While the intention of article 19 of the CBD is to ensure biotechnology transfer, the negotiations leading to the Cartagena Protocol (1996-2000) were very much influenced by the changing attitude towards biotechnology, and as of MOP1 (2004), an anti-biotechnology tone was set, largely driven by some NGOs.

NB: It was in fact MOP1 that triggered a number of public sector scientists to establish PRRI, with the aim to bring more science to the negotiation table. From MOP2 onwards, PRRI has participated in all MOPs. Here is a flavour of how PRRI's participation has developed over time:

- At MOP2 (2005), PRRI presented itself with interventions and side events emphasising the importance of public research and countering misinformation. Feedback from Party delegates was that the arrival of PRRI made a clear and positive difference in the debates.

- During MOP3 (2006) and MOP4 (2008), an additional focus of PRRI became 'damage control', in the form of statements and side events aimed at helping to steer away from calls for blanket bans on gene switches (e.g. GURTS) and GM trees.

- As of MOP5 (2010), PRRI started urging colleagues who had participated once or twice as part of the PRRI delegation to MOP, to participate in next MOPs under their own institute, so that there would be more voices expressing the same message.

- In the run up to MOP6 (2012), PRRI and ISAAA teamed up in organising regional MOP preparatory meetings, and went a step beyond organising side events by arranging a well-attended field trip for MOP delegates to Bt cotton fields outside Hyderabad.

- In the run up to MOP7 (2014), PRRI broadened its internal 'MOP Skype group' with many other colleagues. Aware that several biotechnology related topics were increasingly coming up under the CBD, PRRI also participated with several members in COP11.

- At MOP8 (2016), PRRI and ISAAA aimed to bring the focus back to the potential biotechnology for biodiversity and human well-being. To this end, they teamed up with organisations such as Target Malaria, DDPSC, Island Conservation, iGem, Biotech Youth, CJVI, Cornell Alliance for Science, and EUSynBio. 35 biotechnology students participated in COP/MOP as part of the PRRI delegation.

Returning to the MOP and COP processes themselves: As those of you who participated in this and previous COP/MOPs have experienced, over time these

processes developed some disconcerting characteristics where it concerns discussions on biotechnology, such as:

- An underlying atmosphere that LMOs are fraught with risks and uncertainty,

- No apparent widespread awareness of the potential of these technologies for protecting biodiversity and enhancing human well-being.

- Little scientific foundation in the discussions on biotechnology topics.

- Discussions going beyond the scope of the CBD and CPB.

- An AHTEG process resulting in draft guidance for risk assessment that kept receiving serious concerns during subsequent MOPs about the scientific base and usefulness

- Calls for more guidance despite the concerns expressed, and a sense that the RA AHTEG process was on an 'automatic pilot' that was not being reigned-in by the MOP or the CBD Sec.

- Calls for blanket bans on new scientific developments without justification and without consideration of potential benefits.

- An underlying atmosphere that innovation goes against the interest of indigenous people.

- A misperception that the Precautionary Approach (Rio Principle 15) means 'zero risk'.

- A practice of some NGOs to tarnish individuals and groups with different views, rather than discussing the substance of those views.

2) Signs of change in MOP8 and COP13

Although the trends described above were still very visible at MOP8/COP13 (and sometimes to an even more surreal degree), we also noticed some significant signs of change in several directions, such as:

1) Unlike at previous COP/MOPs, calls for bans on technological developments such as Synthetic Biology and Gene Drives, were not immediately repeated by large numbers of Parties, and the Party interventions about those calls for bans were more balanced. None of the suggested bans were taken over in the final decisions.

2) More than before, Parties included before in their interventions recognition of the potential benefits of certain technological developments.

3) Concerns about the draft guidance on risk assessment, and the process of developing it, were expressed much more explicitly. The negotiations resulted in the decision that the draft guidance was 'taken note of', that 'interested Parties' were invited to use it as a voluntary tool, and for now there will be no further development of new guidance documents.

4) Clear, repeated signals that the negotiations and intersessional activities such as AHTEGs need to stay within the scope of the CBD and CPB, and that straying into the mandates and work of other fora should be avoided.

We have already had some discussions among ourselves about what contributed this change, and it is clear that it was not one single (f)actor that achieved this, but rather a combination of factors and actors:

First, the change in COP13/MOP8 was only possible because a significant number of Parties took strong, well-founded, science and evidence-based positions. In MOP7 there were already some 'pioneers' in this respect, and in MOP8 we saw that number growing, with some clear champions.

Second, as is clear from feedback from many delegates: the participation of our organisations clearly contributed to this change in MOP8 and COP13.

With a view to preparing for the next round of COP/MOP, it is good to analyse our informal, like-minded group a bit further.

From your feedback it is clear that we have concurring ideas about the strengths of our group:

Diversity of organisations: A great asset of our group was that our organisations brought different backgrounds and expertise, e.g. : PRRI (COP/MOP process, risk assessment, SECs, regulatory), ISAAA (technology transfer, science communication, public awareness and participation), CJVI, iGem and EUSynbio (Synthetic Biology), Target Malaria (e.g. malaria, gene drives), DDPSC (gene drives, risk assessment), Island Conservation (e.g. conservation, gene drives), Cornell Alliance for Science (science communication), et cetera.

Participating People: Our group counted over 60 colleagues in total, and during the first 10 days, we had at any given moment around 50 scientists in the negotiations and side events, allowing us to have eyes and ears in every forum, and to bring the voice of science where possible and countering misinformation where necessary. At this point we should specially mention the students: In the same way as the arrival of PRRI at MOPs in 2005 had a positive effect on the process, so had the participation of this very motivated group of young scientists a significant and positive impact.

Modus operandi: key to the functioning of our group were: 1) the collective preparatory meeting on the Saturday before the COP/MOP; 2) daily coordination meetings in the mornings; 3) excellent collaboration, 4) 'real time' communication through WhatsApp, and 5) clear and consistent statements on all key agenda items.

Outreach, e.g.:

- Side events: the Gene Drive side event of Target Malaria/Island Conservation/DPPSC and the SynBio side event of PRRI/ISAAA/students were well attended and appreciated by party delegates for giving factual background information and for allowing ample time for discussion.

- Collaboration with the Cornell Alliance for Science allowed for an formidable boost in outreach through social media.

- Publishing the statements on the PRRI and ISAAA websites, and making translations available into Arabic, Bahasa Indonesia, Bulgarian, French, German, Portugues, Russian, and Spanish.

This is just a compilation of your first reactions. - In the run up to the next COP/MOP we will organise more detailed exchanges and analyse as to what worked well and what can be strengthened.

3) Experiences with holding COP13, MOP8 and MOP2 in parallel.

For the first time, the CBD-COP, the CPB-MOP and the NP-MOP were held in parallel. From your feedback it is clear that this was experienced as having some advantages and disadvantages.

The obvious disadvantages were in logistics and funding due to extended time (two weeks instead of one). Regularly changing meetings also made it difficult to follow at times. An advantage was that one and the same topic (e.g. SynBio) was no longer discussed in isolation in two fora. Another advantage was that we were exposed to the Nagoya protocol on Access and Benefit Sharing, which for many public researchers is still a somewhat distant topic.

4) Keeping the momentum in the run up to MOP9 and COP14

As we already discussed in Cancun: to be well prepared for MOP9 and COP14, it is important to keep the momentum from very early on:

- *Early 2017:*

Until 30 January 2017 we can send to the CBD secretariat a summary of the side events that we held, so that those summaries can be included in a compendium that the CBD Secretariat will publish. For the PRRI/ISAAA/students side event: 10.2.e , please send me the Word version of the flyer. Students and 10.2.e : please send me one paragraph of your presentations. To whoever took notes: please send.

- *2017*

On several occasions we have discussed the need for regional 'COP/MOP de-briefing' meetings, in which we discuss the outcomes of COP/MOPs, the discussions behind those outcomes, and workable ways to incorporate those COP/MOP outcomes on the national front. These meetings could be organised in collaboration with regional organisations such as IICA and ABNE.

These regional meetings could also address some general issues, such as:

a) The impact of blanket bans (e.g. the paper 10.2.e mentioned about the costs of the rapeseed ban in Australia, and see the article below);

b) The fact that CPB procedures are not intended as a blue print for national regulations, and that governments should not be passively waiting for things to come out of MOP,

c) Providing clarity on terms such as SynBio, NBTs etc.

d) Dealing with the concerns of local community organisations, bearing in mind that governing and cooperation will be become harder in the near future, as segments of society and countries become more polarized, as global trends suggest.

e) The need to find we better and less polarized ways for coherent formulation of global policies towards biotechnology.

f) Reaching out to country teams early enough to help reduce contradictions, e.g. between biotech and environmental policies.

