[redacted]

From: [redacted]
Sent: Wednesday, 6 August 2014 14:55
To: [redacted]
Subject: RE: FW: [redacted] visit Aug 13/14 [SEC=UNCLASSIFIED]

Follow Up Flag: Follow up
Flag Status: Flagged

Thanks [redacted]

We would like to discuss

1) how OGTR would implement their current advice that plants bred Zinc Finger delete do not need to be approved. The impression I get is that a submission would need to be made for each crop to get the required advice that an OGTR approval is not required.
2) Does OGTR believe that the advice based on the current legislation is sufficiently robust to counter any likely challenge by an NGO – like what happened in NZ. We realise that you are unable to provide legal opinion.
3) An update on what is happening around the world with the regulation of new breeding techniques. Is OGTR involved in any forums where this is being discussed.
4) Is it time to update the legislation to take account of the multitude of new breeding techniques regulate only on the safety of the crop and not the technique used to produce it

I am sure other topics will come to mind as we talk.
I trust this helps
Thank you again for your help.

Regards [redacted]

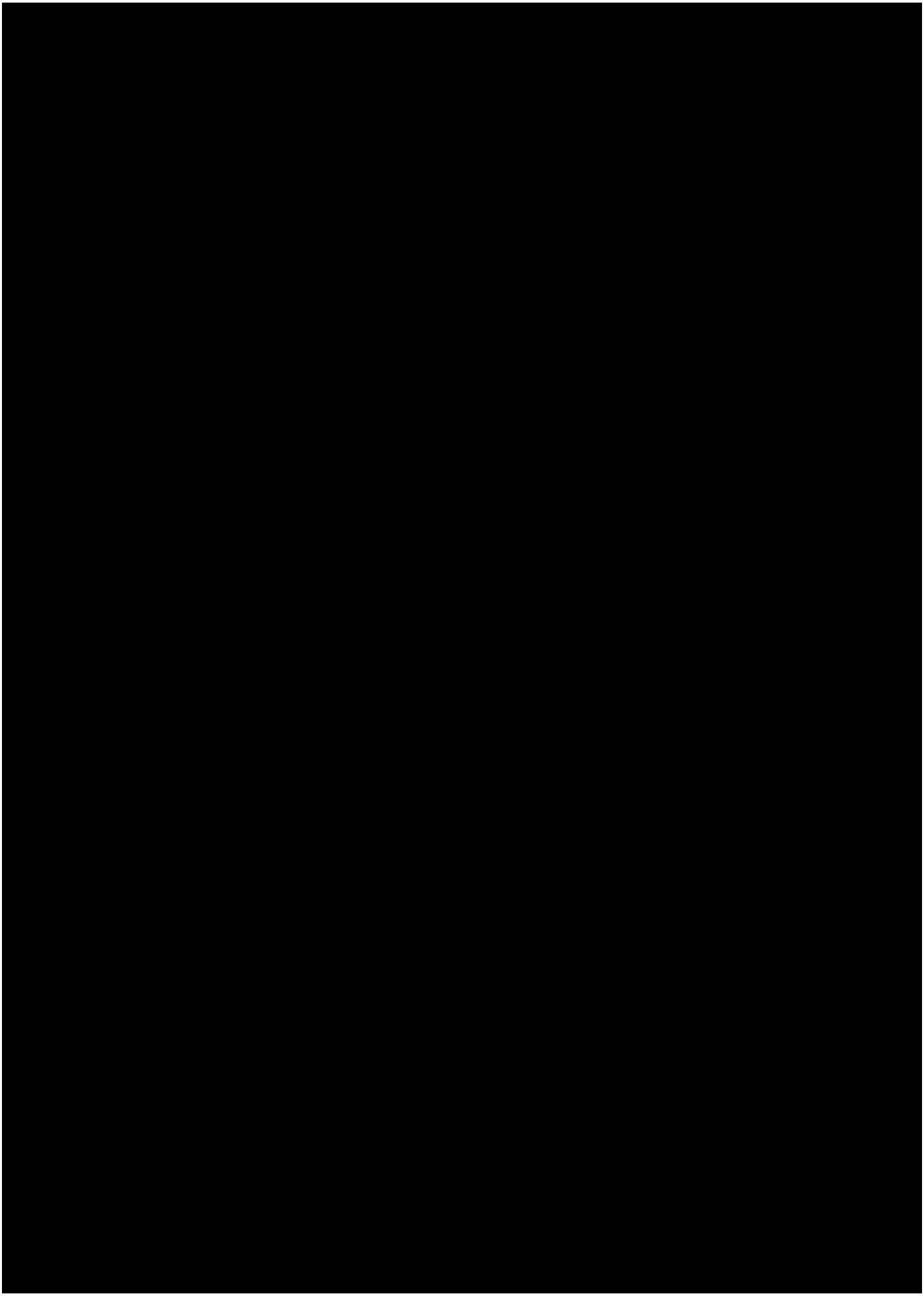
[redacted]

