Field Trials of GM Trees in the USA and a Peek at Global Regulatory Burdens

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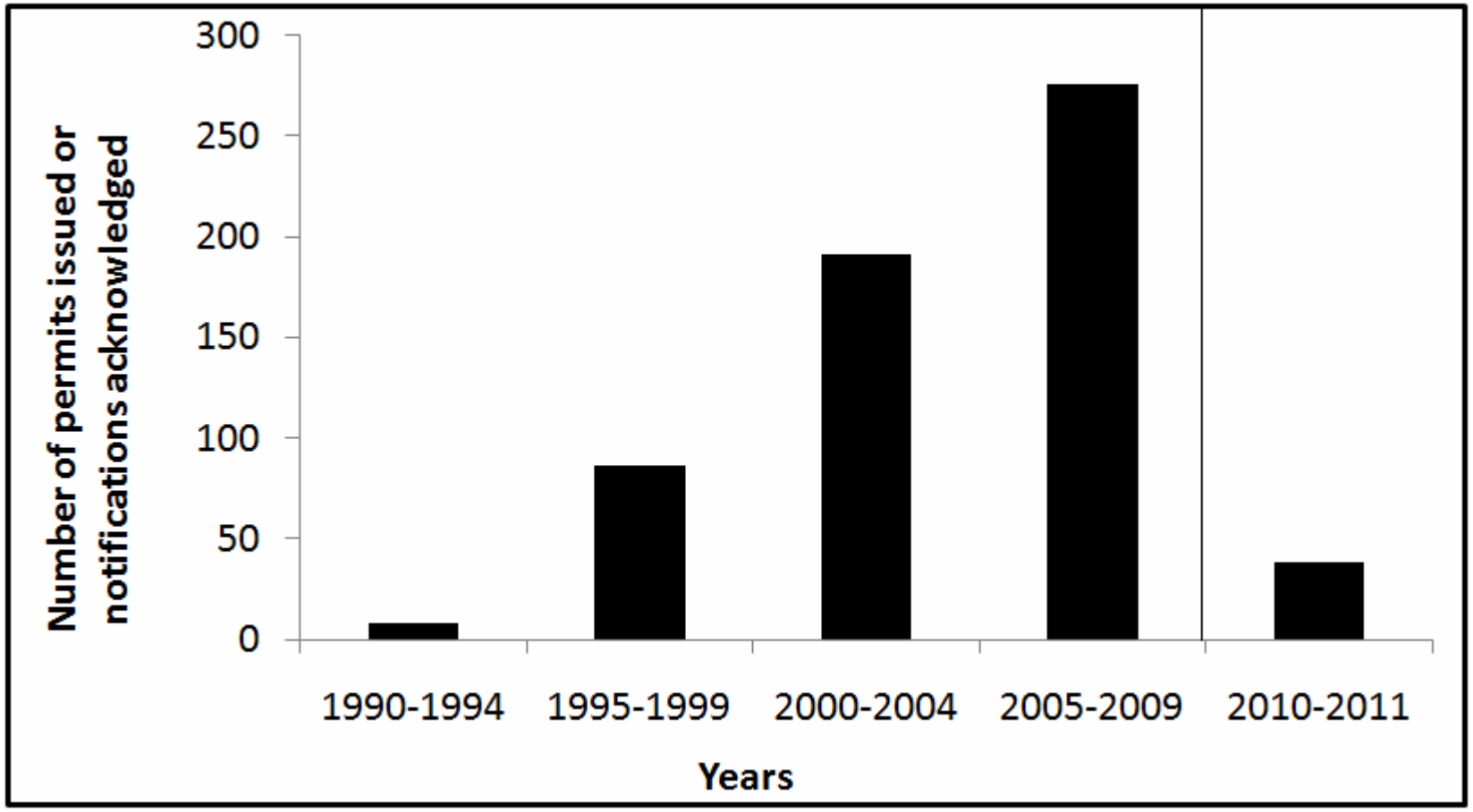
Regulation of field trials in USA

- Regulated in the same manner as agricultural crops.
- Three agencies regulate it
  - United States Department of Agriculture (agricultural safety and economics, endangered species and environment)
  - Food and Drug Administration (safety of human and animal feed)
  - Environmental Protection Agency (transgenic plants with pesticidal or growth regulator properties)

The number of field trials conducted in the USA over the past ten years was ~ 5 times that conducted from 1990-1999



