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From:
To:
CC:
Date: 2015/10/26 7:44 PM
Subject: Re: SynBio - update

I agree with your position,

On Mon, Oct 26, 2015 at 5:52 PM,
wrote:

> Hi thanks for the thoughts.
>
>
>
> As gene editing via small deletions are not discernible from mutations
> that we have not found in nature yet, I would argue that these not be
> regulated differently than conventional breeding, i.e we just haven't found
> it yet, regardless of what process used.
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>
> Similarly null segregants, those that do not contain the transgene should
> not be regulated. This is the stance of course for the everywhere but EU.
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> Best,
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> *From:*
> *Sent:* Monday, October 26, 2015 11:31 AM
> *To:*
> *Cc:*
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>
> Philip Macdonald;
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>
> *Subject:* Re: SynBio - update

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>
> Just now taking some time to digest what you wrote here regarding the
> definition of GMO/LMO and new breeding techniques, so my commentary here is
> intended more to improve my understanding than to take a position. While
> the definition of GMO/LMO seems in principle to be based on process *and*
> novelty, I would be interested to know how the CPB and the EU would deal
> with these two cases in practice: 1) an organism produced by transgenesis
> but expressing a non-novel trait (e.g. a transgenic plant where a native
> gene is introduced from one variety to another because it would be more
> rapid than breeding), or 2) an organism produced by chemical or radiation
> mutagenesis that expresses a novel trait.
>
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>
> Relating to the CPB definition, case 1 possesses a non-novel combination
> of genetic material even though it is obtained through the use of modern
> biotechnology. Case 2 possesses a novel combination, but not through
> modern biotechnology. I would assume case 1 would be treated as an LMO,
> but case 2 would not? If that is the case, then process trumps novelty in
> the definition. So if gene editing techniques were employed to produce
> case 1, would case 1 still be an LMO, because it is captured by the "modern
> biotechnology" element? If so, then process would trump novelty again.
>
>
>
> Relating to the EU definition, case 1 is an organism in which the genetic
> material has *no*t been altered in a way that does not occur naturally by
> mating and/or natural recombination (I'm actually now having trouble
> parsing our this definition). Case 2 has been altered by a process that
> results in a combination that does *not* occur naturally by mating and/or
> natural recombination. I would assume however that in the EU, case 1 would
> still be treated as a GMO, while case 2 would not? Likewise process trumps
> novelty in both cases. To me the hope that is offered by the EU definition
> is that one can argue the process of gene editing makes use of natural
> recombination processes (non-homologous end-joining and repair, for
> example) and therefore could be used to exempt both cases from the GMO
> definition.
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> On Sat, Oct 24, 2015 at 9:57 AM,

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> Dear All,
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> I follow up on our communications about the Synthetic Biology discussions
> under the CBD.
>
> Quick update and request for feedback:
>
> *AHTEG SYNBIO *
>
> The first AHTEG on SynBio took place from 21 to 25 September in Montreal.
> Several people on this email list participated in that AHTEG.
>
> The feedback shows that this process was an eye-opener for many, at times
> frustrating for some, but that nevertheless the resulting report is found
> to be fairly balanced in that it reflects the various views on the topics:
>
> - Relationship between synthetic biology and biological diversity;
>
> - Similarities and differences between LMOs and SynBio
>
> - Adequacy of existing regulatory instruments to address SynBio;
>
> - Operational definition of synthetic biology;
>
> - Potential benefits and risks to the conservation and sustainable use of
> biodiversity
>
> - Best practices on risk assessment and monitoring;
>
>
>
> We will inform you when the final report is posted on the CBD site. The
> report of the AHTEG will be submitted to the SBSTTA (see below).
>
> As the AHTEG documents and discussion show, there are many links to topics
> under the Cartagena Protocol, e.g.:
>
> - definitions
>
> - Environmental Risk Assessment
>
> - Socio – Economic considerations
>
>
>
> As regards definitions, I draw your attention to a discussion we have in
> Europe on the definition of a GMO in relation to New Breeding Techniques. I
> attach below for your information an email exchange with my colleagues in
> Europe. Main message is that while the definitions of GMO and LMO refer to
> certain techniques, the decisive element in those definitions is whether
> the resulting organisms possess novel genetic combinations, i.e. genetic
> combinations that "do not occur naturally by mating or recombination" (as
> phrased in the EU) or "overcome natural physiological reproductive or
> recombination barriers" (as phrased in the CPB). In short, these

