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**From:** Gene Technology Review  
**Sent:** Thursday, 4 January 2018 10:33  
**To:** 'brianr@nexgenplants.com'  
**Subject:** RE: Meeting with Legislative and Governance Forum on Gene Technology [SEC=UNCLASSIFIED]

Dear Brian,

Thank you for your email sent on the 18<sup>th</sup> of December 2017.

As you can appreciate this Christmas period was a busy time for us all and we will consider your suggestion of having discussions with the Chief Technical Officer in the new year.

In the meantime we will be reviewing all submissions as part of our consultation process to inform the review.

### Gene Technology Scheme Review Team

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Office of Health Protection, Department of Health  
MDP 1060 | '(02) 6289 2033' | \*:[Gene.Technology.Secretariat@health.gov.au](mailto:Gene.Technology.Secretariat@health.gov.au)

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**From:** [brianr@nexgenplants.com](mailto:brianr@nexgenplants.com) [<mailto:brianr@nexgenplants.com>]  
**Sent:** Monday, 18 December 2017 5:46 AM  
**To:** Gene Technology Review  
**Subject:** Meeting with Legislative and Governance Forum on Gene Technology [SEC=No Protective Marking]

Nexgen Plants would appreciate the opportunity to meet with one or more members of the Expert Advisory Panel for the above review.

Nexgen is at advanced stages of commercialising a new intragenic plant breeding approach using a technology developed out of the University of Queensland. We also have a plant virus resistance technology platform that has applications across all crops and viruses around the world.

We have completed two commercial deals with large multinational plant and food biotech companies and are in the process of finalising further deals with companies in Israel and Germany. In Australia, we have a large number of university and CSIRO research teams interested in the technology platform.

Of interest to the panel is that the Nexgen technology has a number of advantages over CRISPR/cas9, TALENs and other technologies currently being reviewed.

While we have made a written submission, as Australia's only intragenic technology we would appreciate the opportunity for our Chief Technical Officer to provide a detailed briefing as to how the Nexgen Plants intragenic technology operates and how it will enhance Australia's agricultural competitiveness around the world.

Thank you in advance for your consideration.

Kind Regards  
Brian Ruddle

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**Brian Ruddle**

CEO

Nexgen Plants Pty Ltd

Level 7, General Purpose South Building, The University of Queensland

M: 0407 169979 | Skype: brian.ruddle

[www.nexgenplants.com](http://www.nexgenplants.com)

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s22

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**From:** brianr@nexgenplants.com  
**Sent:** Tuesday, 27 March 2018 9:05  
**To:** s22  
**Cc:**  
**Subject:** RE: Nexgen Plants Intragenic Plant Breeding Approach (INTtrait)  
[SEC=UNCLASSIFIED]

Hi s22

Thanks for the email below and apologies for the delay in responding (I have just returned from the World Agritech Investment Summit).

We understand the position re the USDA decision on our salt tolerant rice line and was only providing this information as it was requested during previous discussions.

Our concern was more that CRISPR and TALENs have been around for a while and have received a fair bit of publicity. As Nexgen's INTtrait technology is relatively new and we have not been in a position to publicise it until we received the USDA advice, we just wanted to make sure that it has been considered. This is particularly as we have not been asked to provide any further information to help with the internal review process and there is very little information that we have released publicly.

That said, we look forward to reviewing the Preliminary Report when it becomes available.

Kind Regards  
Brian

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**Brian Ruddle**  
CEO  
Nexgen Plants Pty Ltd  
Level 7, General Purpose South Building, The University of Queensland  
M: 0407 169979 | Skype: brian.ruddle  
[www.nexgenplants.com](http://www.nexgenplants.com)

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**From:** s22  
**Sent:** Monday, 19 March 2018 11:51 AM  
**To:** 'brianr@nexgenplants.com' <brianr@nexgenplants.com>  
s22

**Subject:** RE: Nexgen Plants Intragenic Plant Breeding Approach (INTtrait) [SEC=UNCLASSIFIED]

Dear Brian

As you are aware, the US regulatory system is different to that which applies in Australia. Therefore, the USDA advice as to the status of your salt tolerant rice line in the USA does not apply in the Australian regulatory system.

While we can confirm that 'intragenesis' has been considered in the Review documentation, as have the broader concepts behind CRISPR and TALEN technology, I am not able to provide any additional information prior to the publication of the Preliminary Report.

If your concern remains once you have had the opportunity to read the Preliminary Report, please feel free to provide comment to this effect through Phase 3 consultation processes.