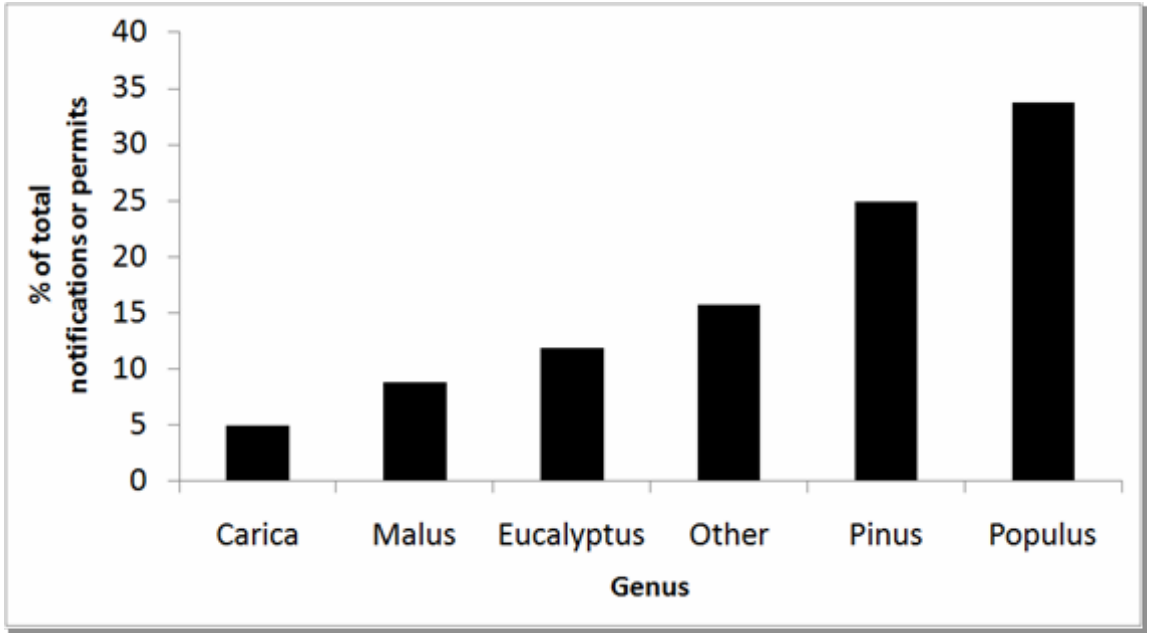
Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Populus and *Pinus* together accounted for ~60% of all field trials

~600 field trials since 1989

Genera tested

- ✓*Castanea* (American Chestnut)
- ✓*Ulmus* (American Elm)
- ✓*Malus*
- ✓*Populus*
- ✓*Persea* (Avocado)
- ✓*Musa* (Banana)
- ✓*Citrus*
- ✓*Coffea*
- ✓*Eucalyptus*
- ✓*Prunus*
- ✓*Pinus*
- ✓*Carica* (Papaya)
- ✓*Pyrus* (Pear)
- ✓*Liquidambar* (Sweetgum)
- ✓*Picea* (White Spruce)
- ✓*Juglans* (Walnut)



