

From: [Andrea F Huberty](#)
To: [Jodene E Fitzpatrick](#)
Subject: Fw: Dow Zinc Finger letter
Date: 05/26/2010 04:37 PM
Attachments: [Dow ZFN IPK1 5-25-10_ODA.docx](#)

Hi Jodene-

Below is Mike's 'official' OK to sign (if needed). Attached is the document. We need this signed by May 28th, if possible. Once signed, could you send a copy to Dr. Rudgers at the address, and also scan a copy for me?

Thanks-
Andie



[Dow ZFN IPK1 5-25-10_ODA.docx](#)

Andrea F. Huberty, Ph.D.
Branch Chief
Regulatory and Environmental Analysis Branch
Communications Branch
USDA/APHIS/BRS
4700 River Road, Unit 146
Riverdale, MD 20737
Tel: 301-734-0485
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Andrea.F.Huberty@aphis.usda.gov

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----- Forwarded by Andrea F Huberty/MD/APHIS/USDA on 05/26/2010 04:35 PM -----

From: Michael C Gregoire/MD/APHIS/USDA
To: [Andrea F Huberty/MD/APHIS/USDA@USDA](#), [Beverly Simmons/MD/APHIS/USDA@USDA](#), [Sidney W Abel/MD/APHIS/USDA@USDA](#)
Cc: [John T Turner/MD/APHIS/USDA@USDA](#), [Douglas W Grant/CO/APHIS/USDA@USDA](#), [John M Cordts/MD/APHIS/USDA@USDA](#), [Farrell C Wise/MD/APHIS/USDA@USDA](#), [Richard S Coker/MD/APHIS/USDA@USDA](#), [Shailaja Rabindran/MD/APHIS/USDA@USDA](#), [Alan Pearson/MD/APHIS/USDA@USDA](#), [Chessa D Huff/MD/APHIS/USDA@USDA](#)
Date: 05/25/2010 08:46 PM
Subject: Re: Dow Zinc Finger letter

Works for me.

▼ [Andrea F Huberty](#)

----- Original Message -----

From: Andrea F Huberty
Sent: 05/25/2010 09:18 AM EDT
To: Michael Gregoire; Beverly Simmons; Sidney Abel
Cc: John Turner; Andrea Huberty; Douglas Grant; John Cordts; Farrell Wise; Richard Coker; Shailaja Rabindran; Alan Pearson; Chessa Huff
Subject: Dow Zinc Finger letter

Good morning-

Attached is a letter to Dow developed by the PSC. This is in response to their request for evaluation of their ZFN-12 maize plants that have a gene deleted using zinc finger nuclease technology. Their original request was for us to determine if plants engineered with their EXACT zinc finger nuclease technology would be considered regulated articles. As discussed at the ODA-PSC meeting on May 21, we will be moving the zinc finger Directive into interagency discussions. However, Dow needed a response by June 1 if they needed authorization to release their ZFN-12 plants. This letter states that the ZFN-12 plants are not regulated articles, but does not give a regulatory determination on the EXACT technology or other plants with induced deletions developed with zinc finger nuclease technology.

Please review by COB Wednesday, May 26th. If edits are required, please send any ASAP. We would like to get the letter signed this week if possible.

Thanks-
Andie

[attachment "Dow ZFN IPK1 5-25-10_ODA.docx" deleted by Michael C Gregoire/MD/APHIS/USDA]

Andrea F. Huberty, Ph.D.
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Re: FOIA 11-089, Please search through Biotech Query and any other
correspondence folders your branch maintains - Thank you
Colleen M Wood to: Cynthia A Eck

02/17/2011 12:07 PM

History:

This message has been replied to.

Cindy---this is the only message we have on zinc finger technology. I'm not sure if this fits the FOIA request since regulatory status is not mentioned in this and Andie had a phone conversation with this person. If this should be included, is there a format I need to follow. This info is from a record in our access database.

Thanks,
Colleen

BiotechQuery Email

Dear Sir:

I am considering a proposal to develop a high 16:0 fatty acid peanut using ZFN technology. I would like to know if this will result in material that is considered to be transgenic and thus a GMO? Before starting any such work I would like to know how the end material resulting will have to be treated. Hopefully you can answer my question.

Sincerely,

Roy Pittman

Peanut Curator

USDA, ARS

1109 Experiment St.

Griffin, Ga 30223

Roy.Pittman@ARS.USDA.GOV

Response:

Dr. Pittman-

Again, my sincere apologies for the delay in responding to your inquiry. If you have any further questions, please let me know. Attached is the zinc finger reference we discussed on the phone, and a link to Dow's EXACT technology.

Regards-

Andie Huberty

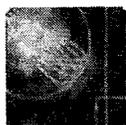
<http://www.exactprecisiontechnology.com/>

Colleen Wood
Communications Specialist
Biotechnology Regulatory Services

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Cynthia A Eck Colleen, We received a FOIA request, 11-089, th... 02/16/2011 04:22:20 PM



Cynthia A
Eck/MD/APHIS/USDA
02/16/2011 04:22 PM

To Colleen M Wood/MD/APHIS/USDA@USDA
cc

Subject FOIA 11-089, Please search through Biotech Query and any other correspondence folders your branch maintains - Thank you

Colleen,

We received a FOIA request, 11-089, that specifically asks for:

Opinion letters or other correspondence prepared by APHIS-BRS concerning the regulatory status under 7 CFR Part 340 of plants or plant products developed using zinc finger nuclease technology; site-specific gene repair oligonucleotide technology; or directed nucleotide editor meganuclease technology for targeted mutagenesis.

