

Email to Dr. Susan Kohler, APHIS/BRS: March 2010.

Dear Susan,

Since it has been close to two years since our last visit to APHIS to discuss zinc finger technology (EXZACT™), and with changes in the USDA administration over the last year, we would still appreciate an hour of APHIS' time on March 18th to update you and your colleagues on EXZACT technology and to re-address our questions regarding the regulation of products developed using EXZACT. In addition, we would like to further understand and discuss the process APHIS will use to regulate products developed using new technologies. The DAS' regulatory team will already be visiting the DC area on March 18th and feel an hour with your team would be very valuable for our future EXZACT discussions with APHIS.

During our visit we would like to focus our discussion on EXZACT Delete (the use of designed zinc finger nucleases to specifically target a native plant gene, generate a precise double stranded break in the targeted DNA and repair of the double stranded break using the plant's natural non-homologous end-joining process; resulting in inactivation of the targeted gene). We consider products produced using this application as non-regulated mutations based on the following:

1: Products do not pose a plant pest risk. Zinc finger DNA constructs contain no plant pest or pathogenic DNA and plants containing the resulting mutation **contain no recombinant or foreign DNA in either the plant or its genome.** Zinc finger DNA constructs are non-integrating, non-replicating and are absent in the final product.

2: Products are indistinguishable to currently described, non-regulated mutational products. Zinc finger delete products cannot be distinguished from mutagenesis products produced using current breeding methods, chemical or radiation techniques.

3: Zinc finger nucleases target only the specific gene of interest. Unlike random mutagenesis produced using chemical or radiation techniques, zinc finger nucleases are designed to target unique, specific DNA sequences resulting in mutations only at the desired location.

We are not anticipating a regulatory decision from APHIS prior to our March 18th visit. We would like to use the time during our visit to update and inform APHIS on our EXZACT Delete product and applications to help APHIS arrive at a timely decision on the regulation of such products. We are also interested in better understanding the process APHIS will use to make decisions on the regulation of products produced through new technologies and how Dow AgroSciences can assist or participate in such a process.

For additional information on Dow AgroSciences' EXZACT technology please refer to the following Nature paper authored by Dow AgroSciences' EXZACT research team: Shukla, V. K. et al. *Nature* **459**, 437–441 (2009).

(<http://www.nature.com/nature/journal/v459/n7245/full/nature07992.html>)

I look forward to our discussion. Please let me know if March 18th still works for APHIS and your team.

Regards,

Gary

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