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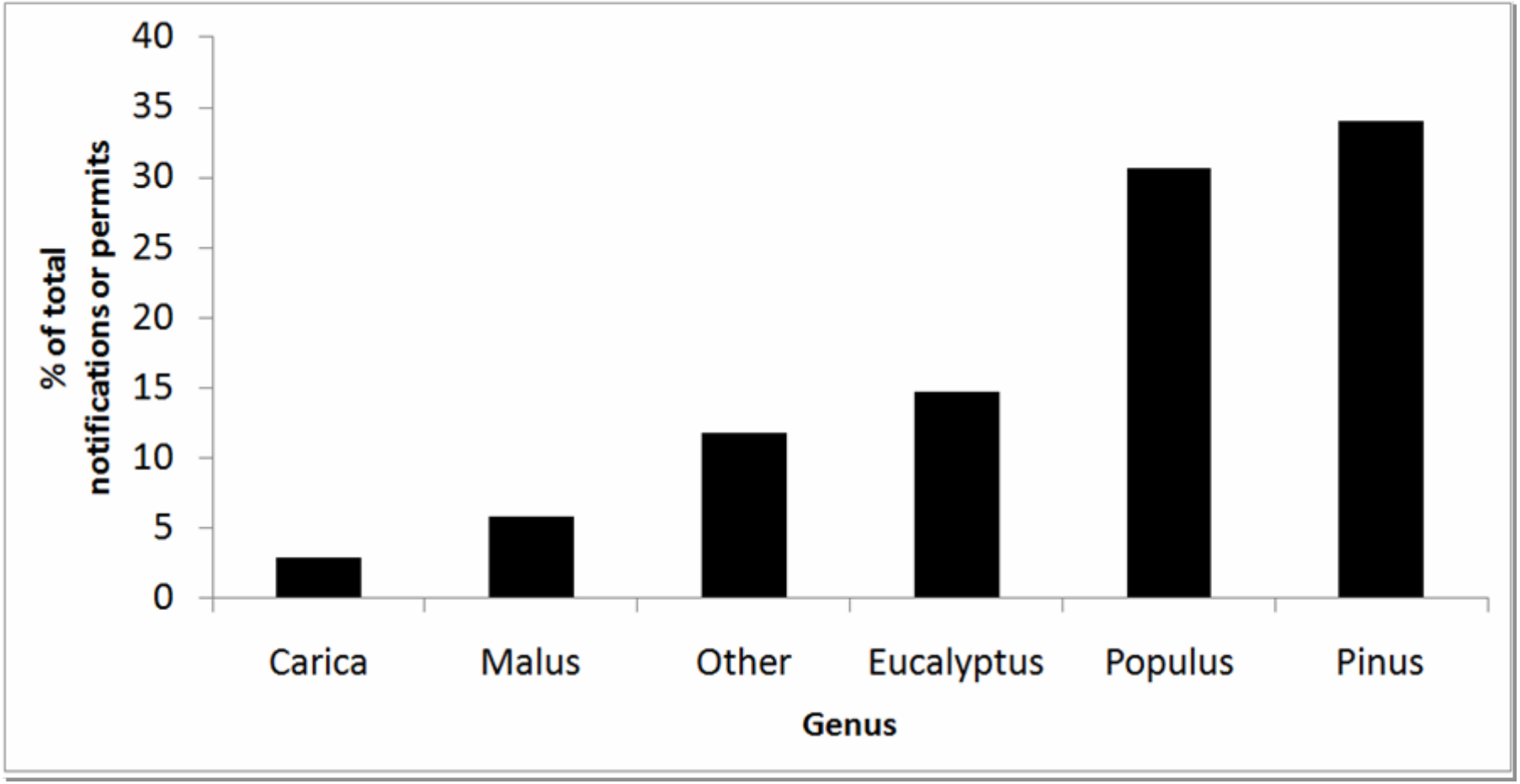
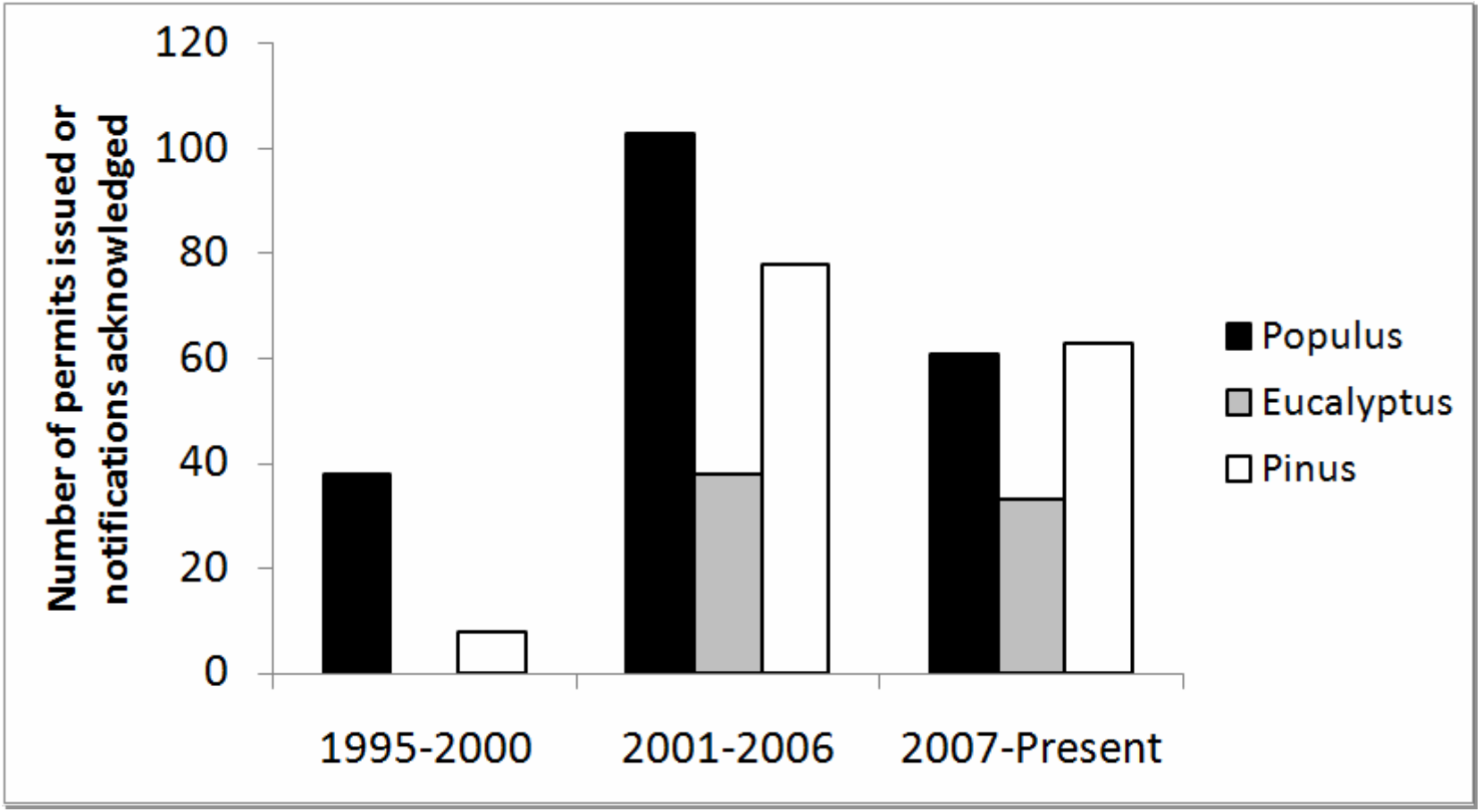
Pinus and *Populus* have remained the two main genera of interest over the last five years, accounting for almost two- thirds of all field trials conducted from