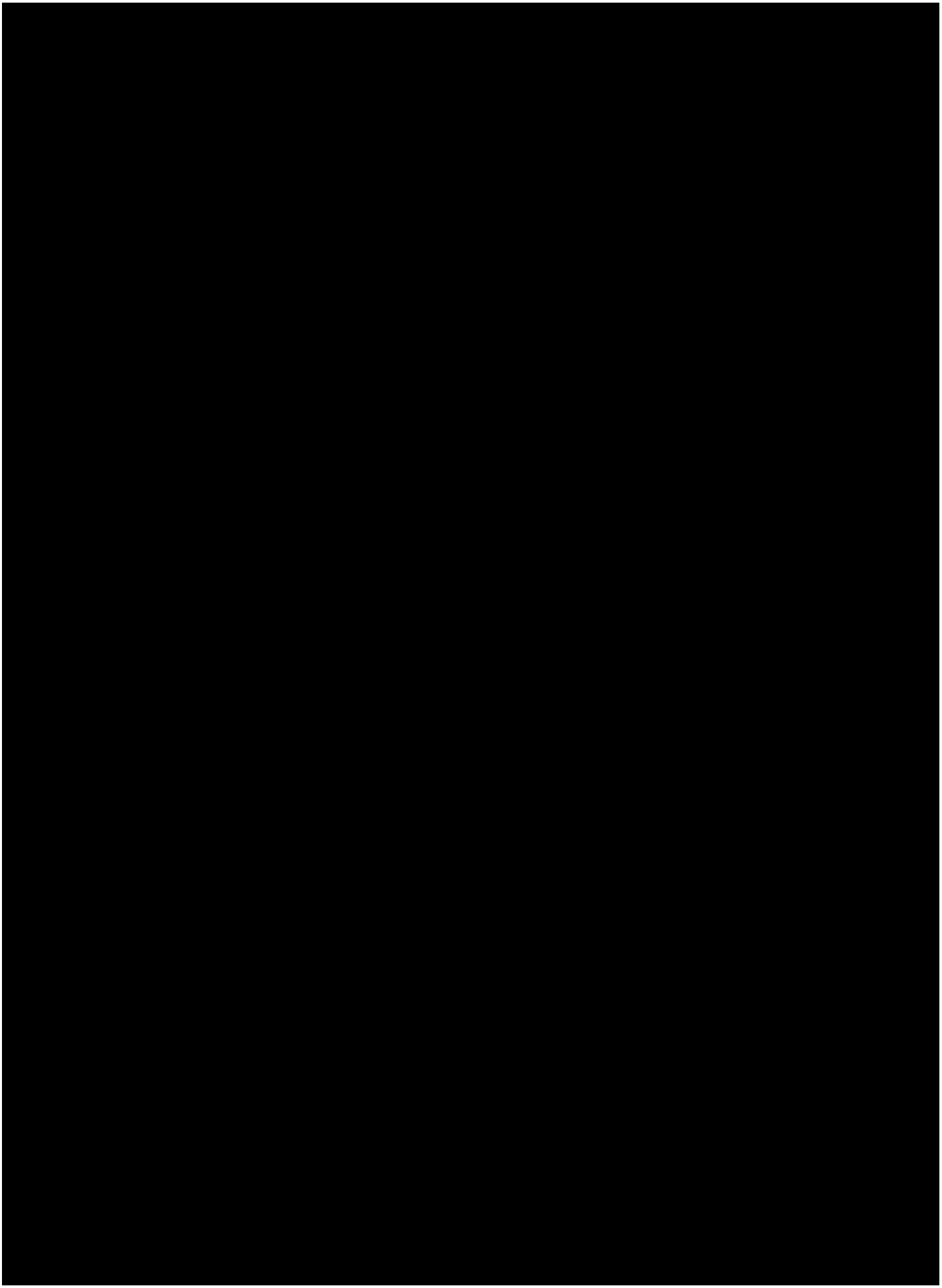
www.dowagrosciences.com.au

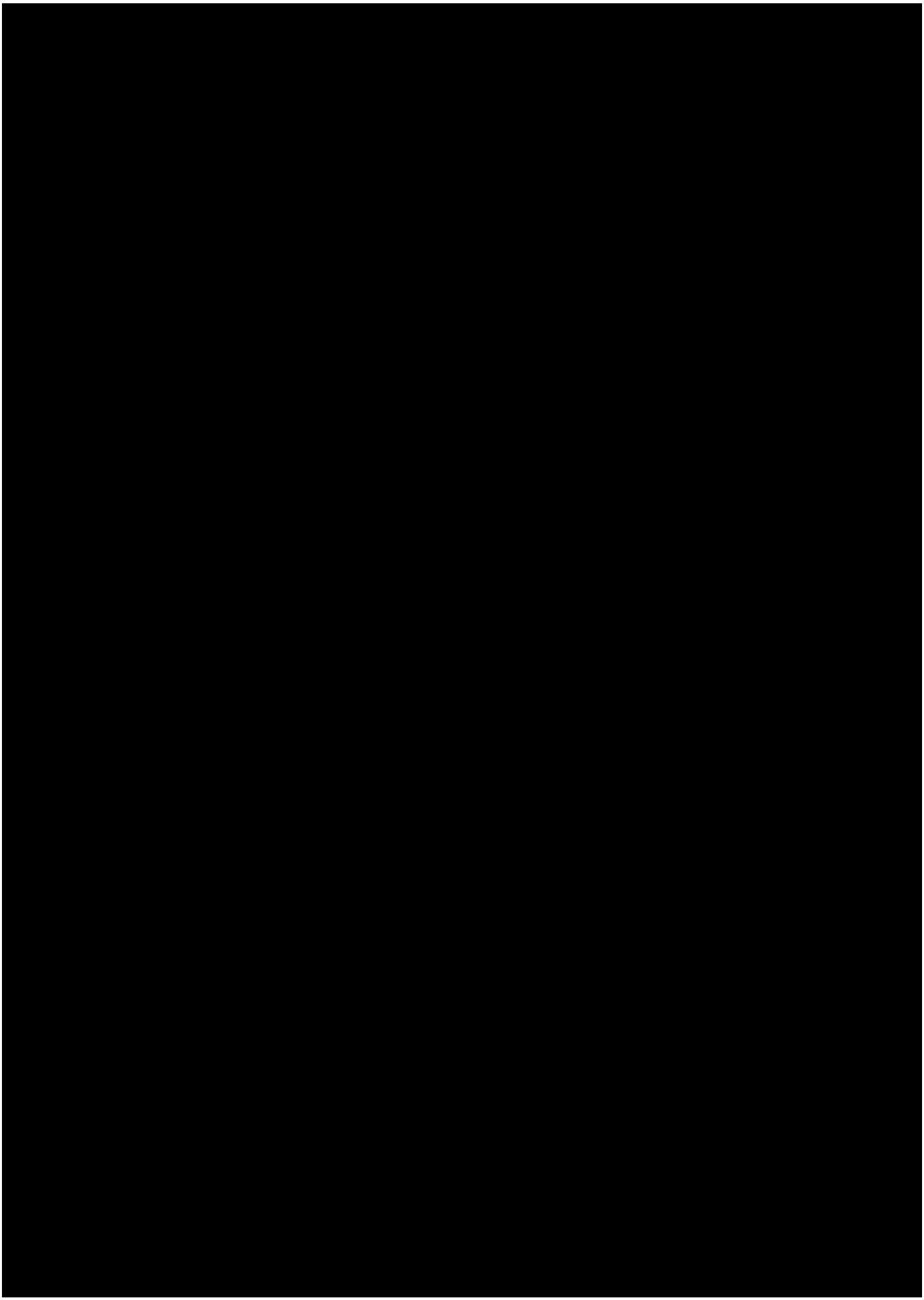
Dow AgroSciences [redacted] *Solutions for the Growing World*

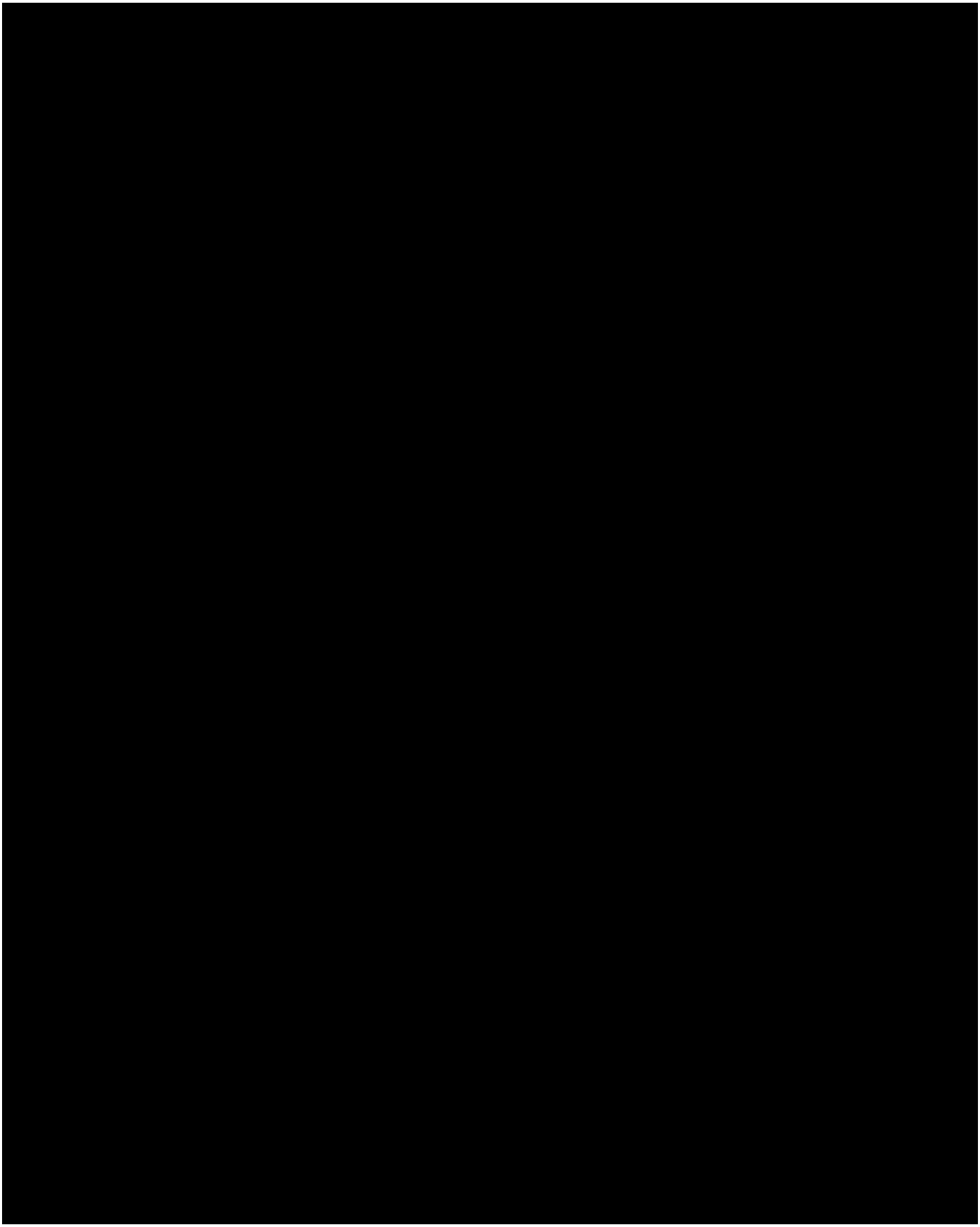
[redacted]

[redacted]









[redacted]

From: [redacted]
Sent: Tuesday, 5 May 2015 3:31 PM
To: [redacted]
Cc: ogtrcommittees
Subject: RE: IBC Forum [SEC=UNCLASSIFIED]

Hi [redacted]

About to call you on your mobile – slides attached fyi.

OGTR hasn't taken a final decision on what will / won't be published on the IBC page of the OGTR website but I am happy for you to share this with your IBC – they could all have been there of course.

Cheers

[redacted]

[redacted]
Regulatory Practice & Compliance Branch
Office of the Gene Technology Regulator
MDP 54 | GPO Box 9848 | CANBERRA ACT 2601 | AUSTRALIA

tel: [redacted] fax: +61-2-6271 4202 Free Call (in Australia) 1800 181 030
[redacted] | www.ogtr.gov.au

[redacted]

[redacted]

From: [redacted]
Sent: Wednesday, 29 April 2015 9:19 AM
To: ogtrcommittees
Subject: permission request [SEC=No Protective Marking]

Hi [redacted]

I have an IBC meeting (Swinburne Uni) next week. No one from the committee was able to attend the IBC forum so I was hoping to provide the committee with an update in regard to new breeding technologies.

Was the material presented at the last GTTAC meeting regarding the review of schedule 1 also presented at the IBC forum., ie, may I have your permission to discuss the upcoming review with my IBC? Were there any aspects of what was discussed at GTTAC (with regard to new breeding technologies) that are not be discussed due to confidentiality?

Finally, would it be possible to obtain a copy of the slides presented at the IBC forum on this topic?

Thanks
[redacted]

[redacted]

From: [redacted]@health.gov.au> on behalf of ogtrcommittees <ogtrcommittees@health.gov.au>
Sent: Wednesday, 10 December 2014 13:02
Subject: Re: Question on CRISPR/CAS, TALEN [SEC=UNCLASSIFIED]

Dear [redacted]

[redacted]

[redacted]

The OGTR currently considers queries regarding whether or not techniques or organisms are regulated under the *Gene Technology Act 2000* on a case by case basis. I'm sure that you can appreciate that provision of the Regulator's view on whether something is or is not subject to regulation under the legislation requires proper consideration, so it can take some time to provide responses.

[redacted]

Kind regards

[redacted]

[redacted]

Office of the Gene Technology Regulator

Committee Secretariat

Ph: [redacted]

Fax: (02) 6271 4202

Email: ogtrcommittees@health.gov.au

MDP 54, PO Box 9848, Canberra, ACT 2601

From: [redacted]

To: "ogtrcommittees@health.gov.au" <ogtrcommittees@health.gov.au>,

Date: 05/12/2014 10:00

Subject: Question on CRISPR/CAS, TALEN [SEC=No Protective Marking]

Hi [redacted]

I have been approached by a senior executive staff member within the University to seek clarification from the OGTR on the following hypothetical question briefly outlined below. Based on the documents that we have been supplied with in the past through the committee (e.g. the recent BBSRC New Techniques PDF), it is still ambiguous to me as to whether the organism in the hypothetical scenario below would be classed as a GMO according to the OGTR current rulings.