We should also use this period to start preparing students (i.e. the next generation of scientists and negotiators) who may wish to participate in MOP9/COP14. Student participation is likely to continue in future COP/MOP and other similar fora. Students are becoming aware of the bottleneck that a paucity of coherent regulation brings to their field. With the characteristic energy and passion of youth, students are ready to get engaged and many are already planning to attend COP14/MOP 9 in Egypt. A concerted effort should be made to encourage student participation in every meeting. Students are an inexhaustible source of new talent and energy and will ensure the continuation of the work we started. Our group greatly benefited from this and conversely the students benefitted from the experienced delegates in our group. The presence of young people may change the perception with many party delegates that biotechnologies are not solely being developed and deployed by big corporations. It is great to see that for example 10.2.e are already developing ideas how to mobilise students at their universities. We look forward to your suggestions on how to coordinate that and will come back to that. In this context

we also ask all the students who participated in COP/MOP to send us a one paragraph impression of their participation, which we can publish on the PRRI website. (NB: talking about students: see also the article below about the Kenyan biotechnology students).

We will seek resources to organise such COP/MOP debriefing meetings.

In the course of 2017 we will also update you on related initiatives and events in 2017 outside COP/MOP sphere, e.g. OECD work on risk assessment, the manual that 10.2.e are working on, ISBGMO, the Arhus Convention, ABBC-2017, ICABR 2017, et cetera.

2018 - Preparing for COP14/MOP9/MOP3

The feedback from the regional preparatory meetings that PRRI/ISAAA and other organisations held in the run up to MOP7 and MOP8 shows that this kind of informal meetings is very useful.

We hope to conduct similar preparatory meetings in 2018, possibly back to back with other regional meetings and will seek resources for that. We will keep you posted.

As said, this is just a summary of your first feedback plus some background. What we need to do in the time to come is analyse what the actual or potential impact of the various actors and elements is, and brainstorm ways to improve preparation and participation in the next COP/MOP in view of the lessons learned.

Looking forward to hearing from you!

10.2.e

Doc 39.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e

Subject: [Spam] Re: Acknowledgment of contribution to the development of the Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment
Date: 06-02-2017 05:27

Dear 10.2.e dear all,

I could not agree more with you 10.2.e. Here are my thoughts on how I see the process of the Guidance, the Secretariat's role and what it is at stake for developing countries. At this stage with the AHTEG dissolved, I have little to loose by sharing a candid appraisal of my experience as an AHTEG member and my concern for developing countries if the Guidance document is published.

After COP13-MOP8, I am now certain that our only role in these UN fora (CBD, CBP, etc) is damage control.There is no hope for any of us to contribute to any meaningful, non-politicized, science-based and coherent policy. We need to find other platforms to develop international oversight for biotechnologies. I believe there are alternatives.

Kind regards to all,

10.2.e

The process of developing the Guidance has always been flawed (to be science-based), or rather, it has been highly politicized and biased from the start, using techniques that are becoming main stream like: "truthiness" (LMOs are risky); "alternate facts" (developing countries concluded the guide was useful and practical after the testing of the guidance) and to push a pre-defined agenda (keep GMOs out, we don't like them).

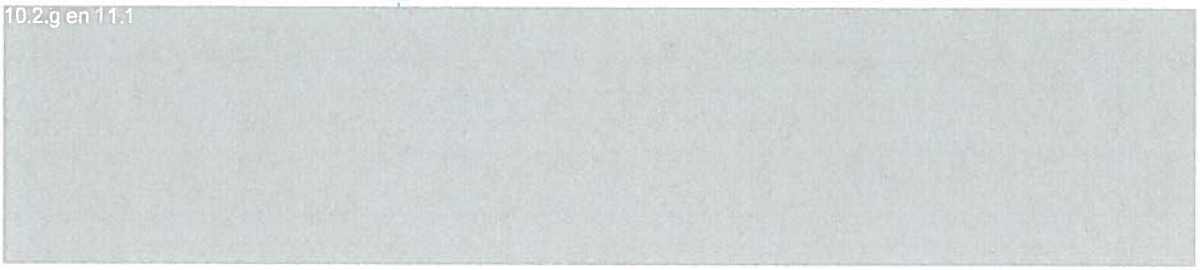
The Secretariat has always had a very Eurocentric approach to GMOs, and thus has adopted a precautionary approach to risk assessment. From the beginning, the Guidance was conceived as a legal tool to put as many hurdles as possible to stop adoption of GMOs, mainly in developing countries. Other legal tools are moratoria and GMO labelling.

Keeping the guidance long, complex and difficult for regulators so GMOs are banned from developing countries, has worked very well. If one accepts this premise, why would the Secretariat want a different guidance? This agenda was pushed on by those who had the same view as the Secretariat. These people won their favour.

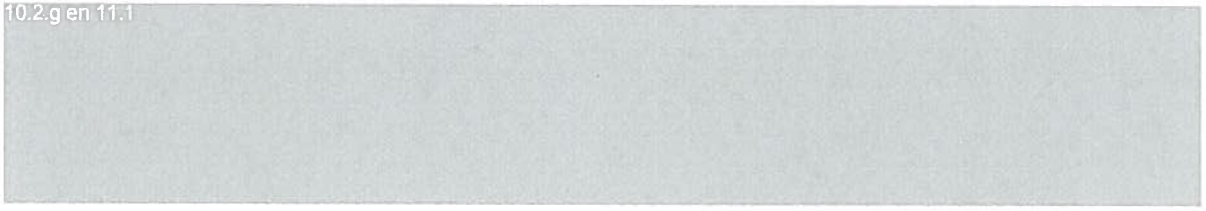
All members of the AHTEG should be equal, but are they? No. If you are an AHTEG member who agrees with this eurocentric, precautionary view of the guide and want to block adoption of GMOs, your opinion is highly valued (10.2.e from Austria, 10.2.e from Mauritania, 10.2.e from Mexico, 10.2.e from Moldavia, 10.2.e from Finland, 10.2.e from China etc) or "independent experts" from activist NGOs.

The legitimate experts from parties like 10.2.e (Mexico), 10.2.e (Colombia), 10.2.e (India), myself (Honduras), where treated differently as where experts from non-parties (10.2.e) or experts from industry or our NGOs (10.2.e). We were all "second-class citizens" compared to the powerful first group of "friends of the Chair" and our opinions largely disregarded. We are "second class" because we disagree with them, and it does not matter if you represent a party or not.

10.2.g en 11.1



10.2.e you are knowledgeable on this. What is the procedure to follow now?



Conclusion: it took 8 years, a huge amount of funds, dozens of people and hundreds of hours of work (many members do this as unpaid, voluntary work) to develop the Guidance document that came crushing down during MOP8, much to the Secretariat's and the "Friends of the Chair" surprise. These resilient and resourceful small group of people now want to keep the document alive (after all, it is a "living document"), so they can mount a capacity building project on risk assessment, mainly for development countries who have not develop their own ERA processes, get funding through the financial mechanisms of the CBD and perpetuate their influence and their well paid international travel.

Who are the winners and the losers? As a representative from a developing country (Honduras) and a national from Bolivia (I know what is going on inside the country) I have an answer: developing countries, will lose by having the AHTEG guide pushed by the Secretariat and Friends, into their future legislation that makes it difficult to adopt GMOs. This will have important consequences for the future development and adoption of biotechnologies.

It is not difficult to see that the future plan would be to develop another RA & RM guide for synthetic biology and repeat the pattern. Industrialized countries and emerging economies are protected from this through their own legislation, yet it some of these same countries who insisted that AHTEG guide be endorsed by parties at MOP8. The irony does not escape me.

Most people in this mailing list are nationals from industrialized countries or emerging economies. Developing countries are not well represented on this side of the science-based or "like-minded" spectrum. Colleagues and friends, I gently request that you, with your higher influence with the Secretariat, help me raise these concerns. I know it is difficult for some of you who have government appointments to speak up. The Secretariat is simply disregarding my view, if I speak alone. You saw what happened with my credential being revoked.

You are also seeing what is happening at the international stage when crazy legislation is being pushed, without due procedure or consultation (the US travel ban for the 7 Islamic countries). I don't think this is a time for keeping safely quiet.

Thanks

On Fri, Feb 3, 2017 at 3:59 PM, 10.2.e @umn.edu> wrote:
They might ask the reps from Parties who were on the AHTEG why they 'agreed' to the recommendations to the MOP (including to endorse) when the report was drafted during the AHTEG meeting, and now they are saying they don't agree. This is, unfortunately, what happened.

Probably should have a good answer ready for that one... for what it is worth.

10.2.g

There is something wrong with this. AHTEG members may be nominated by their Parties, but do they necessarily represent the opinion of their party? I think they are supposed to give their opinion as 'experts'. The opinion of their Party should be expressed in response to the AHTEG recommendation at the MOP, which is just what happened. So this distinction the Secretariat continues to make between 'experts for Parties' and 'experts not from Parties' is truly counterproductive to the purpose of an AHTEG.

My two cents.
10.2.e

On Fri, Feb 3, 2017 at 3:40 PM, 10.2.e @inspection.gc.ca> wrote:
I got the same thing. I have the same question; how will they deal with reps from the parties?

10.2.e

>>> 10.2.e 2017-02-03 2:49 PM >>>
Yes. I got essentially the same response that my input really didn't matter from the start. I wonder how they will respond to Party representatives?