Around 230 field trials from 2006 to 2010



Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

The number of field trials with Eucalyptus, *Populus*, and *Pinus* increased dramatically: 1995-2000 vs. 2001-2006



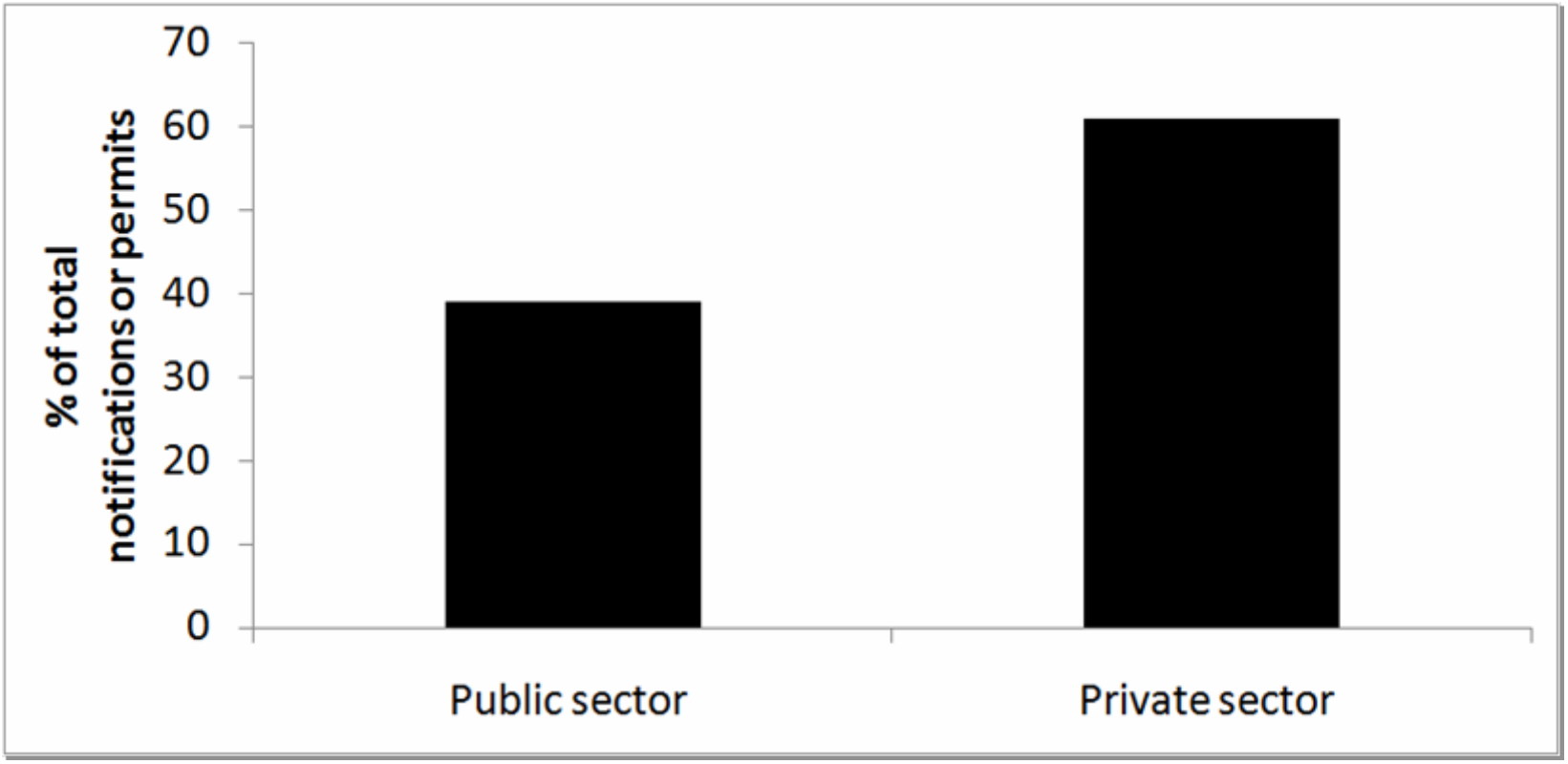
During the same period, the number of field trials with *Populus* increased almost by three-fold. No