The question raised centres on the use of the new CRISPR/CAS and TALEN technologies where a researcher can readily create a specific mutation (that they could also create, at much greater expense and over a much longer time period, by traditional mutagenesis and PCR analysis). As I understand it based on everything the committee has discussed since I have been a member and to the best of my knowledge, the former could/does come under the 'genetically modified organism' category but there has been no cases to test this to date. The latter (traditional mutagenesis) will not, even though the lines produced from the two approaches would be identical (i.e. the same DNA base change, for example). As we know, using the CRISPR/CAS, TALEN technologies does not introduce any foreign DNA sequences. In this day and age when we can readily verify the genome sequence to show that we have made the precise change that could be made by a traditional mutagenesis approach, an organism produced through the CRISPR/CAS, TALEN technology could theoretically be classed as a non-GM organism, as in this case there is no introduction of any foreign DNA to achieve the desired change.

[redacted]

Sincerely,

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

The University of Adelaide

South Australia 5064

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

From: [redacted]@health.gov.au on behalf of OGTR.CDES@health.gov.au
Sent: Monday, 3 November 2014 13:54
Subject: Re: Fw: Enquiry regarding CRISPR technology [SEC=UNCLASSIFIED]

Dear [redacted]

Thank you for your email regarding CRISPR-CAS mediated genome editing technology, and my apologies for the delay in replying. This is a relatively new technology and we have been discussing it for some time now.

The OGTR currently has a working group that are considering organisms modified using new technologies, and whether or not they are regulated under the *Gene Technology Act 2000*. [redacted]
Site-directed mutagenesis using oligonucleotides is also a consideration of this group.

I have forwarded your query to this group, but you should be aware it may take some time before we can provide an answer.

The Regulations are periodically reviewed, in response to suggestions from regulated organisations, as well as from operational experience within the OGTR. The OGTR continually monitors advances in gene technology (including
technologies such as the CRISPR/Cas system), and how they should best be captured by the regulatory framework. These considerations feed into the regular review of the Regulations.

We encourage your organisation to make a submission to the Gene Technology Regulator regarding CRISPR/Cas9 mediated genome engineering so that it can be considered in the next round of the review process. Submissions can be made at
any time, and will be considered at the time of the next review.

I can't give you a specific date for the commencement of the next review of the Regulations, but as with previous reviews, we will correspond with stakeholders when the review process begins.

I hope this helps. Please don't hesitate to contact me if you need to discuss this matter further.

Regards

[redacted]

Contained Dealings Evaluation Section
Office of the Gene Technology Regulator
Ph: 1800 181 030
Fax: 6271 4202
e-mail: OGTR.CDES@health.gov.au

[redacted]

From: [redacted]
To: "OGTR.Applications@health.gov.au" <OGTR.Applications@health.gov.au>,
Cc: [redacted]
Date: 23/10/2014 16:27
Subject: Enquiry regarding CRISPR technology [SEC=No Protective Marking]

Dear Sir/Madam

The MCRI/RCH (Melb) IBC has had several applications recently involving the use of CRISPR/Cas9 system for genetic manipulation of mice. Some issues have arisen that we would seek clarification on before beginning to approve any more projects.

More specifically, there seems to be a difference of opinion amongst researchers as to whether a mouse carrying a point mutation created by CRISPR technology is classified as genetically modified organism. The mice mentioned are created by CRISPR technology but do not have contain any exogenous DNA (for selection, reporters etc) and the only variation is the induced point mutation.

We have checked the OGTR guidelines and interpreted them as follows:
Mice created using CRISPR technology are of two kinds. Firstly, if a dsDNA break is used to make a mutation or deletion by non-homologous end joining (NHEJ), then they are classed as item 1 (therefore not GMO according to schedule 1, and therefore exempt like ENU mice). However, if foreign DNA is introduced at the site of the dsDNA break, e.g. an epitope tag or reporter, then these mice are classified as GMOs, as per other GM mice carrying exogenous DNA.

Can you please advise us as to whether we have interpreted the guidelines correctly in as they might apply to the use of CRISPR technology?

Best Regards
[redacted]

[redacted]

Murdoch Childrens Research Institute
The Royal Children's Hospital
Flemington Road Parkville Victoria 3052 Australia
T [redacted]
M [redacted]
E [redacted]
www.mcri.edu.au

[redacted]

From: [redacted]
Sent: Thursday, 7 May 2015 4:35 PM
To: [redacted]
Cc: [redacted]
Subject: RE: ask starting time [SEC=UNCLASSIFIED]

Dear [redacted]

Attached is the document with answers to your questions.

Regards

[redacted]

[redacted], Contained Dealings Evaluation Section
Office of the Gene Technology Regulator

[redacted] | 🖷: (02) 6271 4202
Free Call: 1800 181 030 | 💻: www.ogtr.gov.au
Post: MDP 54, GPO Box 9848, Canberra ACT 2601 Australia

[redacted]

[redacted]

From: [redacted]
Sent: Monday, 27 April 2015 3:02 PM
To: [redacted]
Cc: [redacted]
Subject: RE: ask starting time [SEC=UNCLASSIFIED]

Dear [redacted]

I read books about 'Risk Analysis Framework2013' you gave us at last meeting and some questions come up accompanying with our understanding the Australian regulation.

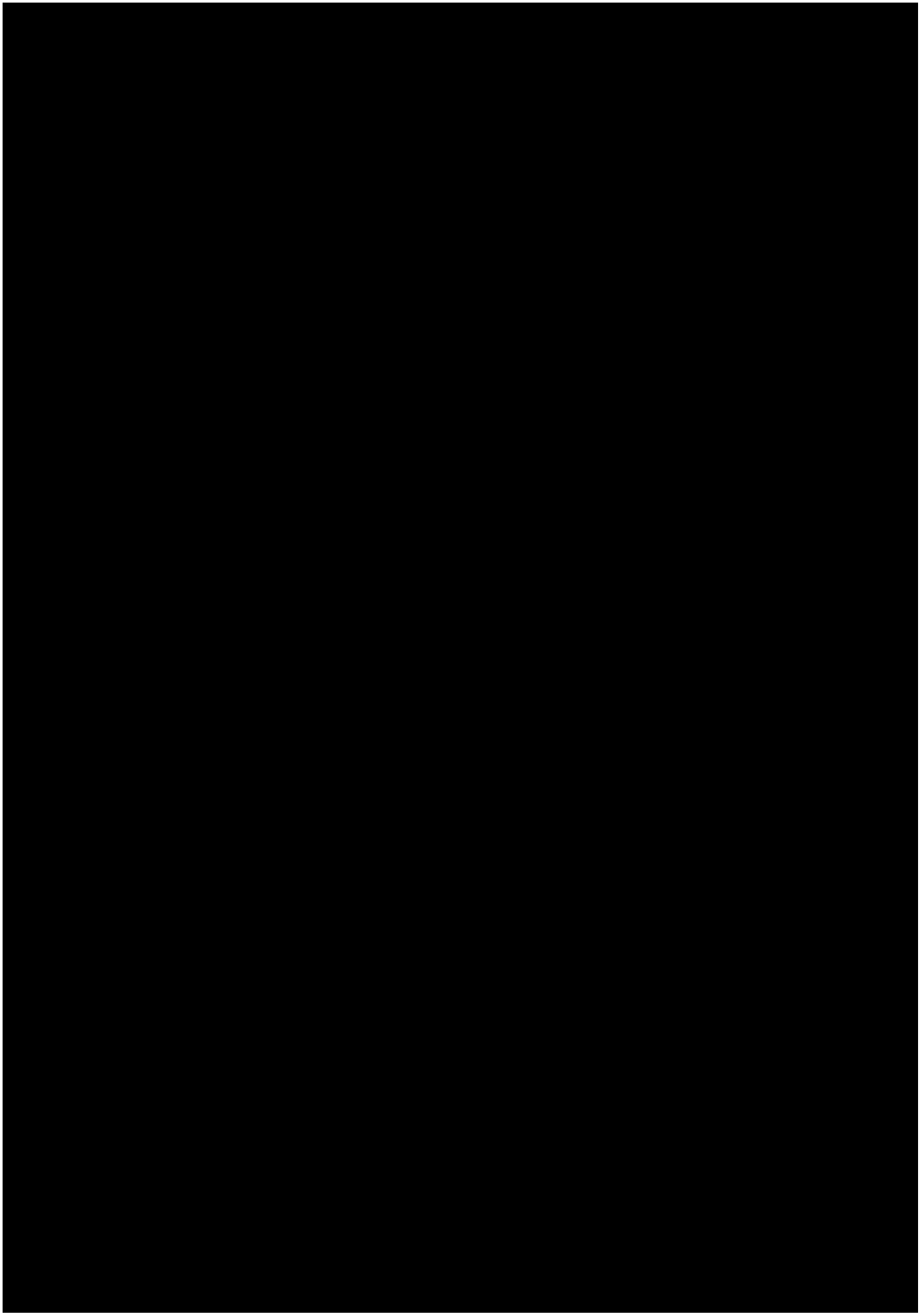
Would you reply me for attached fragmental questions? I think your answers are helpful for our further understanding.