Kind regards

s22

A/g Assistant Director  
Gene Technology Policy Section  
Regulatory Policy Branch

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Office of Health Protection  
Australian Government Department of Health  
T: s22 | E: s22

MDP 13, GPO Box 9848, Canberra ACT 2601, Australia

*The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.*

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**From:** [brianr@nexgenplants.com](mailto:brianr@nexgenplants.com) [mailto:[brianr@nexgenplants.com](mailto:brianr@nexgenplants.com)]  
**Sent:** Thursday, 15 March 2018 1:50 PM  
**To:** s22  
**Cc:**  
**Subject:** RE: Nexgen Plants Intragenic Plant Breeding Approach (INTtrait) [SEC=UNCLASSIFIED]

Hi s22

Thanks for the email.

We have just received the attached letter from the USDA confirming that our INTtrait approach is not regulated in the USA for the salt tolerant rice line submitted for review. This was for the same approach as was submitted to the review committee previously.

Also, while we appreciate that the intent is for the secretariat not to list any specific technologies, we note that CRISPR/cas9 and TALENs are mentioned in the discussion papers. These technologies are 'owned' by companies similar to Nexgen Plants. Our concern is that any mention of these technologies without referring to Nexgen's INTtrait technology will send the wrong message to the market.

Kind Regards  
Brian

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**Brian Ruddle**  
CEO  
Nexgen Plants Pty Ltd  
Level 7, General Purpose South Building, The University of Queensland  
M: 0407 169979 | Skype: brian.ruddle  
[www.nexgenplants.com](http://www.nexgenplants.com)

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**From:** s22  
**Sent:** Wednesday, 14 March 2018 11:37 AM  
**To:** 'brianr@nexgenplants.com' <[brianr@nexgenplants.com](mailto:brianr@nexgenplants.com)>  
s22

**Subject:** RE: Nexgen Plants Intragenic Plant Breeding Approach (INTtrait) [SEC=UNCLASSIFIED]

Dear Brian

Thank you for your email, apologies for the delay in responding.

For the absence of ambiguity, I would like to clarify that the Gene Technology Review secretariat has no authority to list any specific technology as either 'GMO' or 'non-GMO'. The information that you have provided on INTtrait technology has informed the Review alongside other inputs to Phase 1 and Phase 2 Review consultation processes. The outcomes from these consultation phases will be presented in a Preliminary Report which will be released shortly.

If you have any additional information that you would like to provide, this can be provided as part of the Phase 3 consultation process.

To ensure you are kept up to date on the Review progress, please subscribe to email updates by clicking on the subscribe button on the [Review website](#).

Kind regards

s22

Gene Technology Policy Section  
Regulatory Policy Branch

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Office of Health Protection  
Australian Government Department of Health  
E: s22

MDP 13, GPO Box 9848, Canberra ACT 2601, Australia

*The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.*

**From:** [brianr@nexgenplants.com](mailto:brianr@nexgenplants.com) [mailto:[brianr@nexgenplants.com](mailto:brianr@nexgenplants.com)]

**Sent:** Thursday, 8 March 2018 1:38 PM

**To:** s22

**Cc:** Gene Technology Review

**Subject:** RE: Nexgen Plants Intragenic Plant Breeding Approach (INTtrait) [SEC=UNCLASSIFIED]

Hi s22

Just following up on the correspondence below to see how things are progressing.

Let me know if you would like to organise another teleconference to discuss. Alternatively, we can also travel to Canberra to meet if this is of help.

Thanks and Regards

Brian

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**Brian Ruddle**

CEO

Nexgen Plants Pty Ltd

Level 7, General Purpose South Building, The University of Queensland

M: 0407 169979 | Skype: brian.ruddle

[www.nexgenplants.com](http://www.nexgenplants.com)

**From:** [brianr@nexgenplants.com](mailto:brianr@nexgenplants.com) [mailto:[brianr@nexgenplants.com](mailto:brianr@nexgenplants.com)]

**Sent:** Monday, 26 February 2018 5:27 AM

**To:** s22

**Cc:** ' >

Gene Technology Review'

<Gene.Technology.Review@health.gov.au>

**Subject:** RE: Nexgen Plants Intragenic Plant Breeding Approach (INTtrait) [SEC=UNCLASSIFIED]

Hi<sup>s22</sup>

Just following up on the correspondence below to see if any further information is required to get our INTtrait technology listed as non-GMO.

Thanks and Regards

Brian

---

**Brian Ruddle**

CEO

Nexgen Plants Pty Ltd

Level 7, General Purpose South Building, The University of Queensland

M: 0407 169979 | Skype: brian.ruddle

[www.nexgenplants.com](http://www.nexgenplants.com)

**From:** s22

**Sent:** Monday, 12 February 2018 6:39 PM

**To:** 'brianr@nexgenplants.com' <[brianr@nexgenplants.com](mailto:brianr@nexgenplants.com)>

**Cc:** s22 Gene Technology Review

<[Gene.Technology.Review@health.gov.au](mailto:Gene.Technology.Review@health.gov.au)>

**Subject:** RE: Nexgen Plants Intragenic Plant Breeding Approach (INTtrait) [SEC=UNCLASSIFIED]

Hi Brian

Thank you for this further information – it is helpful.