Thanks,
10.2.e

10.2.e

Sent from my iPad

> On Feb 3, 2017, at 11:49, 10.2.e @umn.edu> wrote:
>
> Hi all,
> FYI. Here below is the reply I received from 10.2.e
> I'm not sure what her point is at the end there about 'observers', but she seems to be implying that it only mattered whether 'Parties' agreed, i.e. it was never the expectation that 'observers' would agree.
> I recognize this as a critical flaw with the whole AHTEG process.
> 10.2.e
>
> Dear 10.2.e
>
>
>
> Thank you for your email. It is nice to hear from you.
>
>
>

> After consultation with some Parties at COP-MOP and as explained during the contact group and working group at COP-MOP, the Secretariat will amend the disclaimer at the beginning of the publication to read:
>
>
>
> "The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the Convention on Biological Diversity concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. This publication is the outcome of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management at its meeting in July 2016 (http://www.cbd.int/doc/meetings/bs/bsrarm-ahteg-2015-01/official/bsrarm-ahteg-2015-01-04-en.pdf).
The views reported in this publication were not considered, discussed or otherwise adopted by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety and do not necessarily represent the views of the Parties to the Cartagena Protocol on Biosafety."
>
>
>
> With regards to your point that not all participants agreed with parts of the document, we may need to clarify that experts nominated by non-Parties and organizations participated as observers, which would automatically imply that they did not necessarily agree with the entire text.
>
>
>
> I hope this answers your questions.
>
>
>
> Kind regards,
>
>
>
> 10.2.e
>
>
>
> Secretariat of the Convention on Biological Diversity
>
> United Nations Environment Programme
>
> 413 Saint Jacques, suite 800
>
> Montreal, QC, H2Y 1N9
>
> Canada
>
>
>
> Tel: 10.2.e
>
> Fax: 10.2.e
>
> Web: bch.cbd.int
>
>

>
>
>> On Tue, Jan 31, 2017 at 9:02 AM, 10.2.e
<10.2.e @inspection.gc.ca> wrote:
>> Hi Karen,
>>
>> I sent essentially the same thing. In fact I cut and pasted part of
>> your response for consistency. I had felt all along that I wanted
the
>> enormous effort I put into this project acknowledged and that the
>> Secretariate shouldn't be able to sweep dissent under the rug.
common
>> practice for all kinds of expert reports is to acknowledge dissent.
Why
>> should this be different?
>>
>> Thanks,
>> 10.2.e
>>
>> >>> 10.2.e @umn.edu> 2017-01-31 8:10 AM >>>
>> Hi all.
>>
>> Here's my reply to 10.2.e:
>>
>> *Hello 10.2.e*
>>
>> *From my conversations with many AHTEG members at the MOP and since,
I
>> think the concern we share about having our names listed in
>> association
>> with the Guidance is not because it indicates that we contributed,
but
>> that
>> it implies that we support the final outcome which many of us did
not.
>> If
>> you will be adding an acknowledgement page as proposed, then you
have
>> an
>> opportunity to make this clear.*
>>
>> *The draft states: 'Members of the AHTEG on Risk Assessment and
Risk
>> Management are acknowledged for their valuable contribution to the
>> development of this document.' *
>> *I suggest to add a sentence after this to say: *
>>
>> *'Their participation as listed here does not in anyway indicate
their
>> endorsement of the document. This document was neither endorsed by
the
>> the
>> members of the AHTEG nor by the Meeting of the Parties. See
>> decision: CBD/CP/MOP/DEC/VIII/12.'*
>>
>>
>> *I really appreciate you reaching out to the members of the AHTEG
who
>> expressed concern about having their names listed. I know you are
>> receiving similar responses from other AHTEG members, and I hope
you
>> can
>> find a way to address our concern.*

>>
>> *Thanks,*
>> 10.2.e
>>
>> On Tue, Jan 31, 2017 at 3:49 AM, 10.2.e
>> <10.2.e
>> > wrote:
>>
>> > Dear All,
>> >
>> > Below my reply to 10.2.e ,
>> >
>> > Have a great day!
>> >
>> > 10.2.e
>> >
>> > Dear 10.2.e ,
>> >
>> >
>> >
>> > Thanks for your email.
>> >
>> >
>> >
>> > I very much appreciate it that the Secretariat follows up on the
fact
>> that
>> > during the negotiations some Parties indicated that their AHTEG
>> experts
>> > would feel uncomfortable if the way in which their names are
listed
>> would
>> > suggest that they endorse the draft guidance as it stands and the
>> process
>> > that lead to it.
>> >
>> >
>> >
>> > I share that concern, and agree that in the interest of
transparency
>> and
>> > completeness, it would indeed be appropriate to reflect this
>> officially.
>> >
>> >
>> >
>> > The question is how and where to reflect that.
>> >
>> >
>> >
>> > You suggest to do this by removing names of experts from an
>> acknowledgment
>> > page of the typeset version of document
>> UNEP/CBD/BS/COP-MOP/8/8/ADD1.
>> >
>> >
>> >
>> > I have some queries and concerns about that suggestion:
>> >
>> > 1) What do you mean by "the typeset version"? Does that refer
to
>> an
>> > intention to publish an update of the glossy version of the draft

>> guidance
>> > that was distributed at the side event during MOP8 and placed on
the
>> CBD
>> > website, something that was heavily criticised by Parties at
MOP8?
>> >
>> > 2) Removing names of AHTEG members from any acknowledgment page
would
>> be
>> > factually incorrect and indeed misleading from various
perspectives.
>> The
>> > appropriate, transparent thing to do would be to acknowledge all
>> AHTEG
>> > members who contributed to this process (often in their free time
>> and/or on
>> > their own budget), but to add language to reflect that this
listing
>> does
>> > not necessarily mean that the involved persons fully support the
>> content of
>> > the guidance and the process through which the document was
>> developed.
>> >
>> > 3) Adding an acknowledgement page to document
>> UNEP/CBD/BS/COP-MOP/8/8/ADD1
>> > raises the procedural question whether the Secretariat can change
>> MOP
>> > documents retro-actively.
>> >
>> > 4) Moreover, distributing that MOP8 document as a typeset-version
>> would
>> > run counter to the fact that the MOP did not endorse this document
as
>> well
>> > as to other MOP conclusions. In fact, already now that MOP8
document
>> is
>> > given a prominence on the CBD website (e.g. on the homepage) that
>> gives a
>> > suggestion that goes counter to the MOP conclusions about that
>> document.
>> >
>> > Given the above, I believe that an acknowledgement of all AHTEG
>> members is
>> > best placed on the CBD website, under 'AHTEG", with the
>> disclaimer that the
>> > listing of their names does not necessarily mean that all AHTEG
>> members
>> > fully endorse the draft guidance and the process that lead to it.
In
>> the
>> > interest of completeness, this would then best be followed by the
key
>> MOP
>> > conclusions.
>> >
>> >
>> >
>> > Thanks,
>> >
>> >

>> >
>> > 10.2.e
>> >
>> > On 28 January 2017 at 11:07, 10.2.e
>> <10.2.e >
>> > wrote:
>> >
>> >> Dear All,
>> >>
>> >>
>> >>
>> >> Thanks for your thoughts. Like 10.2.e I found it very useful to
have
>> this
>> >> exchange before replying to the CBD Secretariat's request to
>> indicate
>> >> whether we wish our names to be deleted in the acknowledgement
of
>> AHTEG
>> >> members in Document COP-MOP/8/8/ADD1.
>> >>
>> >>
>> >>
>> >> I take from our discussions that there is a general feeling that
>> deleting
>> >> names in an acknowledgement would not be appropriate, because it
is
>> >> important that all those who have participated are duly
>> acknowledged,
>> >> regardless whether or not they are content with the outcome.
>> Moreover,
>> >> having all AHTEG members listed also gives the outside world an
idea
>> of the
>> >> resources that have been spent on the draft guidance for over 8
>> years.
>> >>
>> >>
>> >>
>> >> What would be appropriate in the interest if transparency, is
that
>> with
>> >> the acknowledgement a disclaimer is added that the listing of
names
>> does
>> >> not necessarily mean that each AHTEG member endorses the draft
>> guidance and
>> >> the process that lead to it.
>> >>
>> >>
>> >>
>> >> The next question is where this acknowledgement plus such a
>> statement
>> >> should be placed.
>> >>
>> >>
>> >>
>> >> The SCB Secretariat talked about document COP-MOP/8/8/ADD1, but
as
>> >> 10.2.e raised: there is no acknowledgement in that document,
and
>> this
>> >> raises the question whether it is procedurally correct to amend

a
>> MOP
>> >> document after the MOP.
>> >>
>> >>
>> >>
>> >> This relates to another procedural matter that goes beyond the
>> AHTEG
>> >> acknowledgement: document COP-MOP/8/8/ADD1 was submitted for
>> >> consideration by the MOP, which decided to 'take note' of
this
>> document.
>> >> Yet, despite that MOP decision, document COP-MOP/8/8/ADD1
features
>> >> prominently on at least two places on the CBD website: 1) on the
CPB
>> home
>> >> page, under "Guidance on Risk Assessment, and 2) under the
page
>> >> Biosafety Technical Series, where it now replaces the glossy
version
>> of the
>> >> draft guidance document.
>> >>
>> >>
>> >>
>> >> This in turn relates to the question what will happen with that
>> glossy
>> >> version.
>> >>
>> >>
>> >>
>> >> For information of those who were not at MOP: before the MOP had
>> started
>> >> discussing the draft guidance document, the Secretariat and
AHTEG
>> chair
>> >> held a side event in which printed, glossy versions of the
guidance
>> were
>> >> presented and distributed. In addition, a pdf version of that
>> glossy
>> >> version was placed under the Biosafety Technical Series
>> >>
>>
<https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=0ahUKEwizgZupm-PRAhXmJcAKHfeCBAoQFggcMAA&url=https%3A%2F%2Fbch.cbd.int%2Fprotocol%2Fcpb_technicalseries.shtml&usg=AFQjCNG7shhV26wrg41ejQM9ozc0w3a_ew&sig2=UqCdhy0JagA6BRqxi-W62g>.
>> >> This led to the very admirable reaction by the Colombian
delegation
>> >> questioning the appropriateness of the Secretariat publishing a
>> document
>> >> that has not even been discussed by the MOP. This concern was
>> supported by
>> >> many other delegations, and several delegations asked that the
>> glossy
>> >> publication be removed from that page and some delegations asked
>> that the
>> >> document be withdrawn entirely.
>> >>
>> >>