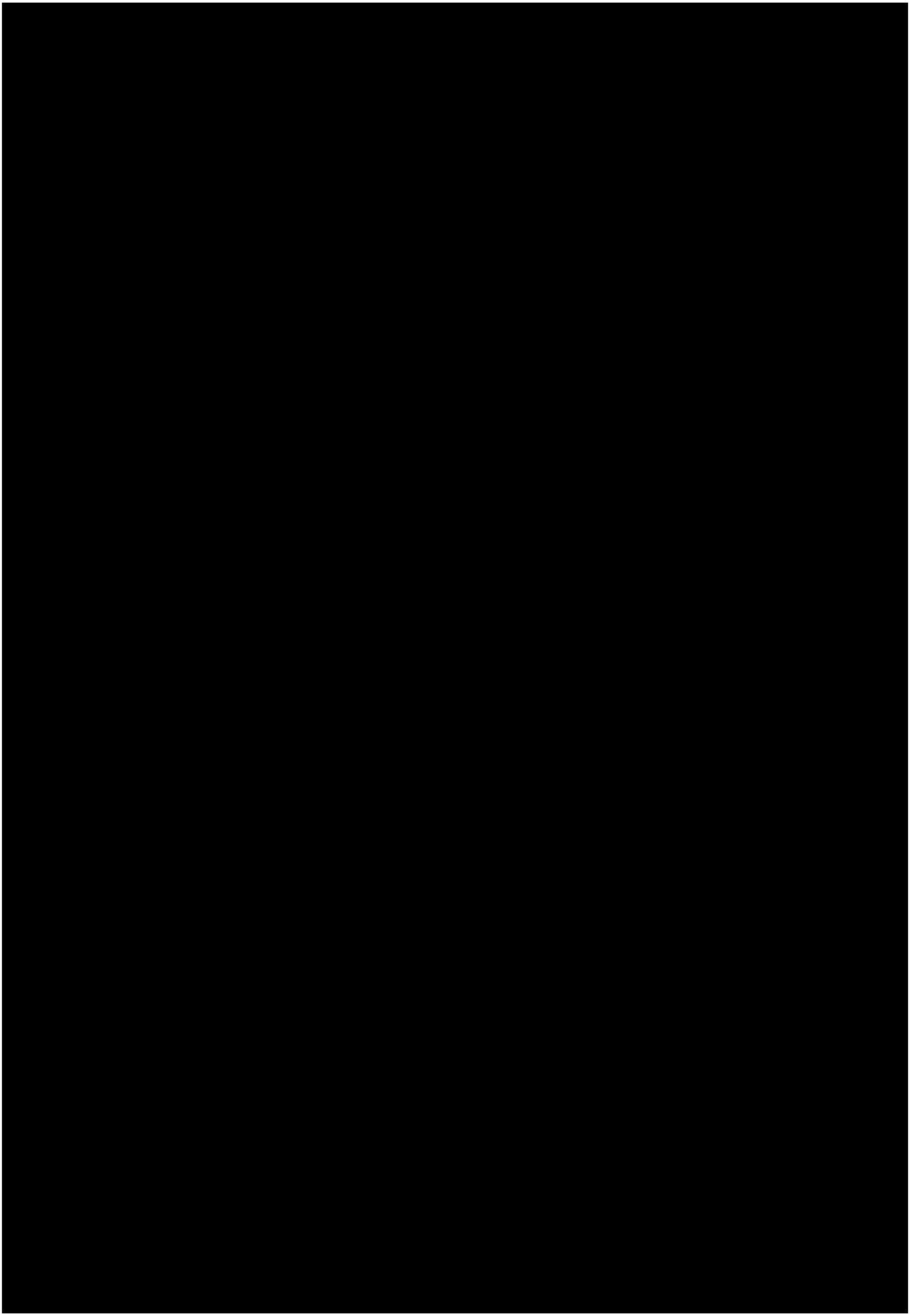
Sincerely yours,
[redacted]

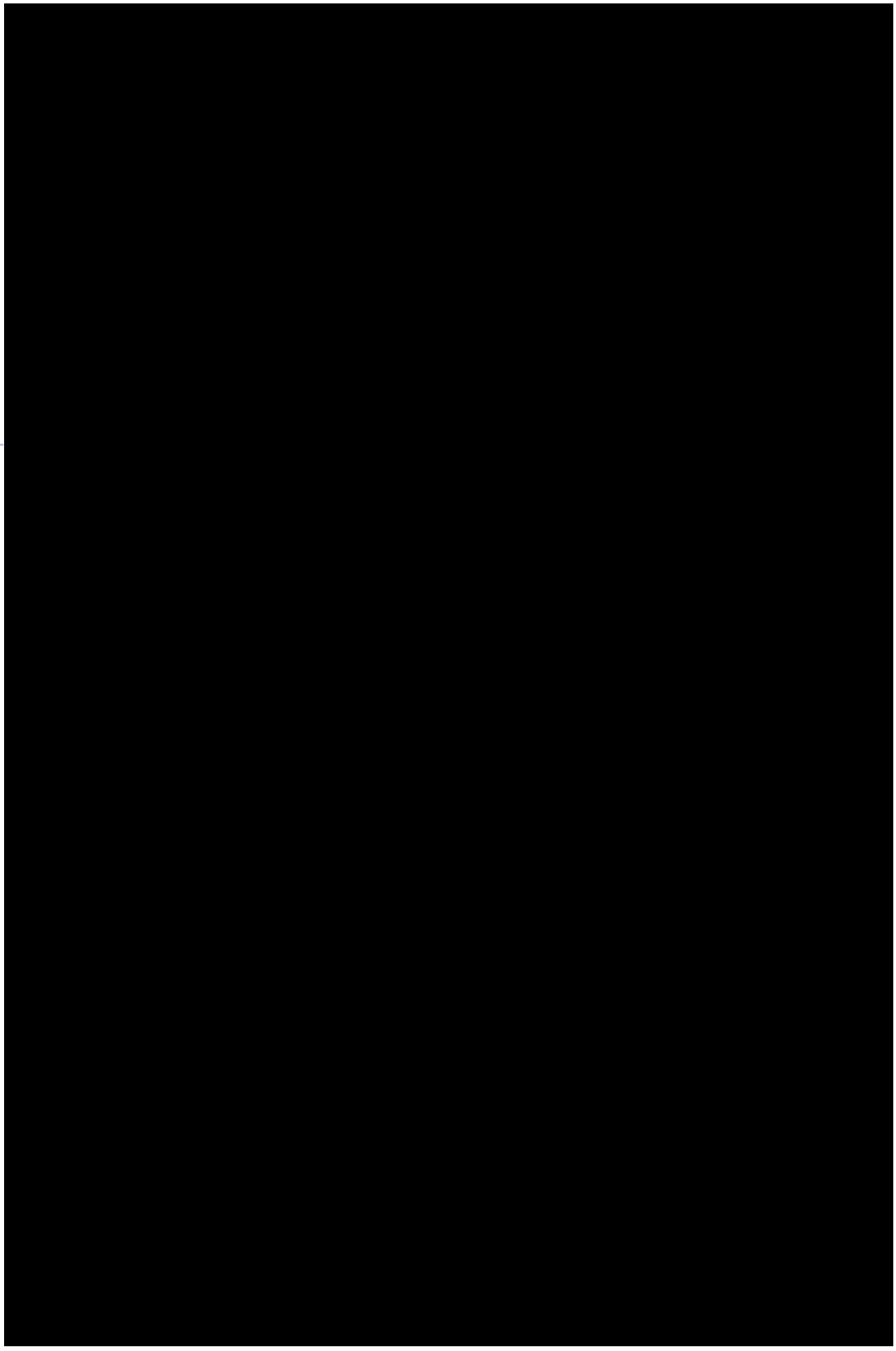
[redacted]