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> regulations are not 'process based', because both the use of the technique
> and the novelty of the resulting genetic combinations are relevant. This
> discussion will also be relevant for SynBio.
>
> As to Environmental Risk Assessment and Socio–Economic considerations, we
> have similar informal discussion groups on those CPB topics and will keep
> you posted of relevant developments there.
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>
> *SBTTA *
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> The result of the on line discussion and the report of the AHTEG will be
> submitted to the Subsidiary Body on Scientific, Technical and Technological
> Advice. The first upcoming meeting of the SBSTTA is SBSTA-19 from 2 - 5
> November 2015, Montreal. The next SBSTTA will be from 25 - 29 April 2016
> in Montreal.
>
> The topic is included on the agenda of SBSTTA-20, in April 2016. (see:
> https://www.cbd.int/doc/?meeting=SBSTTA-20).
>
> It will be very good if some of us who participated in the on line
> discussions and/orteh AHTEG can participate.
>
>
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> *COP13 *
>
> The COP13 will be held from 4 - 17 December 2016, in Cancun.
>
> (See: https://www.cbd.int/doc/?meeting=COP-13).
>
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>
> As discussed, in addition to being prepared for the negotiations, it will
> be good to hold a side event on SynBio during COP13, preferably including
> young students (e.g. the iGEM initiative). and
> have already indicated to be willing to help with that. We will keep you
> posted on that.
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> Wishing you all a great remainder of the weekend !
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> Dear All,
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> Many thanks for your responses to my emails about the EU/CPB definitions
> of GMO/LMO, and the implications for organisms developed by New Breeding
> Techniques (NBTs).
>
> As several more people have been added to this list, let me briefly
> summarise:
>
> While these definitions refer to certain techniques, the decisive element
> in those definitions is whether the resulting organisms possess novel
> genetic combinations, i.e. genetic combinations that "do not occur
> naturally by mating or recombination" (as phrased in the EU) or "overcome
> natural physiological reproductive or recombination barriers" (as phrased
> in the CPB).
>
> In short, these regulations are not 'process based', but rather both the
> use of the technique *and* the novelty of the resulting genetic
> combinations are relevant.
>
> This is concisely reflected in the CPB definition: "an LMO is a living
> organism that 1) possesses a novel combination of genetic material 2)
> obtained through the use of modern biotechnology".
>
> In the EU definition this phrased a bit more opaquely with "*an organism
> in which the genetic material has been altered in a way that does not occur
> naturally by mating and/or natural recombination*". Over the years there
> has been some discussion as to whether "altered in way" refers to the
> technique, to the end result, or to both. As I illustrated in my previous
> emails, the definition and the annexes that belong to that definition shows
> that this "altered in a way" refers to both the technique used and the
> novelty of the genetic combination obtained.
>
> This interpretation is nothing surprising, because this notion of
> 'novelty' has been the consistent element since the first definitions in
> the mid-80s, and (as the European Commission has stated) the EU GMO
> definition is consistent with the definition of the CPB.
>
> Some of you have expressed concern that nevertheless the EC may follow a
> purely 'process based' interpretation. That seems unlikely, if you see for
> example what Commissioner Borg said in reply to questions from MEPs: " .....
> the definition of GMO in the EU legislation is referring both to the
> characteristics of the organism obtained and to the techniques used....". See
> link
> <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bWQ%2bE-2014-006525%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN>.
> In addition, several EU Competent Authorities have written to the EC that
> they are of the view that the EU definition of a GMO relies *both* on the
> process used and the resulting organism/product.
>
> Last but not least, your responses confirm that most – if not all – of you
> endorse the view that a purely technique based interpretation would make
> little sense.
>
> What our email-exchanges have also taught us is that it is important to
> make clear whether we are expressing what we think the definition says, or
> whether we express what we think others believe what the definition says.
