

[REDACTED]

From: [REDACTED]
Sent: Wednesday, 21 August 2013 11:02 AM
To: [REDACTED]
Subject: RE: Update on FSANZ report on NBTs [SEC=UNCLASSIFIED]

Dear [REDACTED]

I am very well thank you and I hope you are well also.

Thank you for the update on the EU situation. It certainly does not look promising for any significant progress in the short term.

Our latest workshop went very well and we had some very useful discussions. We are now in the process of writing up a report, which will be publicly released at some point (still to be decided) although we hope we can do this a bit more quickly than the last time. I can however share with you the following.

In terms of discussion topics, the first half of the workshop was devoted to RNA interference technologies, because as I'm sure you are aware, there has been some scientific debate recently surrounding potential risks and suggestions that the current regulatory approach to risk assessment is inadequate to address these risks. The second part of the workshop was a follow on from our first workshop and picked up a number of techniques that we hadn't previously considered. These were accelerated breeding following early flowering, agro-infiltration, plus a number of targeted mutagenic techniques not covered in the first workshop including meganucleases, CRISPR/Cas 9 and TALENs. I understand your main interest is in relation to the second part of the workshop so I shall confine my summary of outcomes to that.

In terms of the NBTs discussed, and following on from our first workshop, its becoming increasingly clear that these various techniques are falling into particular categories where the same general principles can be applied. So for example, its seems clear that techniques such as SPT and accelerated breeding following early flowering rely on the use of transgenic techniques in the early stages of the breeding process but the final food producing lines are non-transgenic. The consensus round the table was that food products derived using the SPT process should not be regarded as GM and a similar consensus was reached in relation to early flowering at this workshop. Now of course as you know in our first workshop firm conclusions were not reached in relation to reverse breeding and we did not re-visit this technique at the most recent workshop. Despite this, we would consider that reverse breeding fits very much in the same category as SPT and early flowering and therefore we believe the same conclusions about derived food products would apply. (By the way, thanks for the paper, it looks very useful and no I hadn't seen this one).

In terms of the mutagenic techniques, it also seems clear that the various techniques that now exist are merely different ways of introducing a site-specific double-stranded break into the genome – they differ in their ease of use, and their specificity but essentially they are just different tools to achieve the same thing. The mechanism by which the mutation is introduced is essentially the same, irrespective of which tool you have used to introduce the DSB. Therefore the same conclusions reached in relation to ZFN technology, would also apply to these other mutagenic techniques. And so, providing no transgene remains in the final food producing line (where stable transformation is used to introduce the nuclease), the consensus round the table was that the derived food products should be regarded as non-GM.

Agro-infiltration was an interesting one. The consensus was that essentially it is a research technique with limited applicability to food. We did discuss its use to produce high value proteins but it was felt this application was more likely in the therapeutics sphere rather than food. There was some discussion about it being used to produce food processing enzymes for example but it was hard to envisage that this would replace microbial fermentation as a production platform. But in any case food processing enzymes are not food and are regulated differently. But in terms of food we are mainly talking about transient expression

from a non-integrated DNA construct so it was felt that in the main derived food products should be regarded as non-GM.

Best regards

[REDACTED]

From: [REDACTED]
Sent: Monday, 19 August 2013 7:23 PM
To: [REDACTED]
Subject: RE: Update on FSANZ report on NBTs [SEC=UNCLASSIFIED]

Dear [REDACTED]

How are you? I hope this month's workshop on NBTs was productive. Is there anything that you can share regarding the topics/techniques that were discussed, and the (expected) outcome?

As you may know, there are currently no new developments in the EU, apart from the fact that the current reluctance (or inability) to move forward on the subject is increasing the probability that the Commission will not move at all this year. This will mean that the decision on NBTs will be postponed until after the elections; practically, this would mean a standstill until 2015.

As you mentioned in previous contact, there was no decision on Reverse Breeding due to a lack of information. Although the technique may have been discussed already, I believe that attached article from Nature Genetics could be helpful, in case you haven't read it.

I hope to hear from you soon. Thank you in advance.

Best regards,

[REDACTED]

[REDACTED]

[REDACTED]

Van: [REDACTED]
Verzonden: dinsdag 16 juli 2013 2:13
Aan: [REDACTED]
Onderwerp: RE: Update on FSANZ report on NBTs [SEC=UNCLASSIFIED]

[REDACTED]

Yes, that will be fine.