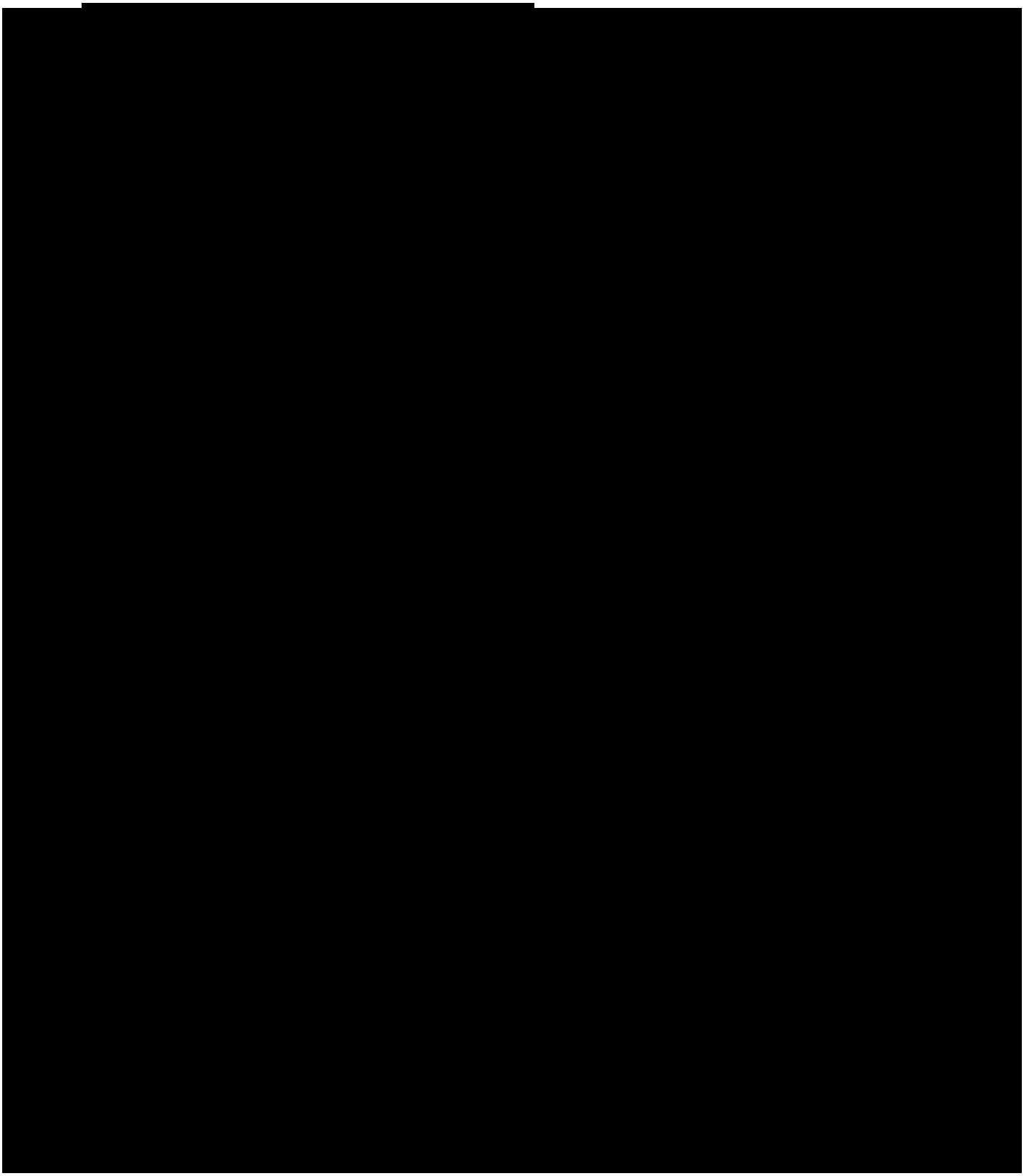
Kao Corporation
1334 Minato Wakayama,
Wakayama prefecture
640-8580 Japan
[redacted]

[redacted]









[redacted]

From: [redacted] on behalf of OGTR CDES
Sent: Monday, 25 January 2016 14:35
To: [redacted]
Cc:
Subject: RE: HackerSpace - import DIY CRISPR kits? [SEC=UNCLASSIFIED]

Dear [redacted]

Thank you for your query regarding DIY CRISPR -kits.

On OGTR website there is some information provided regarding DIY activities which may be useful please feel free to have a read:

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIYBioResearch2-htm

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmo-supply-htm

To give you a brief over view of Australian regulatory system for work involving GMOs, ***The Gene Technology Act 2000* prevents all dealings with GMOs in Australia unless they are:**

- **licenced dealings** approved by the Gene Technology Regulator, subject to conditions on activities, and conducted in particular certified facilities; or
- **notifiable low risk dealings** authorised by an Institutional Biosafety Committee (IBC) on behalf of an accredited organisation, subject to conditions on activities, and conducted in regulated classes of certified facilities; or
- **exempt dealings**, must not involve an intentional release of the GMO into the environment and are set out in *Schedule 2 Dealings exempt from licensing* of the Gene Technology Regulations.

There are offences for dealing with GMOs outside these categories of activity and for not complying with the requirements for these categories of activity.

The most easily accessible level of dealings with GMOs is the exempt dealing category. Some groups in Australia are now moving towards developing their own certified facilities and IBCs and becoming accredited organisations under the regulatory system as part of phased approaches to possibly undertaking higher levels of dealing. In any event, I thought it would be useful to give you the link to our webpage, particularly on Exempt Dealings. It describes these dealings, advises that Exempt dealings do not require a specified level of containment but further says that the Regulator has released Guidance Notes for the Containment of Exempt Dealings, that are effectively equivalent to those for facilities certified by the Regulator to Physical Containment Level 1 (PC1). It also has a link to the List of host/vector systems classified as 'exempt', being the dealings described in Schedule 2, Part 1 of the regulations. The guidance notes advise that the *only further legislative requirement for exempt dealings is that they do not involve an intentional release of the GMO into the environment.*

Thanks again for contacting OGTR and I hope above information is helpful. Please feel free to contact us if you need any further information.

Kind Regards

[redacted]

[redacted] | Contained Dealings Evaluation Section
Office of the Gene Technology Regulator | Level 1, Pharmacy Guild House, 15 National Circuit, Barton ACT 2600
Postal address: MDP 54 - GPO Box 9848, Canberra ACT 2601
Freecall 1800 181 030 | Fax (02) 62714202 | http://www.ogtr.gov.au

Disclaimer: Please note that any response provided by the OGTR is based on the information made available to the Office, and should be considered as general advice and does not constitute legal advice. Therefore, any response provided by the OGTR should be considered in conjunction with any legal advice you may seek.

From:
To:
Subject: HackerSpace - import DIY CRISPR kits?
Date: Mon, 25 Jan 2016 00:02:56 +1000

Hi , My name is . I am a science teacher. I am interested in the idea of Hacker Spaces.

from gave me your email address.

I was hoping that you could help me with a query I have.
Are you aware of whether I can import DIY CRISPR kits?
https://www.indiegogo.com/projects/diy-crispr-kits-learn-modern-science-by-doing#/

Regards,

Skype:
Home:

Mobile : [redacted]

[redacted]

From: [redacted]
Sent: Friday, 23 January 2015 10:58 AM
To: [redacted]
Subject: RE: Information on the Regulatory Status of NBTs [SEC=UNCLASSIFIED]

Dear [redacted]

Thanks a lot for your swift feedback and for this piece of information.

The Reports from the workshops organized by FSANZ are indeed quite interesting. I 'll have a more in depth look at these documents (I had a quick look at the report dated from October 2013) and may then take the liberty to contact you, in case I have any particular question in that respect.

As requested, please find attached a copy of the study on 'the regulatory status of NBTs outside the EU' that we have finalized in October 2013. We are currently in the process of updating this document. We'll be glad to share this paper with you once finalized (within a couple of weeks).

Please feel to come back to us in case you have any particular question in the meantime.

Kind regards,

[redacted]

[redacted]
NBT Platform Secretariat

The NBT Platform is a coalition of SMEs, large industry representatives and members of prominent academic and research institutes which strives to bring clarity to the European debate on NBTs. Its aim is to provide policy makers and stakeholders with clear and precise information on NBTs and to generate awareness about their widespread benefits for the European economy and society as a whole. NBT Platform Secretariat, Rue Belliard 199, bte 22,1040 Brussels, T: [redacted]

From: [redacted]
Sent: maandag 19 januari 2015 5:48
To: 'NBT Secretariat'
Subject: RE: Information on the Regulatory Status of NBTs [SEC=UNCLASSIFIED]

Dear [redacted]

There are no new developments to report regarding regulatory situation for plants derived through NBTs in Australia. Therefore, as previously indicated, the published report from the European Commission Joint Research Centre NPBT meeting in Seville in 2011 still provides a reasonable reflection of the Australian situation.

However, in relation to food regulation, the Australian food regulatory agency (Food Standards Australia New Zealand; FSANZ) held workshops in 2012 and 2013 to consider food derived from such plants. The purpose of these workshops was to enhance FSANZ's scientific knowledge and understanding a number of NBTs, and to discuss related scientific, technical and regulatory issues. The reports from these workshops may be of interest to you, and can be found on the FSANZ website, at http://www.foodstandards.gov.au/consumer/gmfood/Pages/New-plant-breeding-techniques-in-the-spotlight.aspx.

Has the NBT Platform finalised a report on the international regulatory situation for NBTs? If so is it available publically, or are you able to share it with us? As you note, it is useful to understand the approach of other countries when considering local positions.

Regards

[redacted]

[redacted] Contained Dealings Evaluation Section
Office of the Gene Technology Regulator

[redacted] | 🖷: (02) 6271 4202
Free Call: 1800 181 030 | 💻: www.ogtr.gov.au
Post: MDP 54, GPO Box 9848, Canberra ACT 2601 Australia

From: NBT Secretariat [mailto:info@nbtplatform.org]
Sent: Saturday, 17 January 2015 1:17 AM
To: [redacted]
Subject: Information on the Regulatory Status of NBTs [SEC=No Protective Marking]

Dear Sir,

My name is [redacted], and I am contacting you on behalf of [redacted], the Chairman of the 'New Breeding Techniques (NBT) Platform'. The NBT Platform is a coalition of SMEs, large industry representatives and members of prominent academic and research institutes which strives to bring clarity to the European debate on plant new breeding techniques.

We contacted you in early 2013 in order to collect information on Australia's domestic policie(s) and/or legislation(s) targeting at NBTs. We are getting in touch with you again to ask you whether you could report to us any possible new developments on that subject.

As you may be aware, the European Commission is in the process of forming an official position with regards to regulating NBTs. We know by experience that the European Union usually takes account of policies in third countries when adopting its own position (and '*vice versa*'). We therefore strive to gather any relevant information on non-EU countries legislations on that subject.

In case you are not following this particular topic, could you please direct me to one of your colleagues.

Thanking you in advance for your collaboration, I remain at your disposal in case you require any precisions concerning the above request or the NBT Platform activities.