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> Turning to organisms produced through NBTs: as said, for a meaningful
> discussion it is important to make clear to which NBTs we are referring,
> because genome editing techniques are for example very different from DNA
> methylation techniques, again different from Agroinfiltration, etc. etc.
>
> As regards the question to what extent organisms produced through specific
> NBTs fall under the GMO/LMO definition: the answer to that question depends
> on whether these techniques have resulted in novel genetic combinations,
> i.e. combinations that go beyond natural mating or recombination / natural
> physiological reproductive or recombination barriers
>
> Such a nuanced approach is also reflected in the report of the WGNT, which
> for example for the ZFN technique made a distinction in FSN1, FSN2 and FSN
> 3, based on the extent of the alteration.
>
> See also the attached letter of EFSA to the European Commission of 15
> October 2015. While I believe that some details in that letter would need
> some further discussion, the overall approach confirms the notion that when
> talking about definitions the resulting organisms need to be taken into
> account. What I also find very important in the EFSA letter is the
> statement that we should remain aware that this field evolves rapidly. I
> fully endorse the notion that we should keep monitoring future
> developments, and I believe that in doing so we should look beyond NBTs,
> and also look at areas as Synthetic Biology (see some articles below this
> email), e.g. what about XNA?
>
> As discussed, with the rapid development of new techniques and with the
> increasing knowledge of genomic variability, the challenging task is of
> course to fine tune the grey areas, which would be a great topic for a
> scientific brainstorm workshop to discuss 'how novel is novel' and related
> topics.
>
> We have received many enthusiastic reactions to the idea of holding such a
> workshop, and a few of you have already prepared the attached draft
> info-sheet for CRISPR, that can be used in the discussions. Please keep
> that draft info-sheet to yourselves for now.
>
> We have fixed the workshop on 9 December, at the Free University of
> Brussels. Program and details will follow.
>
> Please send me at the latest on 5 November your interest in participation
> (repeated request: please do not copy everyone to avoid clogging of
> inboxes). For those who cannot cover their travel from their own budgets,
> we have secured some extra travel funds with the help of
>
> Looking forward to hearing from you
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> PS: Below some recent articles on NBTs.
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> Faculty of Sciences, Faculty of Law, Ghent University, Belgium
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> Faculty of Science and Bio-Engineering Sciences, Free University Brussels
> (VUB
> <https://caliweb.cumulus.vub.ac.be/caliweb/?page=course-offer&id=008938&anchor=1&target=pr&year=1415&language=en&output=html>),
> Belgium
>
> c/o International Plant Biotechnology Outreach (IPBO)
> <http://ipbo.vib-ugent.be/team/ IIC/UGent
>
> Technologiepark 3, B-9052 Gent-Zwijnaarde, Belgium
>
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> The Economist | Gene editing: Even CRISPR:
> http://www.economist.com/news/science-and-technology/21668031-scientists-have-found-yet-another-way-edit-genomes-suggesting-such-technology-will?frsc=dg%7Ca
>
>
>
> *Wired** covers Monday's National Academy of Sciences meeting on human
> genome editing*
>
> *Wired:* Science Would Like Some Rules for Genome Editing, Please
> <http://www.wired.com/2015/10/science-like-rules-genome-editing-please/>
>
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>
> *Science:* Four synthetic biology inventions that flummox the feds
> <http://news.sciencemag.org/scientific-community/2015/10/four-synthetic-biology-inventions-flummox-feds?utm_campaign=email-news-weekly&et_rid=35367769&et_cid=51999>
>
> *Wilson Center:* The DNA of the U.S. Regulatory System: Are We Getting It
> Right for Synthetic Biology?
> <http://www.synbioproject.org/publications/dna-of-the-u.s-regulatory-system/>
>
> *Bloomberg View:* This Is No Way to Regulate GMOs
> <http://www.bloombergview.com/articles/2015-10-21/this-is-no-way-to-regulate-genetic-modification>
>
> *Nature* (news): CRISPR tweak may help gene-edited crops bypass biosafety
> regulation
> <http://www.nature.com/news/crispr-tweak-may-help-gene-edited-crops-bypass-biosafety-regulation-1.18590>
>
> *Nature Biotechnology:* DNA-free genome editing in plants with
> preassembled CRISPR-Cas9 ribonucleoproteins
> <http://www.nature.com/nbt/journal/vaop/ncurrent/full/nbt.3389.html>
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