field trials were conducted with Eucalyptus between 1995 and 2000.

Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Oregon: Screening of primary transformants for herbicide resistance

Oregon: Two year field trial for herbicide resistance

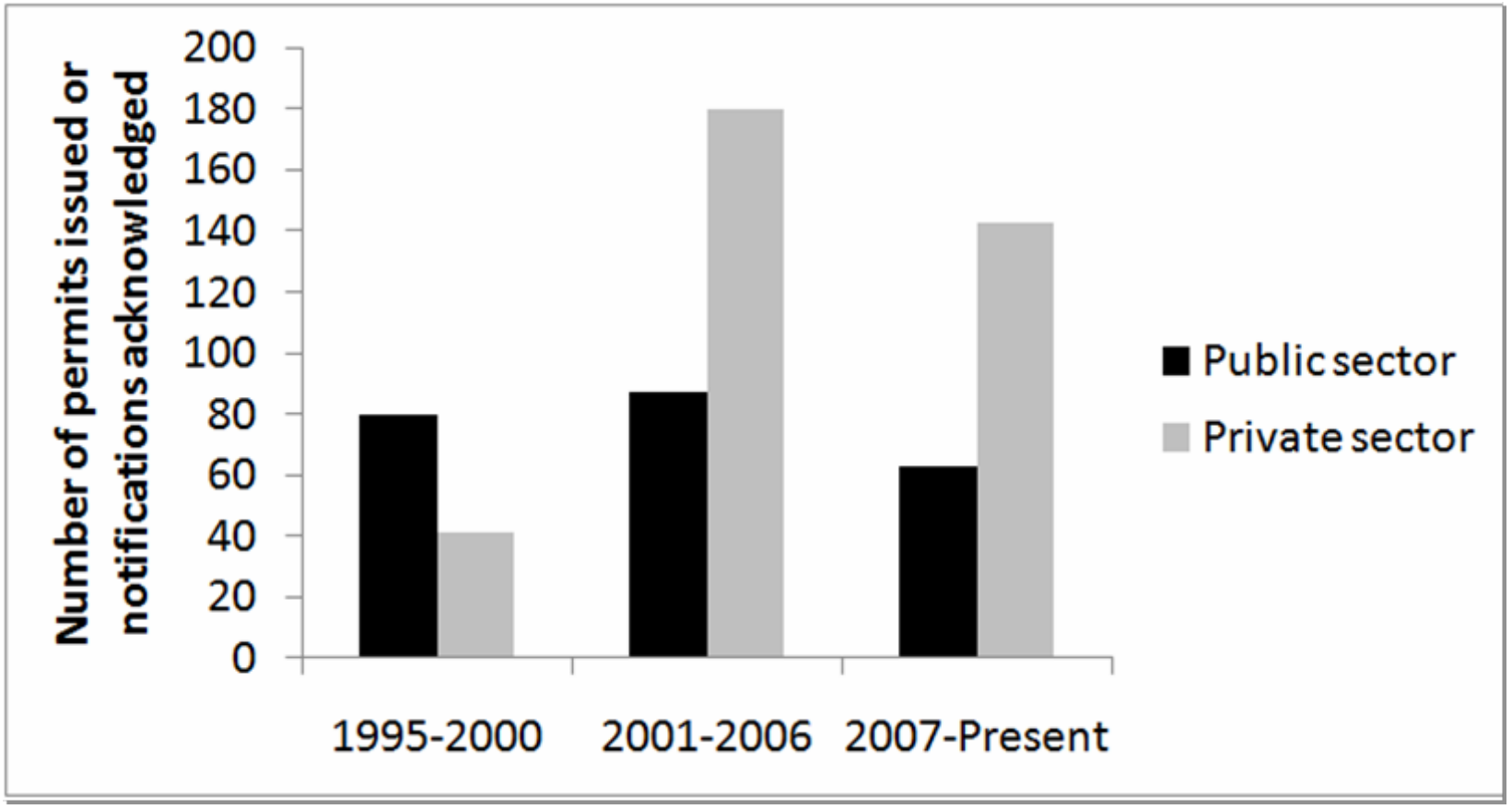
Private sector organizations were responsible for 60% of all field trials