Best regards,

[redacted]
On behalf of [redacted]
Chairman of the NBT Platform

The NBT Platform is a coalition of SMEs, large industry representatives and members of prominent academic and research institutes which strives to bring clarity to the European debate on NBTs. Its aim is to provide policy makers and stakeholders with clear and precise information on NBTs and to generate awareness about their widespread benefits for the European

economy and society as a whole. NBT Platform Secretariat, Rue Belliard 199, bte 22,1040 Brussels, T: [redacted]

[redacted]

From: [redacted]
Sent: Wednesday, 19 March 2014 22:30
To: [redacted]
Cc: [redacted]
Subject: RE: OECD workshop / Report into the regulatory status of NBTs outside EU [SEC=UNCLASSIFIED]
Attachments: REP Regulatory Status of NBTs... Open Doc Oct 13.docx

Dear [redacted]

Thank you for your reply. The document is kept as a working document, so that information can be added whenever there are relevant developments. I have attached a version of the document in which you would be able to make some factual corrections in Track Changes, which would be very much appreciated by us. The document is not regarded as confidential but it is not published anywhere. We share it with relevant stakeholders in the discussion on the regulatory status of NBTs.

I hope to hear from you, thank you in advance for your effort.

Best regards, vriendelijke groet,

[redacted]

[redacted] NBT Platform
Zeestraat 84_2518 AD The Hague, NL_+[redacted]

The NBT Platform is a coalition of SMEs, large industry representatives and members of prominent academic and research institutes which strives to bring clarity to the European debate on NBTs. Its aim is to provide policy makers and stakeholders with clear and precise information on NBTs and to generate awareness about their widespread benefits for the European economy and society as a whole. NBT Platform Secretariat, Rue Belliard 199, bte 22,1040 Brussels, [redacted]

Van: [redacted]
Verzonden: woensdag 19 maart 2014 6:10
Aan: [redacted]
CC: [redacted]
Onderwerp: RE: OECD workshop / Report into the regulatory status of NBTs outside EU [SEC=UNCLASSIFIED]

Dear [redacted]
Thank you for your email and apologies for my delay in replying.

I do recall meeting [redacted] at the OECD meeting, although he did not mention the study that you had conducted.

Unfortunately we have no further information to update the study as the work on regulatory status is still ongoing. However, we would like to provide you with some corrections of factual errors about the Australian regulatory system. Is this document subject to ongoing revision or do you have a deadline for us providing you with such corrections? Is this document currently available publically or is there an intent to male it public?

Kind regards

[redacted]

[redacted] | Assistant Director | Regulatory Practice & Secretariat Section | Regulatory Practice & Compliance Branch | Office of the Gene Technology Regulator | MDP 54 | GPO Box 9848 | CANBERRA ACT 2601 | AUSTRALIA | tel. [redacted], fax. 62714202 | [redacted]

[redacted]

Van: [redacted]
Verzonden: vrijdag 7 maart 2014 15:52
Aan: [redacted]@health.gov.au'
CC: [redacted]
Onderwerp: OECD workshop / Report into the regulatory status of NBTs outside EU

Dear [redacted],

As you may recall, during the OECD workshop on 10 February you met my colleague [redacted]. It is on his behalf that I would like to bring to your attention a study that we have conducted in 2013, titled 'The regulatory status of New Breeding Techniques in countries outside the European Union'. In the report we

have also added a section on Australia, for which I have been in regular contact with the FSANZ and the OGTR (specifically, with [redacted]).

Enclosed, please find the report, which contains the section on Australia on pages 8-11 and has an update on page 41 and 42 based on the FSANZ opinion on several NBTs. I am very interested in your opinion on the information contained in this report, specifically the section on Australia. Also, could you inform me if there have been any developments (from the side of the OGTR and in general) since the study was last updated (October 2013)?

[redacted]

Best regards, vriendelijke groet,

[redacted]

[redacted] NBT Platform
Zeestraat 84_2518 AD The Hague, NL_+[redacted]

The NBT Platform is a coalition of SMEs, large industry representatives and members of prominent academic and research institutes which strives to bring clarity to the European debate on NBTs. Its aim is to provide policy makers and stakeholders with clear and precise information on NBTs and to generate awareness about their widespread benefits for the European economy and society as a whole. NBT Platform Secretariat, Rue Belliard 199, bte 22,1040 Brussels, T: [redacted]

Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

[redacted]
Boehringer Ingelheim Pty Limited
[redacted]

By email: [redacted]

Dear [redacted]

Advice on the classification of live, attenuated Bovine Viral Diarrhea Virus Vaccine strains under the *Gene Technology Act 2000*

I refer to [redacted]'s email of December 2011 (and subsequent liaison between the OGTR and Boehringer Ingelheim Pty Ltd) requesting advice on whether or not two mutant Bovine viral Diarrhea Virus (BVDV) strains are Genetically Modified Organisms (GMOs) under the *Gene Technology Act 2000* (the Act) and Gene Technology Regulations 2001 (the Regulations).

In my view, the organisms you describe meet the definition of GMOs, and are therefore subject to regulation under Australian legislation. The reasoning for this conclusion is outlined below.

Please note that this response is provided based on the information made available to my office at this time, and should be considered as general advice and does not constitute legal advice. This response should be considered in conjunction with any legal advice you may seek.

Classification of the mutant BVDV strains

Section 10 of the Act provides a definition of *genetically modified organism* (GMO).

Genetically modified organism means:

(a) an organism that has been modified by gene technology; or
(b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
(c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

(d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or

(e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

This definition is qualified by specific exclusions listed in Schedule 1 of the Regulations.

In relation to your query, the effect of Item 1 of Schedule 1 was considered. This item reads as follows:

> *A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).*

Your query relates to mutant BVDV strains characterised by loss of nucleic acid sequences in the E^{rns} and N^{pro} coding regions. Gene technology was used to remove specific sequences from the viral genome so as to produce a desired phenotype, therefore these strains meet parts (a) or (b) of the definition of GMO in the Act.

In relation to Schedule 1 Item 1, while no non-BVDV sequences remain at these loci in the final organisms, the mutational events by which the mutant strains were created involved the introduction of non-homologous sequence into the viral genome. The introduced DNA was generated using synthetic oligonucleotides that contained the desired deletions and thus were not identical to wild-type BVDV sequence. These non-homologous sequences were firstly incorporated into sub-genomic viral fragments, and then into the complete viral genomes. Consequently these organisms are not excluded from regulation under the Act by this item.

Other regulatory requirements

In addition to the OGTR, a number of Australian Government Departments and agencies may have requirements that need to be met in relation to the proposed activities. Authorisations or

approvals for import or use of the GMOs may be required from the Department of Agriculture (formerly Australian Quarantine Inspection Service (AQIS)) and the Australian Pesticides and Veterinary Authority (APVMA). We recommend that you contact these agencies to discuss their requirements for the proposed activities.

I trust this information is of assistance. If you wish to discuss this matter further, please contact [redacted].

Yours sincerely

[redacted]

A/g Gene Technology Regulator

12 January 2015

[redacted]

From: [redacted]
Sent: Friday, 1 April 2016 2:07 AM
To: [redacted]
Subject: RE: PBI 2nd roundtable meeting 5-6 April - slides and Qs [SEC=UNCLASSIFIED]

Dear [redacted]

Please find attached my set of slides for the update.

Could I also ask a couple of questions about the meeting.

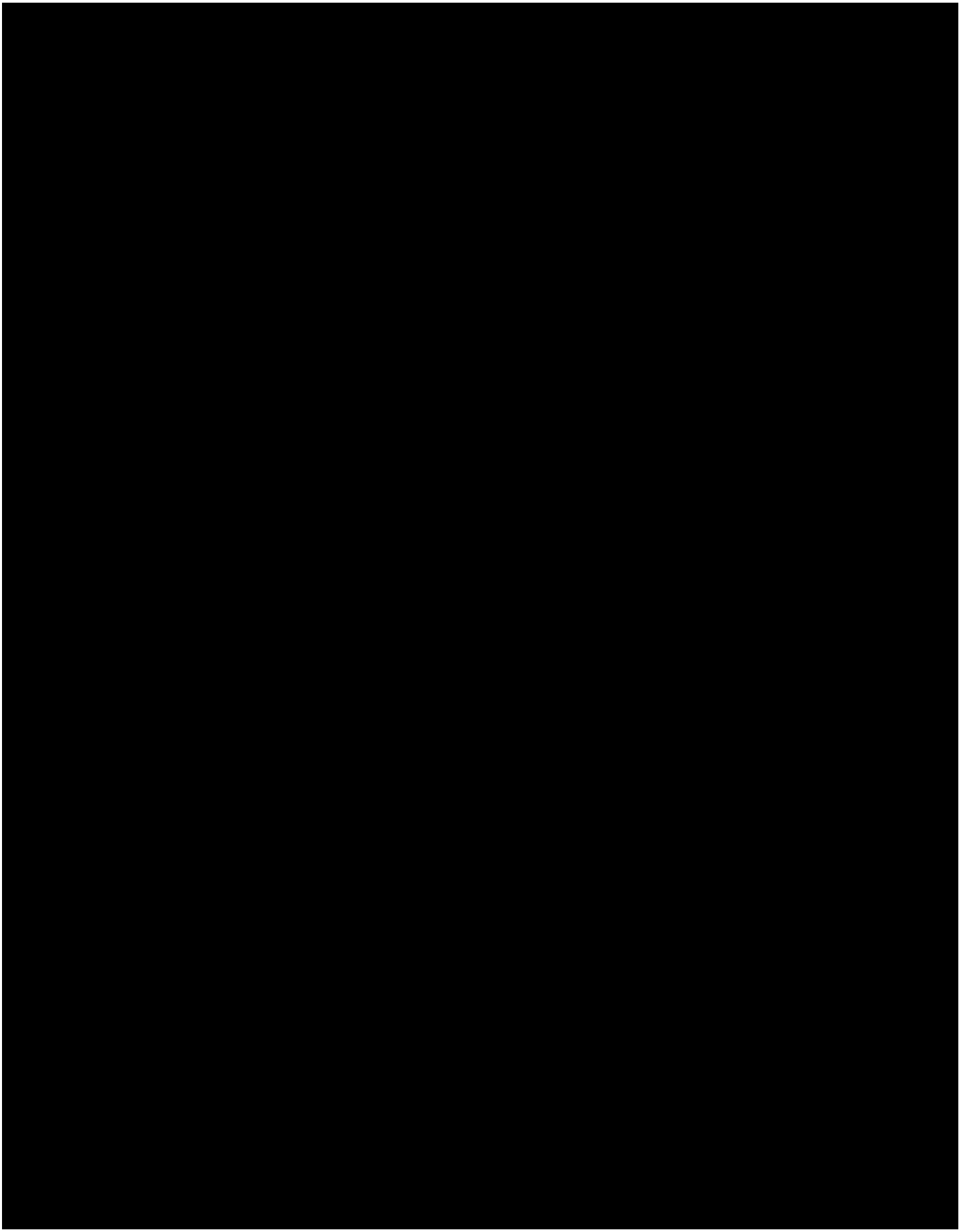
Will there be any media present during the meeting?