>> >>
>> >> Although the Secretariat insisted initially that it has the
mandate
>> to
>> >> publish documents in the Biosafety Technical Series, the pdf
file
>> was later
>> >> that day replaced by its front page only and with the note
>> *"**This
>> >> publication is the outcome of the Ad Hoc Technical Expert Group
on
>> Risk
>> >> Assessment and Risk Management at its meeting in July 2016 (see
>> report
>> >>
>>
<http://www.cbd.int/doc/meetings/bs/mop-08/information/bs-mop-08-inf-03-en.pdf>).
>> >> The views reported in this publication were not considered,
>> discussed or
>> >> otherwise approved or adopted by the Conference of the Parties
>> serving as
>> >> the meeting of the Parties to the Cartagena Protocol on
Biosafety
>> and do
>> >> not necessarily represent the views of the Parties to the
Cartagena
>> >> Protocol on Biosafety."* . That not is still there.
>> >>
>> >>
>> >>
>> >> Somewhere along the line, the Secretariat linked the document
>> COP-MOP/8/8/ADD1
>> >> to the glossy front page.
>> >>
>> >> What remained unclear during the MOP and still remains unclear
is
>> what
>> >> will happen with the glossy document.
>> >>
>> >>
>> >>
>> >> NB: As you will see in the glossy document, our names are listed
>> there
>> >> under the acknowledgements, obviously without any disclaimer.
>> >>
>> >>
>> >>
>> >> Given that there are currently documents around without any
>> >> acknowledgement (e.g. the MOP8 document) and a document with an
>> >> acknowledgement but without disclaimer, I believe that the
>> acknowledgement
>> >> to all AHTEG members is best be placed under 'AHTEG" on the
CBD
>> website,
>> >> with the disclaimer that the listing of their names does not
>> necessarily
>> >> mean that all AHTEG members fully endorse the draft guidance and
>> the
>> >> process that lead to it.
>> >>
>> >>
>> >>
>> >> I will draft my reply to the Secretariat along these lines and

share
>> a
>> >> copy with you.
>> >>
>> >>
>> >>
>> >> Finally, all this relates to the broader procedural question
raised
>> >> during the MOP to what extent the Secretariat can more or less
>> 'bypass' the
>> >> MOP by publishing documents on the website that were not endorsed
by
>> the
>> >> MOP. In this respect we should also be aware that on several
places
>> on the
>> >> website there is reference to "The Guidance" rather than
>> "draft guidance",
>> >> and that the Secretariat also published on the home page a
training
>> manual
>> >> and an e-training on risk assessment, which have not been
discussed
>> by MOP
>> >> and which contain similar things as in the draft guidance
document.
>> This
>> >> of course is more an issue for MOP, rather than for the AHTEG
only.
>> >>
>> >>
>> >>
>> >> Wishing you a good weekend!
>> >>
>> >>
>> >>
>> >> 10.2.e
>> >>
>> >>
>> >>
>> >> PS: I include in this email the new email address of 10.2.e

>> who
>> >> changed jobs.
>> >>
>> >>
>> >>
>> >> On 26 January 2017 at 22:21, 10.2.e
>> <10.2.e >
>> >> wrote:
>> >>
>> >>> Dear all, this is a copy of my answer to 10.2.e.
>> >>>
>> >>>
>> >>>
>> >>> Dear 10.2.e and all,
>> >>>
>> >>>
>> >>>
>> >>> I read carefully your message and this is a bit confusing to me.
I
>> >>> checked again the document CBD/CP/MOP/DEC/VIII/12 that contains
>> the

>> >>> decision on this matter and I cannot find any reference to a
>> request for
>> >>> the Secretariat to re-issue the Guideline in any form. Is there
>> such
>> >>> request in the draft report? (I understand is not available yet
in
>> its
>> >>> final version)
>> >>>
>> >>>
>> >>>
>> >>> The most relevant parts of the aforementioned document related
with
>> your
>> >>> message, are highlighted in the text:
>> >>>
>> >>> *The Conference of the Parties serving as the meeting of the
>> Parties to
>> >>> the Cartagena Protocol on Biosafety,*
>> >>>
>> >>> 1. *Acknowledges *the work of the Ad Hoc Technical Expert Group
on
>> Risk
>> >>> Assessment and Risk Management, having completed its mandate,
as
>> well as
>> >>> the Online Forum on Risk Assessment and Risk Management;
>> >>>
>> >>> 2. * Takes note *of the voluntary Guidance on Risk Assessment
of
>> Living
>> >>> Modified Organisms as the outcome of the Ad Hoc Technical
Expert
>> Group with
>> >>> input from the Online Forum;
>> >>>
>> >>> 3. *Invites* interested Parties, other Governments and relevant
>> >>> organizations to take the Guidance into account as a voluntary
tool
>> to
>> >>> assist in conducting risk assessment in accordance with the
>> Cartagena
>> >>> Protocol while acknowledging that other guidance documents and
>> national
>> >>> approaches can also assist in conducting risk assessment in
>> accordance with
>> >>> the Protocol;
>> >>>
>> >>> .....
>> >>>
>> >>> 10. *Requests* the Subsidiary Body on Scientific, Technical and
>> >>> Technological Advice to review the information provided and to
>> recommend a
>> >>> way forward to address the needs, priorities and gaps identified
by
>> Parties
>> >>> for consideration of the Conference of the Parties serving as
the
>> meeting
>> >>> of the Parties to the Cartagena Protocol at its ninth meeting,
>> including
>> >>> the possible establishment of a new ad hoc technical expert
group,

>> with
>> >>> the understanding that new guidance proposals should only be
>> presented upon
>> >>> approval by the Conference of the Parties serving as the meeting
of
>> the
>> >>> Parties to the Cartagena Protocol;
>> >>>
>> >>>
>> >>>
>> >>> I also asked the Colombian delegation about your question. If
>> their
>> >>> recollection is correct, there is no specific mandate for the
>> Secretariat
>> >>> to ammend the list of AHTEC members that participated in the
>> drafting of
>> >>> the guidance. Therefore, I will suggest that the text presented
to
>> the MOP
>> >>> is not modified in any way, reflecting a factual situation and
>> respecting
>> >>> what was discussed and agreed by the Parties in Cancun.
>> >>>
>> >>>
>> >>>
>> >>> The real and undeniable fact is that all the members of AHTEG
>> >>> participated in the discussions and contributed with the best
of
>> our
>> >>> knowledge and with high commitment to this effort. Of course,
there
>> are
>> >>> always different opinions and approaches, which were part of
the
>> >>> discussions, and constitute a very important part of the
richness
>> and
>> >>> relevance of the document. Consequently, I consider that the
list
>> of the
>> >>> AHTEG should remain complete. Nevertheless, this do not mean
that
>> all the
>> >>> members of AHTEG endorsed the draft, or fully support all the
>> contents,
>> >>> which must be clearly stated in the guidelines draft.
>> >>>
>> >>> The guidelines draft - not totally endorsed by AHTEG members or
by
>> the
>> >>> Parties-, should acknowledge disagreeing opinions, which is not
>> rare in
>> >>> these type of working groups.
>> >>>
>> >>>
>> >>>
>> >>> Kind regards,
>> >>>
>> >>>
>> >>>
>> >>> 10.2.e
>> >>>
>> >>>

>> >>>
>> >>>
>> >>>
>> >>> Enviado desde Correo
>> <https://go.microsoft.com/fwlink/?LinkId=550986>
>> >>> para Windows 10
>> >>>
>> >>>
>> >>>
>> >>> 10.2.e
>> >>> *Enviado: *jueves, 26 de enero de 2017 2:54 p. m.
>> >>> *Para: 10.2.e
>> >>> *CC: *10.2.e
10.2.e
>> >>> *Asunto: *Re: Acknowledgment of contribution to the development
of
>> the
>> >>> Guidance on Risk Assessment of Living Modified Organisms and
>> Monitoring in
>> >>> the Context of Risk Assessment
>> >>>
>> >>>
>> >>> Dear all,
>> >>>
>> >>> As indicated in another email, I will respond personally and
>> separately.
>> >>> If someone were to draft a letter for a larger group to sign, I
>> will
>> >>> consider it. However, this approach may have political
challenges.
>> If the
>> >>> Secretariat is not open to "concrete text proposals", a letter
may
>> go
>> >>> nowhere. I am also sensitive to the fact that some
representatives
>> of
>> >>> governments may not be at liberty to sign.
>> >>>
>> >>> Thanks,
>> >>> 10.2.e
>> >>>
>> >>> 10.2.e
>> >>>
>> >>> Sent from my iPad
>> >>>
>> >>> On Jan 26, 2017, at 10:44, 10.2.e @umn.edu>
>> wrote:

>> >>>
>> >>> Hi all,
>> >>>
>> >>> I agree that it seems better now to leave names of participants
>> listed,
>> >>> but that there should also be some statement there to say that
not
>> everyone
>> >>> agreed. I like 10.2.e 's suggestion to use the text from the
>> decision
>> >>> too.
>> >>>
>> >>> Would it be appropriate for us to draft a letter explaining
this
>> with
>> >>> some suggested text, that we could be sent to the Secretariat
from
>> all of
>> >>> us?
>> >>>
>> >>> We might be able to find a few more people from the list, in
>> fact...
>> >>>
>> >>> We would have to pull this together in short order, since 10.2.e
has
>> >>> requested a response by Jan. 31 (Tuesday). If there is
interest,
>> *would
>> >>> someone be able to quickly draft something?*
>> >>> Valt buiten reikwijdte verzoek
>> >>>
>> >>> Thanks,
>> >>> 10.2.e
>> >>>
>> >>> On Thu, Jan 26, 2017 at 8:05 AM, 10.2.e <
>> >>> 10.2.e wrote:
>> >>>
>> >>>> Dear all,
>> >>>>
>> >>>> I was one of the people who felt uncomfortable having my name
>> >>>> associated with a document that was presented "ready for
>> endorsment" at
>> >>>> MOP as a nice glossy printed version -- and stated so at a
>> Contact Group.
>> >>>>
>> >>>> Given that some sense prevailed and many parties protested
this, I
>> also
>> >>>> support the view of having a full list of participants in the
>> AHTEG, and
>> >>>> that removing names would be counterproductive.
>> >>>>
>> >>>> Best regards,
>> >>>>
>> >>>> 10.2.e
>> >>>>
>> >>>> 10.2.e
>> >>>>
>> >>>> *Consult MRS*
>> >>>> *Biotechnology and Biosafety*
>> >>>> *341 San Arturo Oriente, Valle Real, Zapopan, CP 45019*
>> >>>> *Jalisco, Mexico*

>> >>>> 10.2.e
>> 10.2.e
>> >>>> *10.2.e *
>> >>>>
>> >>>>
>> >>>> On Wed, Jan 25, 2017 at 4:35 AM, 10.2.e
>> >>>> 10.2.e wrote:
>> >>>>
>> >>>>> Dear All,
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> I guess you all have received the email below.
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> During the negotiations some Parties did indeed indicate
that,
>> given
>> >>>>> the process and given the resulting draft guidance, their
experts
>> would
>> >>>>> feel uncomfortable if the way in which they are listed would
>> suggest that
>> >>>>> they endorse the draft guidance as it stands.
>> >>>>>
>> >>>>> While I share that concern, I do believe that having names
>> simply
>> >>>>> removed would not be the most appropriate way to address
that,
>> because:
>> >>>>>
>> >>>>> · It would be factually incorrect to only list part of
>> the
>> >>>>> people who have contributed to this process;
>> >>>>>
>> >>>>> · It would give a wrong "black or white"
impression,
>> i.e.
>> >>>>> those on the list fully endorse the guidance and those not in
the
>> list
>> >>>>> completely reject it. I for one believe that while the draft
>> guidance as a
>> >>>>> whole is confusing rather than helpful, I do believe that
there
>> are also
>> >>>>> useful parts in it.
>> >>>>>
>> >>>>> · Removing names would mean that those who pick up
this
>> draft
>> >>>>> guidance some time from now may have no idea that this
guidance
>> was not
>> >>>>> fully supported by all who contributed to the process.
Moreover,
>> if people
>> >>>>> have questions about the guidance they logically only go to
those
>> listed as
>> >>>>> contributors.
>> >>>>>

>> >>>>> I believe that the appropriate way to address the above is
that
>> – to
>> >>>>> be factually correct - all names are listed, but to add
language
>> to reflect
>> >>>>> that this listing does not necessarily mean that those
persons
>> fully
>> >>>>> support the content of the guidance or the process in which
the
>> document
>> >>>>> was developed.
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> Looking forward to your thoughts
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> Regards
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> 10.2.e
>> >>>>>
>> >>>>>
>> >>>>> ---------- Forwarded message ----------
>> >>>>> From: 10.2.e @cbd.int>
>> >>>>> Date: 24 January 2017 at 17:42
>> >>>>> Subject: Acknowledgment of contribution to the development of
>> the
>> >>>>> Guidance on Risk Assessment of Living Modified Organisms and
>> Monitoring in
>> >>>>> the Context of Risk Assessment
>> >>>>> To: 10.2.e @cbd.int>
>> >>>>> Cc: 10.2.e @cbd.int>
>> >>>>>
>> >>>>>
>> >>>>> Dear Former Members of the AHTEG,
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> Further to the discussions that have taken place at the
eighth
>> meeting
>> >>>>> of the Conference of the Parties Serving meeting of the
Parties
>> to the
>> >>>>> Cartagena Protocol in December 2016 in Cancun, Mexico,
several
>> participants
>> >>>>> indicated that they would like their name and/or the name of
the
>> expert
>> >>>>> nominated by their country removed from the acknowledgment
page
>> (draft
>> >>>>> attached) of the typeset version of document
>> UNEP/CBD/BS/COP-MOP/8/8/ADD1
>> >>>>> "Guidance on Risk Assessment of Living Modified Organisms
and
>> Monitoring in

>> >>>>> the Context of Risk Assessment" (available at
>> >>>>> https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-0
>> >>>>> 8-08-add1-en.pdf).
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> In following up with these requests we would like for you, as
a
>> former
>> >>>>> member of the AHTEG, to confirm whether or not you would like
>> your name
>> >>>>> removed from this acknowledgment page at your earliest
>> convenience *but
>> >>>>> no later than 31st January 2017*.
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> Many thanks in advance for your prompt reply.
>> >>>>>
>> >>>>> Kind regards,
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> 10.2.e
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> Secretariat of the Convention on Biological Diversity
>> >>>>>
>> >>>>> United Nations Environment Programme
>> >>>>>
>> >>>>> 413 Saint Jacques, suite 800
>> >>>>>
>> >>>>> Montreal, QC, H2Y 1N9
>> >>>>>
>> >>>>> Canada
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> Tel: 10.2.e 10.2.e
>> >>>>>
>> >>>>> Fax: 10.2.e 10.2.e
>> >>>>>
>> >>>>> Web: bch.cbd.int
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>>
>> >>>>> [image: International Day for Biological Diversity 2016]
>> >>>>> <http://www.cbd.int/idb/2016/>
>> >>>>> --
>> >>>>>
>> >>>>>
>> >>>>
>> >>>
>> >>>
>> >>> --
>> >>>
>> >>>
>> >>>

Doc 40.

From: 10.2.e
To: 10.2.e

Subject: Session 6 today
Date: 23-03-2017 09:12

Dear All,

As I will unfortunately not be able to attend today's session, I paste below some quick thoughts with regard to your Session 6 today, with the kind request to bring these on my behalf forward in the group you are participating in.

1) Gene drives have the potential to address some very serious problems in areas such as health care (e.g. zika, malaria) and environmental protection (e.g. eradication of invasive alien species) in a way that is complementary with other approaches.

2) Given their modus operandi, the potential use of gene drives has also lead to questions regarding safety, with reference to the possible eradication of entire populations and off-target effects.

3) Such concerns can be addressed under existing biosafety systems, because:

a) the current and foreseeable gene drive applications fall under the definitions of GMO, LMO, GEO, et cetera of most national biosafety systems as well as of the Cartagena Protocol on Biosafety and the EU regulations,

b) the case by case risk assessment approaches and paradigms of those systems also apply to organisms with gene drives, but will need some further fine tuning (in fact, in the same way as the current guidance for GM plants still needs further fine tuning in case of trees, as most guidance for plants focuses on annual crop plants).

4) There is therefore no need to change the existing regulatory frameworks because of the development of gene drives.

5) As regards taking into account the benefits of gene drives: most of the current regulatory frameworks allow for taking into account benefits in the decision making (e.g. the CPB talks about whether a certain risk is "acceptable", i.e. acceptability of risks of a certain application can only be concluded if compared with rusks of that application. I would strongly advise against incorporating assessment if that kind of benefits in the risk assessment.

6) Further research would be very welcome in identifying more cases of gene drives nature and the effectiveness of gene drives vis a vis the development of resistance against gene drive (see 10.2.e 's talk for example).

When you bring these thoughts forward on my behalf, please feel free to say that bringing them forward does not necessarily mean you agree with all of them.

Valt buiten reikwijdte verzoek

Wishing you a great discussion!

10.2 e

Doc 41.

From: 10.2.e
Reply To:
To: 10.2.e @jcvi.org
Subject: Re: Gene drive article to be published in Nature Biotechnology
Date: 08-06-2017 17:38

Dear 10.2.e, Thanks!
Kind regards,
10.2.e

Delivered to you by RIVM Mobile environment.