I will discuss with the team and get back to you.

Best regards

s22

---

Gene Technology Review Support  
Australian Government Department of Health  
Tel: s22 | Mob: s22 | Email: s22  
MDP: 1050 | PO Box 9848, Canberra ACT 2601, Australia

**From:** [brianr@nexgenplants.com](mailto:brianr@nexgenplants.com) [mailto:[brianr@nexgenplants.com](mailto:brianr@nexgenplants.com)]

**Sent:** Monday, 12 February 2018 6:02 AM

**To:** s22

**Cc:**

**Subject:** Nexgen Plants Intragenic Plant Breeding Approach (INTtrait) [SEC=No Protective Marking]

Hi<sup>s22</sup>

Further to our teleconference last week, please find attached an overview of the Nexgen Plants intragenic technology using salt tolerant rice as an example.

This provides an example of how the Nexgen INTtrait technology can be used to overexpress a plant trait, we also have downregulating approaches as well.

We believe that it is important that intragenics be non-regulated in Australia and look forward to entering into discussions with the technical review team to provide further information as required.

Thanks and Regards  
Brian

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**Brian Ruddle**

CEO  
Nexgen Plants Pty Ltd  
Level 7, General Purpose South Building, The University of Queensland  
M: 0407 169979 | Skype: brian.ruddle  
[www.nexgenplants.com](http://www.nexgenplants.com)

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4700 River Road  
Riverdale, MD  
20737

Dr. Lloyd T. Wilson  
Professor and Center Director  
Jack B. Wendt Endowed Chair in Rice Research  
Texas A&M University  
AgriLife Research  
Beaumont, Texas 77706

Re: Request for regulatory status of salinity tolerant rice genotypes

Dear Dr. Wilson,

Thank you for your letter dated September 15, 2017, inquiring whether the salinity tolerant rice cultivars described in your letter are regulated articles. Your letter describes Nexgen's rice cultivars that mimic natural gene duplication and recombination processes associated with an increased salinity tolerance phenotype.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States. The APHIS mission is to protect the health and value of American agriculture and natural resources.

APHIS regulates the importation, interstate movement and environmental release (field testing) of certain genetically engineered (GE) organisms that are, or have the potential to be, plant pests. Regulations for GE organisms that are or have the potential to be plant pests, under the PPA, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations, a GE organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in §340.2 and meets the definition of a plant pest, or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe it is a plant pest.

In your September 15, 2017 letter, you explain that Nexgen developed salinity tolerant GE rice cultivars via particle bombardment (biolistic) transformation and that the entirety of the inserted genetic material is derived from the rice genome. The construct used for transformation consists of a rice *ACTIN* promoter and a 5' untranslated region (UTR) sequence fused to a rice *DREB1A* (Dehydration-responsive element binding protein 1A) gene coding sequence and *DREB1A* 3' UTR and terminator sequence. The rice events mimic naturally occurring gene duplication and recombination processes resulting in extra copies of the native salt tolerance gene *DREB1A*.

Based on the information you provided in your letter, APHIS has determined that *Oryza sativa* L. (rice) is not a plant pest, no organisms used as sources of the genetic material to create the GE rice cultivars are plant pests, and the method used to genetically engineer the

rice cultivars did not involve plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the GE rice cultivars as described in your September 15, 2017 letter to be regulated under 7 CFR part 340. As such outdoor field testing of your GE rice cultivars do not require an APHIS 2000 permit from BRS.

Cultivated rice is not listed as a Federal noxious weed under 7 CFR part 360 and is not known to escape cultivation. In addition, there are no sexually compatible Federal noxious weeds present within the U.S. However, as indicated in your inquiry, weedy red rice, *Oryza sativa f. spontanea*, is a problematic weed within U.S. rice fields and is sexually compatible with cultivated rice. APHIS is currently analyzing whether the genetically engineered additional copies of the rice DREB1A gene could potentially increase the weediness of red rice and make it a more troublesome weed. We will communicate those conclusions to you within the next month.

Although your GE rice cultivars are in the early phases of development, until we respond to your inquiry on any weediness concerns, we encourage you to take appropriate stewardship steps to minimize potential outcrossing of your GE rice cultivars with red rice.

Please be advised that the importation of rice seeds or plants, like all other rice, is subject to APHIS Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these rice seeds or plants, you may contact the PPQ general number for such inquiries at (877) 770-5990.

Please be advised that Nexgen's salinity tolerant rice, while not regulated by APHIS under 7 CFR part 340, may still be subject to other regulatory authorities such as FDA or EPA.

Should you become aware at any time of any issues that may affect the Agency's conclusion regarding this inquiry, you must immediately notify the Agency in writing of the nature of the issue. We hope that you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,

BY  


Michael J. Firko, Ph.D.  
APHIS Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture

3/14/2018

Date

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