Is it anticipated that there will be any summary or report published (eg on the web) after the meeting, and if so what form it is likely to take?

Kind regards

[redacted]

[redacted]



[redacted]

From: [redacted] on behalf of OGTR CDES
Sent: Wednesday, 15 April 2015 12:07
To: [redacted]
Subject: RE: Response to query regarding use of siRNA, oligos and CRISPR-CAS genome editing [SEC=UNCLASSIFIED]

Dear [redacted]

[redacted]

As [redacted] mentioned that CRISPR-CAS relatively new technology and the subject of ongoing discussion as to the extent to which it's captured by the current regulatory scheme.

After looking at the information provided, I would agree with the IBC that *in vitro* dealings with lentiviral system proposed to be used would meet the criteria as described under Schedule 2.1(l) as it currently stands.

However, *in vivo* dealings with the lentiviral system may or may not meet the criteria as described under Schedule 2.1(l), depending upon the characteristics of CAS9 gene encoded by the lentiviral system.

[redacted]

I hope this helps

Kind Regards

[redacted]

[redacted] | Contained Dealings Evaluation Section | Phone [redacted]
Office of the Gene Technology Regulator | Street address: Level 1, 15 National Crt, Barton ACT 2600 | Postal address: MDP 54 - GPO Box 9848, Canberra ACT 2601 | Freecall 1800 181 030 | Fax (02) 62714202 | http://www.ogtr.gov.au

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From: [redacted]
Sent: Friday, 13 March 2015 11:21 AM
To: OGTR Applications
Cc: [redacted]
Subject: FW: Response to query regarding use of [redacted] oligos and CRISPR-CAS genome editing [SEC=UNCLASSIFIED]

Dear OGTR,

In relation to your response below I would like to ask for advice regarding the application attached.

As I understand, introducing CRISPR-CAS into cells would fall under the exempt schedule. However, the researcher is aiming to use CRISPR technology to generate non-replicative recombinant lentivirus, so we would classify this as PC2 dealing.

Our questions are

a) Could you please confirm that the CRISPR/Lenti vector system is regulated under Schedule 2.1.(l)
b) Could you please let us know whether the dealings with the different delivery systems should be recorded and reported separately?

Thanks and Kind Regards
[redacted]

[redacted]
SA Pathology
[redacted]

http://www.sapathology.sa.gov.au/

Research Directorate
SA Pathology
PO Box 14 Rundle Mall, Adelaide, SA, 5000

For our patients and our population

From: [redacted]@health.gov.au] **On Behalf Of** OGTR CDES
Sent: Tuesday, 27 January 2015 1:37 PM
To: [redacted]
Cc: [redacted]
Subject: Response to query regarding use of [redacted] oligos and CRISPR-CAS genome editing [SEC=UNCLASSIFIED]

Dear [redacted]

In response to your query last week, I can offer the following advice.

[redacted] **oligos introduced into:**

Cell lines
[redacted] oligos are considered non-vector systems in Schedule 2 Part 2 of the Regulations. Thus, this would be an exempt dealing under Schedule 2 item 4 of the Regulations, as long as all the criteria listed are met. Once the [redacted] oligo is no longer present in the cells, provided it has not caused any persistent changes (e.g. through changes to DNA methylation), the cells would no longer be considered GMOs.

Animals (non-germline cells)
As animals are not exempt hosts, our view is that the actual dealing (introducing the [redacted]) would be an NLRD under Schedule 2 Part 2.1 (c). Once the [redacted] is no longer present in the animal, provided germline cells have not been modified, the animal itself would not be considered a GMO (Schedule 1 Item 2). However, should the [redacted] have caused a genetic change that persists in the (non-germline) cells it entered, further work with the animal could be considered as an exempt dealing under Schedule 2 Item 3.

Single cell embryos
Early non-human embryos, cultured *in vitro*, are an exempt host, so the advice given for tissue culture cells would apply. If they are used to produce animals, and the [redacted] oligo causes a heritable change in the cells, then dealings with the resulting animals would be as for other transgenic animals i.e. PC1 NLRD under 1.1(c) or PC2 NLRD under 2.1(aa).

CRISPR-CAS-mediated genome editing technology

This is a relatively new technology and the subject of ongoing discussion as to the extent to which it's captured by the current regulatory scheme. OGTR can provide advice on specific examples on a case-by-case basis, but this is a lengthy process. At this stage, it may be prudent to assume that work with CRISPR-CAS does fall within the scheme. Under the current regulations, CRISPR-CAS technology could be considered as involving the introduction of a non-vector system and/or non-conjugative plasmid (crRNA and Cas9 RNA/expression plasmid). Classification of dealings and resulting organisms would then be similar to the advice given in relation to [redacted] oligos, save that changes to the genome would be heritable.

The Gene Technology Regulations are periodically reviewed in response to input from regulated organisations as well as operational experience within the OGTR. The OGTR continually monitors advances in gene technology and how they should best be captured by the regulatory framework. These considerations feed into the regular review of the Regulations.

We encourage your organisation to make a submission to the Gene Technology Regulator regarding CRISPR/CAS-mediated genome engineering so that it can be considered when the Regulations are next reviewed. While a commencement date for the next review has not been set, submissions can be made at any time.

Please don't hesitate to ask if you need any further information regarding this query.

Kind regards,

[redacted]

[redacted]
Contained Dealings Evaluation Section
Office of the Gene Technology Regulator
Ph: [redacted] | Fax: 02 6271 4202
Email [redacted]

[redacted]

From: [redacted]
Sent: Friday, 19 December 2014 22:24
To: [redacted]
Subject: Draft Report On International Conference On New Plant Breeding Molecular Technologies -Technology Development And Regulation [SEC=No Protective Marking]
Attachments: Draft Report .docx

To: Speakers Of International Conference On New Plant Breeding Molecular Technologies – Technology Development And Regulation

Dear All

I am sending here with the Draft Report of "International Conference On New Plant Breeding Molecular Technologies –Technology Development And Regulation" held on October 9, 2014 and October 10, 2014 in Jaipur. We will appreciate your suggestions on incorporating any changes in the Report by **December 28**.

If you feel that this may take lots of time during the Holiday Season, you may kindly go through report of your presentation only which is based on your Abstract and PPT.

If we do not hear from you by 28 December, 2014, we will assume that you have agreed with the report.

Wish you a very Merry Christmas And Happy New Year.

With best regards

[redacted]
ILSI-INDIA
G-7, 2nd Floor
Lajpat Nagar-III
New Delhi-110024
Phone [redacted]
Fax: [redacted]
Website: www.ilsi-india.org

[redacted]

From: [redacted]
Sent: Wednesday, 18 March 2015 19:22
To: [redacted]
Cc: [redacted]

Subject: Agenda for our meeting, KAO corporation [SEC=No Protective Marking]
Attachments: KAO-OGTR meeting.pdf; Ref Gene targeting and editing in crop plants_a new era.pdf

Follow Up Flag: Follow up
Flag Status: Completed

Dear [redacted]

I send pdf of agenda containing our status and the discussion matters.
Also, I attached a published paper concerning about the meeting topics written by an Australian authors.

We explain the details of each contents of this sheet, when we visit.
If you have question about the contents before the meeting, please email to me.

We are looking forward to seeing you.

Sincerely yours,

[redacted]

[redacted]

Kao Corporation
1334 Minato Wakayama,
Wakayama prefecture
640-8580 Japan
[redacted]

[redacted]

[redacted]

From: [redacted] on behalf of OGTR CDES
Sent: Tuesday, 1 December 2015 14:02
To: [redacted]
Subject: RE: OGTR - contact us [SEC=UNCLASSIFIED]

Dear [redacted]

Thank you for your query and letting us know about diy-crisper-kits and my apologies for delay in providing the response.

On OGTR website there is some information provided regarding DIY activities which may be useful please feel free to have a read:

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIYBioResearch2-htm

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmo-supply-htm

To give you a brief over view of Australian regulatory system for work involving GMOs, ***The Gene Technology Act 2000* prevents all dealings with GMOs in Australia unless they are:**

- **licenced dealings** approved by the Gene Technology Regulator, subject to conditions on activities, and conducted in particular certified facilities; or
- **notifiable low risk dealings** authorised by an Institutional Biosafety Committee (IBC) on behalf of an accredited organisation, subject to conditions on activities, and conducted in regulated classes of certified facilities; or
- **exempt dealings**, must not involve an intentional release of the GMO into the environment and are set out in *Schedule 2 Dealings exempt from licensing* of the Gene Technology Regulations.