From: 10.2.e @jcvi.org>
Sent: 8 jun. 2017 09:06
To: 10.2.e @rivm.nl>
Subject: Gene drive article to be published in Nature Biotechnology

Still in draft, so please do not distribute.

10.2.e

10.2.e
10.2.e
J. Craig Venter Institute
4120 Capricorn Lane, La Jolla, CA 92037
phone: 10.2.e
cell phone: 10.2.e

Doc 42.

From: 10.2.e
To: 10.2.e
Cc: 10.2.e
Subject: RE: Invitation to exchange and discuss ideas on syn-bio-nano
Date: 09-07-2017 03:20

Hi 10.2.e

I am delighted to accept your invitation. Thank you! After checking my calendar, I think early 2018 is probably best for me. November might work, but knowing that I will be losing a full week to the CBD AHTEG meeting in December makes me a bit cautious.

As you know, I have strong interests in regulation of biotechnology (including, of course, synthetic biology). I have also worked quite a bit on biosecurity implications, and as we discussed, the US and the Netherlands were both "center stage" in the gain of function debates.

Yet another interest may be too academic, but perhaps not. I have been working with colleagues in the US and Canada on "soft governance" approaches for rapidly developing technologies such as synthetic biology. I know 10.2.e in the UK is working in this area, too, but would be curious to find out about new approaches being explored in the Netherlands. I am trying to get a US Foundation to fund a group to go back and review the very long list of regulatory experiments going back to the late 1970s.

Finally, 10.2.e, excellent posting on the online forum. If nobody else from the US does so, I may have to assemble the long list of NASEM (and other US) reports over the last two years as you did.

Thanks again and best regards,
10.2.e

10.2.e
10.2.e
J. Craig Venter Institute
4120 Capricorn Lane, La Jolla, CA 92037
phone: 10.2.e
cell phone: 10.2.e

From: 10.2.e @rivm.nl]
Sent: Thursday, July 6, 2017 1:09 PM
To: 10.2.e @jcvi.org>
Cc: 10.2.e @rivm.nl>; 10.2.e @rivm.nl>
Subject: Invitation to exchange and discuss ideas on syn-bio-nano

Dear 10.2.e

I hope this email finds you well! It was nice to meet you at the ISBGMO and discuss biotech over lunch.
We also briefly talked about the possibility of inviting you to the Netherlands to talk about the Craig Venter Institute and share ideas about developments in synbio + related topics.

10.2.e (in Cc) and I are enthusiastic about this and exchanged ideas over coffee last week on a joint GMO office / COGEM lecture at the RIVM institute ("National institute of public health and the environment" where we are both located). We also included 10.2.e (RIVM. in Cc) in our initiative, as we all work on the same topics

(biotech, synbio, bionano). With the right setup, we think this could be a very fruitful event for all parties involved.

With this e-mail we want to share some topics we would like to address and enquire after your ideas concerning a potential visit to The Netherlands.

What we would be interested in:
- to hear more about the work at CVI on synthetic biology and related topics such as bionanotechnology and gene drives,
- to learn about your perspective / view on (policy) issues that need to be addressed on a national and/or international level,

What we can provide / offer:
- organise a lecture at the RIVM institute,
- set up additional meetings / visits with other organisations of your interest (or a shared interest by all of us),
- and of course, to share and discuss information on the work we ourselves are doing in these fields,
- travel / accomodation costs

As for planning, we're thinking of somewhere in November or start of 2018 (December is usually a very busy month).

We'd like to know whether you'd be interested in this and we look forward to hear more about your ideas!

Kind regards,

Scientific secretary Ethics and Societal Aspects
The Netherlands Commission on Genetic Modification (COGEM)
T: 10.2.e
M: 10.2.e
E: 10.2.e @cogem.net
I: www.cogem.net
Twitter: @COGEMnet

Doc 43.

From: 10.2.e
To: 15.4
Subject: Re: Follow up of COPMOP2016 and preparation of COPMOP2018 (1)
Date: 13-07-2017 22:04
Attachments: Follow up of COPMOP2016 and preparation of COPMOP2018 (1).docx

Dear colleagues,

For your information I send you the update (below and attached) that was sent to the COPMOP2016 delegates of PRRI, ISAAA, iGem, CJVI, Target Malaria, DDPSC, EUSynBioS, Alliance for Science and Island Conservation and other colleagues about follow up of COPMOP2016 and preparation of COPMOP2018.

I look forward to any further updates or corrections you may have, but kindly ask you not to distribute this update widely.

As you will see in the update, we will start again the email groups on the topics mentioned in the update, and - as before – a small number of colleagues from other organisations, governments and the private sector with long experience in COPs and MOPs will be invited to join these groups as observers.

I hereby extend that invitation to you, with the understanding that – as before - we will have to limit the number of observers to a few per group.

Wishing you a most excellent weekend!

10.2.e

To the delegates of PRRI, ISAAA, iGem, CJVI, Target Malaria, DDPSC, EUSynBioS, Alliance for Science and Island Conservation and other colleagues involved in COP13/MOP8/MOP2, December 2016, Cancun, Mexico.

Dear All,

Greetings! - It has been a while since we sent you a summary analysis of our participation in COPMOP2016 in Cancun.

As concluded in our analysis, COPMOP2016 showed some cautiously promising signs of change. For example, more Parties included in their interventions recognition of the potential benefits of biotechnological developments, unsubstantiated calls for bans were not widely supported, concerns about draft guidance were expressed much more explicitly, and there were clear signals that the negotiations and activities should stay within the scope of the CBD and its protocols. A combination of (f)actors contributed to this change, e.g. more Parties took science and evidence-based positions, and also the participation of our organisations contributed to this change.

As discussed in Cancun, it is important to keep the momentum and that we prepare ourselves well in advance for the COP and MOPs in 2018 (click here for the tentative dates and venue of COPMOP2018).

With this email we send you an update on the follow up of COPMOP2016 and the preparation of COPMOP2018, with the request for your feedback.

If you have on the short term limited time to digest this entire update, please have a look at the part on the on line discussions on Synthetic Biology and consider submitting a post at the latest this Sunday.

We are aware that the attached update is long and detailed, but we want to make sure that everyone is on the same sheet, including those who were not at COPMOP2016.

After this email, we will limit update emails as much as possible to one topic.

Part of the feedback we request is in indication whether you wish to attend COPMOP2018 and whether you wish to be included in one or more of the email groups per topic. Please only copy others on your feedback if you believe that your feedback is important to others.

In addition to email groups on the specifc topics mentioned below, we will also (re)establish email groups on:

- CBD-COP-general

- CPB-MOP-general

- NP-ABS – MOP

- NKL SP – MOP (if the SP comes into force soon)

For the updates we will use email, but for the communication about these topics during COPMOP2018 we will use the corresponding WhatsApp groups.

Looking forward to hearing from you and sending you best regards on behalf of 10.2.e and 10.2.e

10.2.e

Doc 43.1

FOLLOW UP OF COPMOP2016 AND PREPARATION OF COPMOP2018 (1)

1) Summary of COPMOP2016 side events.

Several of our organisations have submitted to the CBD Sec a summary of their COPMOP2016 side events, to be included in a compendium that the CBD Secretariat will publish. (For the summary of the PRRI-ISAAA side event, please click here).

2) COPMOP 'debriefing'.

As discussed in Cancun, it is important that Parties have, in addition to the official lists of the decisions of COP13, MOP8 and MOP2, access to the background on the discussions on the COP and MOPs agenda items as well as practical ways to incorporate the COPMOP outcomes on the national level.

This kind of 'debriefing' would preferably done in regional meetings in 2017. Unfortunately, despite intense efforts, we have not been able to secure the necessary funding for that. Given the short term, this is not surprising, and we will start initiatives in the course of this year to seek funding for COPMOP2018 debriefing meetings in the first half 2019.

Given that regional COPMOP debriefing meetings in 2017 is not an option, we aim to prepare a 'debrief-package' that we will make available to you so that you can use it in your communications with your government and others.

3) Laying the groundwork for COPMOP2018 preparatory meetings.

Laying the groundwork for COPMOP2018 preparatory meetings means preparatory work on dates, venues, collaborating organisations, programs, identifying participants, funding, etc.

Over the years, these preparations have become increasingly complex, because we have moved from preparatory meetings focusing on CPB/MOP, to preparatory meetings looking at CPB/MOP and CBD/COP, and later also included the Nagoya Protocol on ABS/MOP. It is possible that this time we also have will have to dedicate some time to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (NKL-SP L&R), because if two more countries ratify soon, we will have in 2018 also have the first MOP for the NKL-SP L&R.

