ARBORGEN

Les Pearson
Director Regulatory Affairs
2011 Broadbank Court
Ridgeville, SC 29472-9006
PII

www.arborgen.com

September 14, 2012

Mr. Michael Gregoire
Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98
Riverdale, MD 20737

Re: Loblolly pine modified for increased density which is not a regulated article

Dear Mr. Gregoire,

ArborGen Inc. is submitting this letter to confirm that a loblolly pine (*Pinus taeda*) with increased wood density developed without the use of any plant pest components is not subject to APHIS regulations at 7 C.F.R. Part 340 (Part 340).

ArborGen has extensive experience in the identification, testing and development of genes that encode important traits in trees. Through our program we have identified genes from plant species that result in increased wood density, a valuable economic trait for the pulp and paper industry, the solid wood products industry, as well as bioenergy applications. We are now developing new varieties of loblolly pine using these genes. As described below, no plant pest components are being used in developing these new varieties, the recipient organism itself is not a plant pest, and there is no reason to believe that any components used to develop these new varieties would make loblolly pine become a plant pest. Therefore these varieties do not meet the definition of a "regulated article" under Part 340 and, as such, are not subject to APHIS regulation.

In response to a series of recent letters BRS has confirmed that modified plants which meet certain criteria are not regulated under Part 340. Based on this information and the information provided below, we conclude that the modified pine described herein is not subject to BRS regulations.

The recipient organism, loblolly pine, is not a plant pest.

Loblolly pine is native to the U.S. south[1] and is grown on over 50 million acres[2]. Loblolly pine is not listed as a plant pest under 7 C.F.R. 340.2 nor is it listed as a Federal noxious weed[3].

The donor organisms are well characterized and are not plant pests.

The genes for increased density being used to develop these new varieties were isolated from *Pinus radiata* or Monterey pine, native to parts of California. *P. radiata* is not a plant pest nor is it listed as a Federal noxious weed.

The selectable marker gene, NPT II, was isolated from *Escherichia coli* strain K-12, and is a commonly used selectable marker in plants. BRS has previously acknowledged that *E. coli* is not considered a plant pest and that there is no reason to believe that the NPT II marker gene would make a plant become a plant pest[4].

Other inserted genetic elements are non-coding DNA sequences which function as promoter or terminator sequences and are derived from the following plant species: loblolly pine (*Pinus taeda*); American sweetgum (*Liquidambar styraciflua*); and *Arabidopsis thaliana*, none of which are plant pests.

Method of transformation does not utilize plant pest components.

ArborGen is using the biolistics method in the development of these new pine varieties. This method does not use any plant pests, nor does it use any components derived from a plant pest.

In conclusion, loblolly pine is not a plant pest, the genetic components used in the development of these new loblolly pine varieties come from fully classified organisms, and no plant pests were used for the transfer of DNA to loblolly pine. There is no reason to believe that the loblolly pine described herein may be a plant pest. Therefore, ArborGen is submitting this letter to BRS to confirm that loblolly pine trees with increased wood density, developed as described above, are not a regulated article or subject to BRS regulations.

Please do not hesitate to contact me if you have any questions.

Sincerely,

PII

Les Pearson
Director Regulatory Affairs.

---

[1] *Pinus taeda* L. Loblolly Pine. Baker J.B. and Langdon O.G. in: *Silvics of North America. Volume 1. Conifers.* Burns, R.M. and Honkala, B.H. technical coordinators. 1990. USDA Forest Service Agriculture Handbook 654.
[2] *U.S. Forest Resources Facts and Historical Trends.* Smith, W.B. and Darr, D. 2004. USDA Forest Service publication FS-801. Note: classified as Forest-type group 160: Loblolly / shortleaf pine group.
[3] Listing of Federal noxious weeds at: http://plants.usda.gov/java/noxious
[4] Response to inquiry on the regulated status of two genetically engineered petunia lines. Letter from M. Gregoire, Deputy Administrator, APHIS BRS, to Dr. M. Boase, Senior Scientist, NZ Crop and Food Limited; dated May 19, 2008.