Here is the link to the report

<http://www.foodstandards.gov.au/consumer/gmfood/Pages/New-plant-breeding-techniques-in-the-spotlight.aspx>

Regards

[REDACTED]

From: [REDACTED]
Sent: Monday, 15 July 2013 6:35 PM
To: [REDACTED]
Subject: RE: Update on FSANZ report on NBTs [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you for your reply, and the additional info. I look forward to the report, and suggest we keep in touch regarding any developments in the field of NBTs in Australia/New Zealand as well as the EU. If you don't mind, I will contact you again around the end of August, to check the outcome of the new workshop.

If you have any additional questions, please let me know.

Best regards,

[REDACTED]

[REDACTED]

[REDACTED]

Van: [REDACTED]
Verzonden: vrijdag 12 juli 2013 1:19
Aan: [REDACTED]
Onderwerp: RE: Update on FSANZ report on NBTs [SEC=UNCLASSIFIED]

Dear [REDACTED]

We are actually holding a follow-up workshop on 6 August, to discuss a few more techniques that weren't covered in our first workshop – agro-infiltration, early flowering, and some of the other targeted mutagenic techniques. We hope we will be able to get a report out a bit more promptly this time!

I'm not aware of any specific plans of either the OGTR or the EPA in response to our report, however we collaborated closely with both agencies on this work and continue to work closely with them on this topic. All three agencies however operate under completely separate legislative frameworks and our responses to NBTs are very much dictated by that. You might not also be aware that the legislation under which the OGTR operate (the Gene Technology Act 2000) was reviewed in 2011, and in its submission to that review, the OGTR proposed that consideration be given to a mechanism to facilitate more expeditious clarification of the need for, and degree of, regulatory oversight of organisms resulting from such techniques. However, any amendments to the GT Act will require agreement from a majority of Australian states and territories, and therefore could take years.

Best regards

[REDACTED]

From: [REDACTED]
Sent: Thursday, 11 July 2013 3:55 PM
To: [REDACTED]
Subject: RE: Update on FSANZ report on NBTs [SEC=UNCLASSIFIED]

Dear [REDACTED]

That's great news. I will make sure to check the website on the 16th.

Now that the report has been published, what will the next steps be? Are you aware of any plans at the OGTR or ESA in light of your report?

I hope to hear from you.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

----- Oorspronkelijk bericht -----

Van: "[REDACTED]"

Datum:

Aan: [REDACTED]

[REDACTED]

Onderwerp: RE: Update on FSANZ report on NBTs [SEC=UNCLASSIFIED]

Dear [REDACTED]

We have been awaiting clearance from our Minister's office to publish our report, and unfortunately this has taken considerable time. However I am happy to report that I have received notification today that we can go ahead and publish our report. The report will be released on our website on Tuesday 16 July.

Best regards

[REDACTED]

From: [REDACTED]
Sent: Wednesday, 10 July 2013 5:15 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: Update on FSANZ report on NBTs

Dear [REDACTED]

In the last months you have been in contact with my colleagues [REDACTED] regarding our research into the regulatory status of NBTs. On this topic, I have also had frequent contact with your colleague [REDACTED]

I was wondering if you could give me an update on the status of the FSANZ's report on NBTs? We are very interested in the results from your review.

Thank you in advance, I hope to hear from you soon.

Best regards,

[Redacted signature block]

Van: [Redacted]
Verzonden: zaterdag 1 juni 2013 1:21
Aan: [Redacted]
Onderwerp: RE: thank you

Thanks [Redacted]

It was good to talk to you and [Redacted]

Re our report, it seems this will not be released on 3 June as I advised. Our Parliament is still in session next week and our CEO has decided it would be prudent to wait until the following week when Parliament will not be sitting. Unfortunately this means the report will not be available before your meeting on June 5, so I apologise for this. I will be in touch when I know a revised date.

Best regards

[Redacted signature]

From: [Redacted]
Sent: 31 May 2013 16:40
To: [Redacted]
Subject: thank you

Dear [Redacted]

Thanks again for having the teleconference with us last week. The information you provided was very helpful for our NBT study, and we look forward to exchanging our reports as they are finalised. Let's keep in touch.

Kind regards,

[Redacted signature]

[Redacted signature]

[Redacted signature]

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