We will start working on most of those preparations in the second half of this year, but for now we seek your feedback for the following:

a) Please alert us of any planned regional meetings pertaining to biotechnology in 2017 and 2018 that might offer the possibility of holding back-to-back COPMOP2016 debriefings and/or COPMOP2018 preparations.

b) Given the great success of having students participate with PRRI in COPMOP2016, we hope to increase the number of students in COPMOP2018. We are already discussing this with 10.2.e , 10.2.e and others, and suggestions and offers to help are warmly welcome.

c) Similar to the participation of students, we also hope to help a delegation of innovation oriented farmers to participate in COPMOP 2018. We have already discussed this with the colleagues from ISAAA-Asia, ISAAA-Africa and the European 'Farmers-Scientists-Network, and there is clearly enthusiasm for this. Here too, your suggestions and offers to help are warmly welcome.

d) As discussed in Cancun, prior to COPMOP2018 we should try to reach out to environmental organisations that seem open to a balanced approach toward biotechnology and start a dialogue. One of those organisations might be the Environment Defense Fund. You can find their position on biotechnology on this link: https://www.edf.org/our-position-biotechnology.

Please send us your thoughts on this and any suggestions for other environmental organisations with which we might start a dialogue.

e) All these plans depend to a large extent on funding, and we very much look forward to your suggestions for potential donors, and your offers for help to approach those donors. Likewise, we urge you all to inform your own organisations of the importance of participating in these international discussions, and that they are encouraged to provide funding for your participation.

4) Intersessional activities organised by the CBD Sec.

As you will have noted, the CBD Sec has started quite a number of intersessional activities under the CBD, CPB and NP-ABS (Nagoya Protocol on Access and Benefit Sharing).

Below is an overview of the intersessional activities the CBD Sec has started on the various topics.

As before, PRRI and ISAAA will establish email groups of colleagues who are interested in those topics and intersessional activities, to inform each other and discuss input in those intersessional activities. As you will see, certain topics are discussed under multiple fora. This is why we will need 'all hands on deck' and it is great to see that some groups have already started collating information and informing others on the topic of SynBio. We will try to coordinate with those groups as much as possible.

Whenever the CBD Sec announces intersessional activities on additional topics, we will establish email groups on those topics too if there is interest among colleagues.

We seek your confirmations in which email groups you would like to participate. As before, we will also invite colleagues from other organisations, governments and the private sector with long experience in COPs and MOPs to join these groups as observers.

Overview of key intersessional activities

NB: as COPMOP participants you should have received the CBD notifications referred to below.

Convention on Biological Diversity

- **SBSTTA**

Background: The Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) is an important preparatory body for the upcoming COPs and MOPs.

SBSTTA 21 will take place from 11 to 14 December 2017. The pre-session documentation will be made available at https://www.cbd.int/doc/?meeting=SBSTTA-21.

PRRI colleagues on this email are invited send to info@prri.net at the latest on 1 October any views on the SBSTTA documentation they propose to be submitted on behalf of PRRI, and/or whether they wish to participate in SBSTTA. ISAAA colleagues are invited to send their feedback to [redacted]@isaaa.org.

SBSTTA 22 will take place from 2 – 7 July 2018, and is expected to discuss risk assessment (see below under 'risk assessment').

- **Emerging issues.**

Note: the discussions in the OP on Synthetic Biology were triggered by raising this topic under "Emerging issues".

CBD notification 2017-014 invited to provide information on new and emerging issues relating to the conservation and sustainable use of biodiversity and the fair and equitable sharing of benefits arising from the use of genetic resources.

CBD Notification 2017-054 invites relevant information and views related to the proposals for new and emerging issues, as well as on the process for the identification of new and emerging issues. The information and views received will serve to prepare for the twenty-first meeting of the Subsidiary Body on Scientific, Technical and Technological Advice. (SBSTTA).

PRRI members on this email are invited to send to info@prri.net at the latest on 5 August any views and information they propose to be submitted on behalf of PRRI. ISAAA colleagues are invited to send their feedback to 10.2.e @isaaa.org.

- **Synthetic Biology**

On line discussions on Synthetic Biology

Note: Participation in on line discussions is important, because those contributions are then "on the record", i.e. the AHTEG and Secretariat will have to consider those comments. It is therefore important that you participate by making statements that need to be "on record", and by correcting things that need to be corrected, in particular from a scientific perspective.

Quite a number of people on this email are included in the list of participants. (People can still register via: https://bch.cbd.int/synbio/nomination_natl_experts/.).

The topics for the current and Upcoming on line Discussions are:

Topic 1: Reviewing recent technological developments within the field of synthetic biology to assess if the developments could lead to impacts on biodiversity and the three objectives of the Convention, including unexpected and significant impacts *3-17 July 2017* ***(deadline Sunday 16 July)***
Topic 2: Further analysis of evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention *17-31 July 2017*
Topic 3: Identifying any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol. *4-18 September 2017*
Topic 4: Evaluating the availability of tools to detect and monitor the organisms, components and products of synthetic biology. *4-18 September 2017*
Topic 5: Gathering information on risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology. *18 September-2 October 2017*

The on-line discussion on Topic 1 will end this Sunday 17 July.

Some impressions from this first discussion:

- Already a large number of posts (over 130), split in some sub threads of discussion.
- A number of you have contributed to the first round of discussions
- Some contributions are well focussed on the questions raised by the moderator, but many others are all over the place.

- As before, these discussions do not gradually mature, but have a tendency to start from square one at various moments, reopening decades old debates, and thereby adding to the fatigue.
- There has some discussion on the unease of some participants on the current operational definition of synthetic biology. Yet, the moderator reminded the participants that this operational definition is a compromises outcome of SBSTTA and COP13, and not open for discussion in this forum.
- A number of contributions focus on Gene Drives. Although Gene Drives is by many scientists not considered a form of Synthetic Biology, a group of Gene Drive experts has been formed to prepare reactions where need be (see below under Gene Drives).

After consulting some colleagues who have been following this debate closely, we urge all of you to take the following into account when making contributions to the this and the next online debates on SynBio: Urge people to focus on the questions posed by the moderator and to be concise

- Urge participants to focus on real life examples of SynBio rather than on hypothetical applications;
- Remind participants of the difference between research activities and final commercial applications of SynBio.
- Remind participants that SynBio is not any particular technique but rather a 'mindset' that starts with "design".
- Give examples of the potential benefits
- As regards risks, underline that the current biosafety systems (e.g. CPB) apply and are adequate
- Gene Drives in themselves are not SynBio (see also below under Gene Drives)
- When talking about "off target", speak of "off target changes" rather than "of target effects", and remind aprticiapnts that off target changes are not unique to SynBio, they also occur (and even more so) with conventional breeding (see the sublime post of 10.2.e of CSIRO).

Other information:

We draw your attention to ETC list of SB applications compiled at the site "synbiowatch"

- **Integrated Implementation of the CBD and its Protocols**

As we have seen in COPMOP2016: there is a movement to integrated implementation of the CBD and its protocols. This as such makes sense, provided it is done sensibly. In this context it would be good to alert your government colleagues to the call for expression of interest to participate in the project on "Integrated implementation of the Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, and the Convention" (CBD Notification 2017-040).

Cartagena Protocol on Biosafety

- **Socio-Economic Considerations (SECs)**

Background: SECs are mentioned in article 26 of the CPB as a certain discretion in decision making. Although article 26 does not contain an obligation, SEC is an important topic, because it may significantly influence decision making and/or confuse risk assessment. In the background package we will outline some important distinctions to be made.

CBD Notification 2017-050 – called for the nomination of experts to participate in the Ad Hoc Technical Expert Group on Socio-Economic Considerations and submission of information (deadline 22 June 2017).

A meeting of the AHTEG is tentatively scheduled for the fourth quarter 2017.

- **Gene Drives**

Gene Drives was not a specific topic in the agendas of COPMOP2016, but it did come up under SynBio (COP) and Risk Assessment (MOP), and is expected to return with some intensity during COPMOP2018, possibly also under the topics 'socio-economic considerations' and/or 'liability and redress'.

To be prepared for possibly multiple discussions under different headings, we are working with some organisations to see how best we can inform and help each other.

For now we have identified the following areas/groups:

- Cross cutting and regulatory aspects of Gene Drives: PRRI/ISAAA
- Application of Gene Drives in mosquito/vector control. Target Malaria
- Application of Gene Drives in control of invasive alien species: Island Conservation
- Application of Gene Drives in agriculture: PRRI/ISAAA

These groups are in close communication and will keep the various groups informed.

Additional points of interest:

ILSI will organise the symposium: "Gene Drive Modified Organisms and Practical Considerations for Environmental Risk Assessments" on 19 July 2017 from 1:00 pm – 5:00 pm, in : Washington DC, at the National Academies of Sciences, Engineering, and Medicine, Keck Center, 500 Fifth Street NW. In-person and live webcast participation possible. Click here for more information.

A recent article that has caused quite some discussion:
https://www.theatlantic.com/science/archive/2017/07/a-scientists-plan-to-protect-the-world-by-changing-how-science-is-done/532962/

- **Public Awareness**

On the CBD website:
21 March 2017: The report of the second joint Aarhus Convention/CBD round table on public awareness, access to information and public participation regarding living modified organisms (LMOs)/genetically modified organisms (GMOs) is available.

2 March 2017: Two new biosafety self-paced learning modules on public access to biosafety information and public participation in decision-making regarding LMOs are available in the new e-Learning Platform

2 March 2017: Launch of the Biodiversity e-Learning Platform

Online discussions in April Reviewed a module on public education regarding LMOs (see: http://bch.cbd.int/onlineconferences/portal_art23/pe_forum.shtml?forumid=17479&threadid=8230#8230).

