



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
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Chloe Pavely  
Global Regulatory Director  
Calyxt Inc.  
2800 Mount Ridge Road  
Roseville, MN 55113

Re: Confirmation of the regulatory status of Calyxt's high oleic low linolenic soybean developed using TALEN technology

Dear Chloe Pavely:

Thank you for your letter dated March 4, 2020, inquiring whether the soybean (*Glycine max*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of TALEN® technology, resulting in the KO soybean product with the desired high oleic low linolenic seed oil profile.

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.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain organisms developed using genetic engineering that are, or have the potential to be, plant pests, under 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 regulations, an 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 organism is a plant pest or has reason to believe it is a plant pest.

In your March 4, 2020 letter, you describe the expression of the TALEN® reagent that resulted in the targeted knockout of five genes in the KO soybean product. Your letter describes that a selectable marker was used to identify the soybean line with the TALEN® expression cassette and the selectable marker. Polymerase Chain Reaction (PCR) was then used to screen regenerated soybean plants to identify the specific transgenic plants that contained the targeted site disruption in the genes claimed as CBI. Self-pollination of the soybean line resulted in the high oleic low linolenic KO soybean product, in which both cassettes have been removed and only the targeted disruption of the genes claimed as CBI remained. While the TALEN® reagent and certain other genetic sequences used in the development of KO soybean were derived from plant pests, your letter states that none of the inserted DNA remained in the KO soybean product. The soybean line was subjected to whole genome sequencing which confirmed that the final KO soybean

product contains only the genetic material present in the original soybean plant and deletions in the five targeted genes.

Based on the representations you made in your letter, including your description of the results of your confirmation methods, your genome edited KO soybean is not a plant pest and contains only deletions produced as a result of the plant's DNA repair mechanism. Consistent with previous responses to similar letters of inquiry, USDA does not consider your KO soybean product to be regulated pursuant to 7 CFR part 340.

Although your soybean product is not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of soybean seeds or plants will be subject to Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these KO soybean seeds or plants, you may contact the PPQ general number for such inquiries at 877-770-5990. To inquire about the regulatory status of your product with the Environmental Protection Agency, please contact Alan Reynolds at 703-605-0515. To inquire about the regulatory status of your product with the Food and Drug Administration, please contact Robert Merker at 240-402-1226.

As described, APHIS does not consider your genome edited KO soybean product to be a Regulated Article. However, please be aware that accidental release of soybean that does contain intentionally introduced genetic material may be a violation of our regulations. We encourage Calyxt to continue to use both phenotypic and molecular analyses to confirm that your genome edited products do not contain intentionally introduced genetic material.

Should you become aware at any time of any issues that may affect USDA's conclusion regarding this inquiry, you should immediately notify us in writing of the nature of the issue.

Sincerely,



Bernadette Juarez.  
APHIS Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture

May 28, 2020  
Date