Please use this search sheet to record your time: [attachment "fee worksheet.doc" deleted by Colleen M Wood/MD/APHIS/USDA]

Place any responsive records here:

I:\BRS - Biotechnology Regulatory Services\Document Warehouse\FOIA & Lawsuit Requests\FOIA 11-089\FOIA 11-089, BRS Response\Search Response - Colleen Wood

We are behind in our response time so as soon as you can respond - I am grateful! Thanks!

Cindy

Cynthia A. Eck
Document Control Officer
Biotechnology Regulatory Services
Animal Plant Health Inspection Service
U.S. Department of Agriculture
6th Floor, 6A-020, Unit 91
4700 River Road, Riverdale, MD 20737
Office: (301) 734-0667
cynthia.a.eck@aphis.usda.gov

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United States
Department of
Agriculture

March 25, 2004

Animal and
Plant Health
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Programs Business
Services

4700 River Road
Riverdale, MD
20737

(b)(6)

Cibus Genetics, LLC
14 Chesapeake Landing
Annapolis, MD 21403

Dear (b)(6)

APHIS BRS has determined that under our current regulations, the agency has no authority to regulate products created by mutagenesis techniques such as Genoplasty. Therefore it is not necessary under current USDA-APHIS regulations to file a notification to conduct a field trial for a product created by this technology

Sincerely,

Neil E. Hoffman
Director, Regulatory Programs
Biotechnology Regulatory Services



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United States
Department of
Agriculture

Animal and
Plant Health
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Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

May 26, 2010

(b)(6)

Global Regulatory Leader - New Ventures
Dow AgroScience LLC
9330 Zionsville Road
Indianapolis, IN 46268

Re: APHIS review as to whether *Zea mays* plants with the IPK1 gene deleted using zinc nuclease technology is regulated by APHIS.

Dear (b)(6)

Thank you for your presentation on March 18, 2010 describing the zinc finger nuclease deletion technology used to create *Zea mays* plants with a nonfunctional IPK1 gene. IPK1 gene encodes inositol-1,3,4,5,6-pentakisphosphate 2-kinase, an enzyme that catalyses the final step in phytate biosynthesis in maize seeds (Shukla et al., 2009). When the IPK1 gene is disrupted using the zinc finger nuclease deletion technology, the resulting phenotype is maize with reduced phytate production. These plants have been described in detail in Shukla et al., 2009.

APHIS regulates the environmental release of certain genetically engineered organisms which are, or are believed to be, plant pests. Regulations for genetically engineered organisms that have the potential to be plant pests, under the Plant Protection Act, 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 genetically engineered (GE) organism is deemed a regulated article if it has been genetically engineered from a donor organism, recipient organism, or vector or vector agent listed in §340.2, and the listed organism meets the definition of "plant pest" or 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.

APHIS has evaluated the ZFN-12 maize plants as described in Shukla et al. 2009. The ZFN-12 plants (Figure 1, Shukla et al., 2009) all have similar deletions to the IPK1 gene, and these deletions were created using zinc finger nuclease technology. The ZFN-12 maize plants containing the induced deletion of sections of the IPK1 gene have reduced phytate production. Phytate is an anti-nutritional component of feed grain. Phytate reduction results in more biologically available phosphorus in feed so animal feed products have a higher nutritional quality. Subsequently, feed with more nutritionally available phosphorus utilized by animals results in decreased amounts of phosphorus that ordinarily leaves agricultural lands as environmental pollution.

As described by Dow during the March 18, 2010 presentation, no plant pest was used to create the ZFN-12 maize plants, which contain deletions at the IPK1 gene. There is no



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reason to believe that *Zea mays* containing an IPK1 deletion is a plant pest or is likely to pose a plant pest risk. Therefore, the ZFN-12 maize plants with induced deletions due to the use of zinc finger nuclease technology are not considered regulated articles.

If you have any questions about our review, please call Dr. John Turner, Director of the Policy Coordination Program, at (301) 734-8365.

Sincerely,

Michael Gregoire
Deputy Administrator
Biotechnology Regulatory Services

References

Shukla, V.K., Y. Doyon, J. C. Miller, R. C. DeKolver, E. A. Moehle, S. E. Worden, J. C. Mitchell, N. L. Arnold, S. Gopalan, X. Meng, V. M. Choi, J. M. Rock, Y.-Y. Wu, G. E. Katibah, G. Zhifang, D. McCaskill, M. A. Simpson, B. Blakeslee, S. A. Greenwalt, H. J. Butler, S. J. Hinkley, L. Zhang, E. J. Rebar, P. D. Gregory & F. D. Urnov. 2009. Precise genome modification in the crop species *Zea mays* using zinc-finger nucleases. *Nature* **459**, 437-441 (21 May 2009). doi:10.1038/nature07992