There are offences for dealing with GMOs outside these categories of activity and for not complying with the requirements for these categories of activity.

The most easily accessible level of dealings with GMOs is the exempt dealing category. Some groups in Australia are now moving towards developing their own certified facilities and IBCs and becoming accredited organisations under the regulatory system as part of phased approaches to possibly undertaking higher levels of dealing. In any event, I thought it would be useful to give you the link to our webpage, particularly on Exempt Dealings. It describes these dealings, advises that Exempt dealings do not require a specified level of containment but further says that the Regulator has released Guidance Notes for the Containment of Exempt Dealings, that are effectively equivalent to those for facilities certified by the Regulator to Physical Containment Level 1 (PC1). It also has a link to the List of host/vector systems classified as 'exempt', being the dealings described in Schedule 2, Part 1 of the regulations. The guidance notes advise that the *only further legislative requirement for exempt dealings is that they do not involve an intentional release of the GMO into the environment.*

Thanks again for contacting OGTR and I hope above information is helpful. Please feel free to contact us if you need any further information.

Kind Regards

[redacted]

[redacted] | Contained Dealings Evaluation Section
Office of the Gene Technology Regulator | Level 1, Pharmacy Guild House, 15 National Circuit, Barton ACT 2600
Postal address: MDP 54 - GPO Box 9848, Canberra ACT 2601
Freecall 1800 181 030 | Phone [redacted] | Fax (02) 62714202 | http://www.ogtr.gov.au

Disclaimer: Please note that any response provided by the OGTR is based on the information made available to the Office, and should be considered as general advice and does not constitute legal advice. Therefore, any response provided by the OGTR should be considered in conjunction with any legal advice you may seek.

[redacted]

[redacted]

[redacted]

[redacted]

From: WCMPRD01/SVR/Health@health.gov.au [mailto:WCMPRD01/SVR/Health@health.gov.au]
Sent: Monday, 16 November 2015 12:46 PM
To: VOICEMAIL, OGTR
Subject: New feedback received for OGTR - contact us

FILTER: Contact form

NAME: [redacted]

EMAIL: [redacted]

COMMENTS: Hi,

I was considering purchasing a DIY Crispr kit as part of an Indiegogo campaign - https://www.indiegogo.com/projects/diy-crispr-kits-learn-modern-science-by-doing#/story

Are there any approvals that need to be obtained for this to be imported?

Thanks for your time.

[redacted]

COMPLAINTS:

SUBMIT: Submit

Excel formatted data (copy and paste this text into Column A, on a new row, in Excel)
****
Contact form,[redacted],Hi,

I was considering purchasing a DIY Crispr kit as part of an Indiegogo campaign -

https://www.indiegogo.com/projects/diy-crispr-kits-learn-modern-science-by-doing#/story

Are there any approvals that need to be obtained for this to be imported?

Thanks for your time.

[redacted],,Submit,,

[redacted]

From: [redacted]@health.gov.au on behalf of OGTR.CDES@health.gov.au
Sent: Friday, 9 May 2014 15:07
Subject: Re: Definition of NOT a Genetically Modified Organism - [redacted] [SEC=UNCLASSIFIED]

Hello [redacted]

As discussed on the phone this morning, the OGTR currently has a working group that are considering organisms modified using new technologies, and whether or not they are regulated under the *Gene Technology Act 2000*. [redacted] I'm happy to pass on your query to this group, but you should be aware it may take some time before we can provide an answer. [redacted]

Site-directed mutagenesis using oligonucleotides is also a consideration of this group.

As discussed, until we can provide you with advice on this, you may wish to continue to cover these GMOs under an NLRD. As noted in the footer below, this is general advice, and your organisation may also want to consider getting your own legal advice.

I hope this helps - please let me know if you have any further questions.

Kind regards,

[redacted]
A/g Director
Contained Dealings Evaluation Section
Office of the Gene Technology Regulator
Ph: 1800 181 030
Fax: 6271 4202
e-mail: OGTR.CDES@health.gov.au

[redacted]

From: [redacted]
To: "ogtr@health.gov.au" <ogtr@health.gov.au>,
Date: 14/04/2014 16:24
Subject: Definition of NOT a Genetically Modified Organism - [redacted] [SEC=No Protective Marking]

Hello OGTR,

[redacted] the IBC at La Trobe University.

[redacted]

[redacted]

It also appears that organisms mutated using Oligonucleotide directed mutagenesis are not 'genetically modified organisms' as there is no foreign DNA from another organism incorporated, only nucleotide changes. Is this the case? Do the nucleotide changes constitute 'foreign DNA' (from another host).

Hoping you can help clarify these questions

Thanks

[redacted]

[redacted]
La Trobe University | Bundoora 3086
T: [redacted] | F: [redacted]
E: [redacted]

[redacted]

From: [redacted]@health.gov.au on behalf of OGTR.CDES@health.gov.au
Sent: Friday, 21 November 2014 11:29
Subject: Re: CRISPR technology [SEC=UNCLASSIFIED]

Dear [redacted]

Thank you for your email regarding CRISPR-CAS mediated genome editing technology. This is a relatively new technologies and we have been discussing them for some time now.

The OGTR currently has a working group that are considering organisms modified using new technologies, and whether or not they are regulated under the *Gene Technology Act 2000*. [redacted] I'm happy to pass on your query to this group, but you should be aware it may take some time before we can provide an answer.

I hope this helps. Please don't hesitate to contact me if you need to discuss this matter further.

Kind regards,

[redacted]
Contained Dealings Evaluation Section
Office of the Gene Technology Regulator
Ph: 1800 181 030
Fax: 6271 4202
e-mail: OGTR.CDES@health.gov.au

From: [redacted]
To: "OGTR.CDES@health.gov.au" <OGTR.CDES@health.gov.au>,
Date: 18/11/2014 14:10
Subject: CRISPR technology [SEC=No Protective Marking]

Dear OGTR,

Our IBC has been approached by a researcher who wants to start experiments in mice with CRISPR technology. As this is the first of its kind for our IBC and we could not find a regulation in the OGTR guidelines, we have approached other IBCs in Adelaide and their feedback was that mice with DELETIONS generated by CRISPR do not require individual NLRD approval. However, if anything is added back into the genome (including generating a point mutation), this will require an NLRD approval.

We would like a confirmation whether you agree with this approach?

Thanks and kind regards
[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

http://www.sapathology.sa.gov.au/

Research Directorate
SA Pathology
PO Box 14 Rundle Mall, Adelaide, SA, 5000

For our patients and our population

[redacted]

From: [redacted]@health.gov.au
Sent: Tuesday, 23 September 2014 13:01
Subject: RE: Query: Genome editing technology [SEC=UNCLASSIFIED]

Hi [redacted]

Thank for the response, I have forwarded your query and details to the OGTR working group that is considering organisms modified using new technologies, and whether or not they are regulated under the *Gene Technology Act 2000*. However, please note that it may take some time before we can provide an answer.

Regards

[redacted]
Contained Dealings Evaluation Section
The Office of the Gene Technology Regulator (OGTR)
Postal Address: MDP 54, GPO Box 9848, Canberra ACT 2601
Ph: [redacted]; Fax: 02 6271 4202
e.mail: [redacted]
Website: www.ogtr.gov.au

[redacted]

[redacted]

From: [redacted]
Sent: Friday, 12 September 2014 3:41 PM
To: [redacted]
Subject: Re: Query: Genome editing technology [SEC=UNCLASSIFIED]

Dear [redacted]

Thank you for your email regarding CRISPR-CAS and TALEN mediated genome editing technology, and my apologies for the delay in replying. These are relatively new technologies and we have been discussing them for some time now.

We agree with the IBC Committee that CRISPR-CAS and TALEN technology will have a variety of uses. Therefore, the requirement and type of authorisation would be dependent on how and for what purpose these technologies are being used.

The OGTR currently has a working group that are considering organisms modified using new technologies, and whether or not they are regulated under the *Gene Technology Act 2000*. [redacted] I'm happy to pass on your query to this group, but you should be aware it may take some time before we can provide an answer. [redacted]

I hope this helps. Please don't hesitate to contact me if you need to discuss this matter further.

Kind regards,

[redacted]
Contained Dealings Evaluation Section
The Office of the Gene Technology Regulator (OGTR)
Postal Address: MDP 54, GPO Box 9848, Canberra ACT 2601
Ph: [redacted] ; Fax: 02 6271 4202
e.mail: [redacted]
Website: www.ogtr.gov.au

[redacted]

[redacted]

[redacted]

From: [redacted]
To: "ogtr@health.gov.au" <ogtr@health.gov.au>,
Date: 03/09/2014 15:59
Subject: Query: Genome editing technology [SEC=No Protective Marking]

To whom it may concern

The University of Adelaide IBC is seeking information on whether the genome editing technology using the engineered nucleases of TALENs and CRISPR requires a GMO Dealing authorisation.

The Robinson Research Institute is launching a SA Genome Editing Facility (SAGE) for the production of KO mice.
The Committee has discussed CRISPR-CAS and TALEN technology and believes this technology will have a variety of uses.
The SAGE Facility at this point is only generating mutations, not introducing new DNA into the mice.
Information from the SAGE website indicates future directions would include transgenic mice (Knock In). Does this then require a GMO Dealing authorisation ?

If you require further information please email me.

Regards
[redacted]

--
[redacted]
The University of Adelaide, AUSTRALIA 5005
[redacted]
Ph [redacted]
Fax [redacted]
e-mail: [redacted]

http://www.adelaide.edu.au/ethics/genetech/

CRICOS Provider Number 00123M