Other point of interest:

Several institutions are organizing a viewing of the documentary "Food Evolution", produced by Academy Award-nominated director Scott Hamilton Kennedy and narrated by science communicator Neil deGrasse Tyson. As the documentary website announces: *"FOOD EVOLUTION is set amidst a brutally polarized debate marked by fear, distrust and confusion: the controversy surrounding GMOs and food. Traveling from Hawaiian papaya groves, to banana farms in Uganda to the cornfields of Iowa, FOOD EVOLUTION wrestles with the emotions and the evidence driving one of the most heated arguments of our time".*

- **Risk Assessment**

MOP8 took note of the voluntary Guidance on Risk Assessment of LMOs as the outcome of the AHTEG. With this, the work of the AHTEG had ended.

MOP8 invited interested Governments and organizations to take the Guidance into account as a voluntary tool, while acknowledging *"that other guidance documents and national approaches can also assist in conducting risk assessment in accordance with the Protocol"*.

Furthermore, MOP8 invited Parties to submit:

a. information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms;
b. proposals on criteria, including the technical justification, that may facilitate the selection of topics for the development of further guidance; and,
c. views on perceived gaps in existing guidance materials.

and decided to extend the Online Forum on Risk Assessment and Risk Management to exchange experiences on risk assessment, provide information and views on, and perceived gaps in existing guidance materials, and proposals to address any gaps identified.

MOP8 requested the SBSTTA to review the information provided and to recommend a way forward to address the needs, priorities and gaps identified by Parties for consideration by MOP9, with the understanding that "new guidance proposals should only be presented upon approval by the MOP". The 22nd meeting of the SBSTTA (2-7 July 2018) is expected to consider related to risk assessment and risk management.

A tentative calendar of activities will be available in due course.

Nagoya Protocol on ABS

- **Digital Sequences**

COP13 and MOP2-NP-ABS decided to consider at COP14 and MOP3-NP-ABS potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention, and for the objective of the Nagoya Protocol.

CBD Notification 2017-037 gives the timeline for undertaking this process, an invitation to submit views and information pursuant and a call for expressions of interest for the fact-finding and scoping study. CBD Notification 2017-049 calls for nominations to the AHTEG on Digital Sequence Information on Genetic Resources and sends a Reminder Regarding the Submission of Views and Information.

The AHTEG is to:
(a) Consider the compilation and synthesis of views and information as well as the fact-finding and scoping study being commissioned in order to examine any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and the objective of the Nagoya Protocol and implementation to achieve these objectives;
(b) Consider the technical scope and legal and scientific implications of existing terminology related to digital sequence information on genetic resources;
(c) Identify the different types of digital sequence information on genetic resources that are relevant to the Convention and the Nagoya Protocol;
(d) Meet at least once face-to-face, subject to the availability of financial resources, prior to the fourteenth meeting of the Conference of the Parties and make use of online tools to facilitate its work, as appropriate;
(e) Submit its outcomes for consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice to be held prior to the fourteenth meeting of the Conference of the Parties.

PRRI members on this email are invited to send to info@prri.net at the latest on 5 August:
- their interest to be nominated for participation in the AHTEG on behalf of PRRI.
- any views and information they propose to be submitted in behalf of PRRI.

Doc 44.

From: 10.2.e
To: 10.2.e
Subject: Re: Your posting from last session,,,
Date: 18-07-2017 09:17

Hi 10.2.e

Good to hear from you.
10.2.g en 11.1

About the gene drives: my colleague 10.2.e is working with a small group of European biosafety officers on an harmonised risk assessment for contained use of organisms with gene drives, to be able to come to the right containment level.
As far as I know the biosafety officers from Germany and France are included. I do not know of others in the EU who are working on this, I had the impression from the workshop in Leiden (Lorentz workhop) that the Netherlands has taken the lead on this subject, at least in the EU.

About your second remark, the cell free systems. My colleague, 10.2.e , wrote the first version of our joint respons. I added to that and posted it.
10.2.g en 11.1

I realise this is in conflict with my post in the online forum that started yesterday, but I hope to start some discussion

Met vriendelijke groet,
10.2.e

▼ 10.2.e ---17-07-2017 23:21:43---Hi 10.2.e — Glad you jumped in right away to (one hopes) set a tone for this session. I have been mean

From: 10.2.e @jcvi.org>
To: 10.2.e @rivm.nl>,
Date: 17-07-2017 23:21
Subject: Your posting from last session,,,

Hi 10.2.e

Glad you jumped in right away to (one hopes) set a tone for this session. I have been meaning to follow up on your post from last session.

First, your comment on gene drives (i.e., that you are working with "several European partners". We heard from France and Germany (as I mentioned in my posting). Are you working with or do you know of others?

Second, why did you include cell-free systems? These are not living (cannot reproduce or hijack reproductive machinery like viruses). Are you worried about uptake of DNA and incorporation into microbes in the environment? Why would this be more likely than any other free DNA?

Thanks!
10.2.e

10.2.e
10.2.e
J. Craig Venter Institute
4120 Capricorn Lane, La Jolla, CA 92037
phone: 10.2.e
cell phone: 10.2.e

From: bch@cbd.int [mailto:bch@cbd.int]
Sent: Friday, July 7, 2017 1:16 AM
To: 10.2.e @jcvi.org>
Subject: Synbio Forum: Reviewing recent technological developments within the field of synthetic biology - A new message has been posted to the forum

Dear 10.2.e ,

The following message has been posted by 10.2.e , Netherlands on 2017-07-07 00:12
RE: Opening of Discussion *[#8439]*

Dear all, dear 10.2.e

It is a pleasure to contribute to this online forum. As requested by 10.2.e , we like to focus on the specific questions posed.

1) What are the potential negative impacts, including unexpected and significant adverse effects, of the most recent technological developments in synthetic biology on biodiversity and the three objectives of the Convention?

We would have preferred if this question would mention the potential for both positive and negative impacts of the most recent technological developments in synthetic biology as well as of their applications. On a case-by-case basis these technological developments and their applications can have positive, neutral of negative effects on biodiversity and the three objectives of the Convention. This topic has been iterated in depth in both the previous on-line discussion as well as the AHTEG, and we consider this topic does not need further deliberation.

2) What research and cooperation activities are being conducted on the possible benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity to fill knowledge gaps and identify how those effects relate to the objectives of the Convention and its Protocols?

In the Netherlands the following activities have been and are currently undertaken.

- Four reports commissioned by the Dutch National Institute for Public Health and the Environment (RIVM) were delivered. They describe experience gained with environmental risk assessment of LMO's and new developments in white, green and red biotechnology. These RIVM reports van be can be found on: http://www.stw.nl/nl/content/biotechnology-and-safety.
- Based on these reports a call for research into the safety aspects of these new developments in modern biotechnology - including synthetic biology - was released last year.
- Ten different research projects have been awarded and will make a start this year. The overall budget of the program was 9 million Euro`s.
- Last year the RIVM issued a policy report on gene drives resulting in adjustment of the Dutch legislation for working with gene drives in contained use facilities (http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Rapporten/2016/februari/Gene_drives_Policy_report). RIVM is now working on aspects of risk assessment for contained use of gene drives in cooperation with several European partners.
- Modern biotechnology - including synthetic biology - is developing and maturing rapidly. At RIVM the potential impact of these new developments on risk assessment methodology is currently being researched. A policy report is expected towards the end of 2017.
- The Commission of Genetic Modification, together with the Health Council of the Netherlands, published in 2016 a report that describes major new developments and applications in biotechnology and possible stumbling blocks and (ethical and societal) dilemmas which arise from these developments and trends. This trend analysis can be found on: http://www.cogem.net/index.cfm/en/publications/publication/trend-analysis-biotechnology-2016

3) Are there other recent technological developments that have taken place within the field of synthetic biology that need to be considered in this discussion?

- The application of CRISPR Cas-based gene drives in organisms, especially in insects, needs to be considered with respect to potential benefits and potential risks on ecosystem level.
- The accessibility of the biotech tools (e.g. CRISPR) is increasing and is now also more or less available for the public (CRISPR kits can be ordered over the internet). This technology in general will become more and more accessible to e.g. DIY and other communities.
- Another new development is the development and application of external genome regulation methods, e.g. RNA interference in the form of sprays to control pests or influence plant characteristics, which raises questions about the risk assessment framework (if needed) for these applications.
- GM algae production platforms might be an important route for the production of chemical substances. The intrinsic need for relatively `open` (due to the need of sunlight) production ponds/facilities requires well designed safety and containment measures, either physical of biological.
- Whole cell sensor development is being pursued more actively. Sensor use inside and outside the laboratory may require well designed containment strategies.
- Cell free systems - e.g. again for sensor type applications - are being developed. Risk assessment methodology for these type of applications needs to be scrutinized.
- An important element that needs to be stressed is the ever-increasing speed of development of the field of biotechnology. New biotechnology tools (e.g. CRISPR) combined with automated laboratories (e.g. `foundries`), DNA circuitry design tools and bioinformatics are important enablers for developing new techniques and applications. This development is supported by substantial research and investment funding.

Kind regards,

10.2.e
GMO Office/Dept. of Gene Technology and Biosafety
Dutch National Institute for Public Health and the Environment (RIVM)