



Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Unit 98  
Riverdale, MD  
20737

August 28, 2014  
Dr. Les Pearson  
Director Regulatory Affairs  
ArborGen Inc.  
2011 Broadbank Court  
Ridgeville, SC 29472-9006

Re: Request for confirmation that loblolly pine is not a regulated article

Dear Dr. Pearson:

Thank you for your letter dated September 14, 2012 regarding the genetically engineered (GE) loblolly pine (*Pinus taeda*) that your company is developing. The letter stated that the trees are being modified for increased wood density.

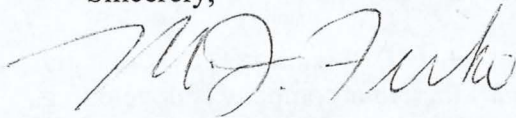
APHIS regulates the introduction of certain genetically engineered organisms which are, or have the potential to be plant pest. Regulations for genetically engineered organisms that have the potential to be plant pests, under the Plant Protection Act, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pest 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 is a plant pest.

APHIS has evaluated the description of GE loblolly pine in your September 14, 2012 letter. As described, the trees are being created using the biolistic method of transformation and includes genetic material (promoters, terminators, and genes) from *Pinus taeda*, *Pinus radiata*, *Liquidambar styraciflua*, *Arabidopsis thaliana* and *E. coli K-12*.

APHIS has evaluated the description of the loblolly pine described in your September 14, 2014 letter. As described, APHIS has determined that loblolly pine itself is not a plant pest, no organisms used as sources of the genetic material to create the trees are plant pests, and the method used to genetically engineer the loblolly pine does not involve plant pests. No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to genetically engineer the loblolly pine. Therefore APHIS does not consider the trees described in your September 14, 2012 letter to be regulated under 7 CFR part 340.

Please be advised that the forest genetics community has established principles for producing and using GE forest trees. These principles can be found at [http://www.forestbiotech.org/wp-content/uploads/2013/02/Responsible\\_Use\\_Biotech\\_Tree\\_Principles\\_v.P.1.0.B.pdf](http://www.forestbiotech.org/wp-content/uploads/2013/02/Responsible_Use_Biotech_Tree_Principles_v.P.1.0.B.pdf). APHIS strongly encourages ArborGen Inc. to consider and follow this guidance when introducing these GE trees. Please also be advised that the use of these GE trees and the lines derived from them may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "M. J. Firko". The signature is written in a cursive style with a large initial "M" and a long horizontal stroke extending to the right.

Michael Firko  
Deputy Administrator  
Biotechnology Regulatory Services