Among the public sector institutions, Cornell University, Oregon State University, SUNY-ESF, University of Florida, University of Hawaii, University of California, Davis, and USDA-ARS accounted for more than 160 of the ~230 field trials

Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Public sector institutions dominated the field trial scenario during the early years (1990's). The situation has changed since the onset of the new millennium.

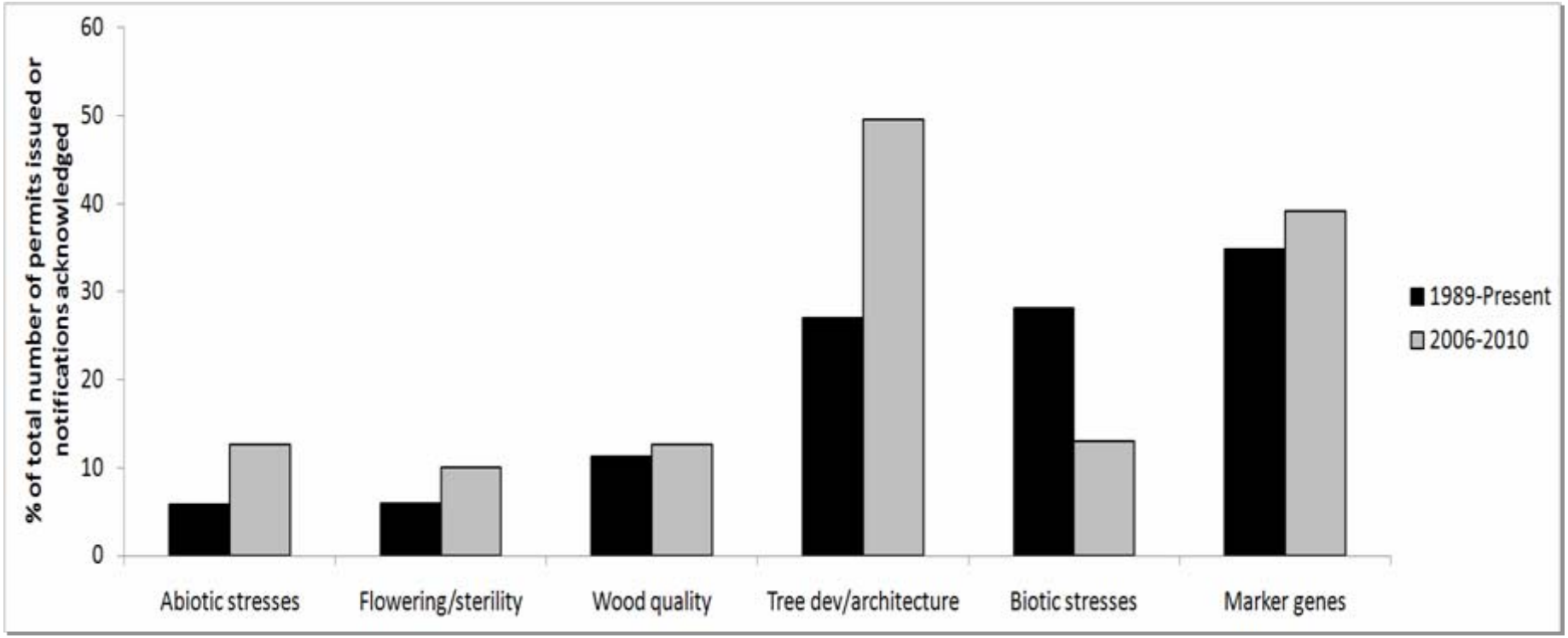


Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Marker genes, tolerance to biotic stresses, and modification of tree growth and form were the most important research objectives

Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Between 2006 and 2010, the % of trials testing abiotic stresses had increased by two-fold, while that for biotic stresses had decreased by two-fold.



Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Recent regulatory developments- Cold tolerant Eucalyptus (ArborGen)

Results from first winter in South Carolina

Control

Lead line

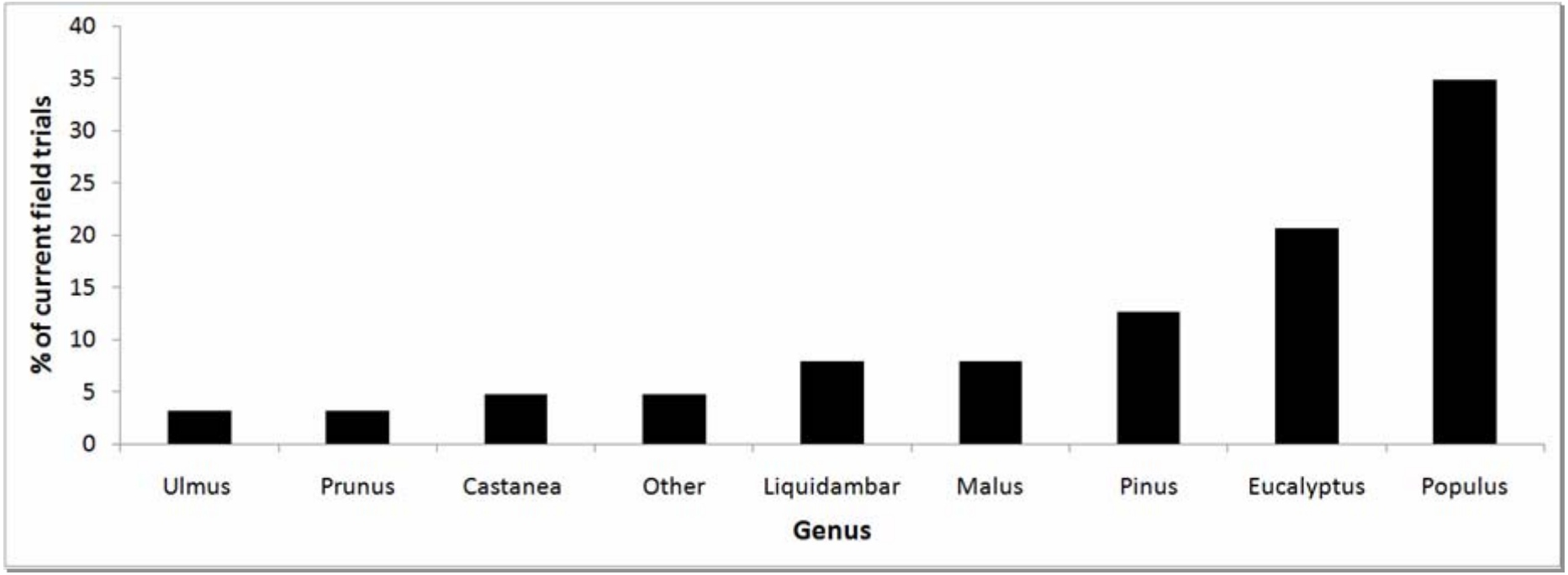
Results from second winter in Alabama

Control+ lead line

Images provided by Nancy Hood, Arborgen

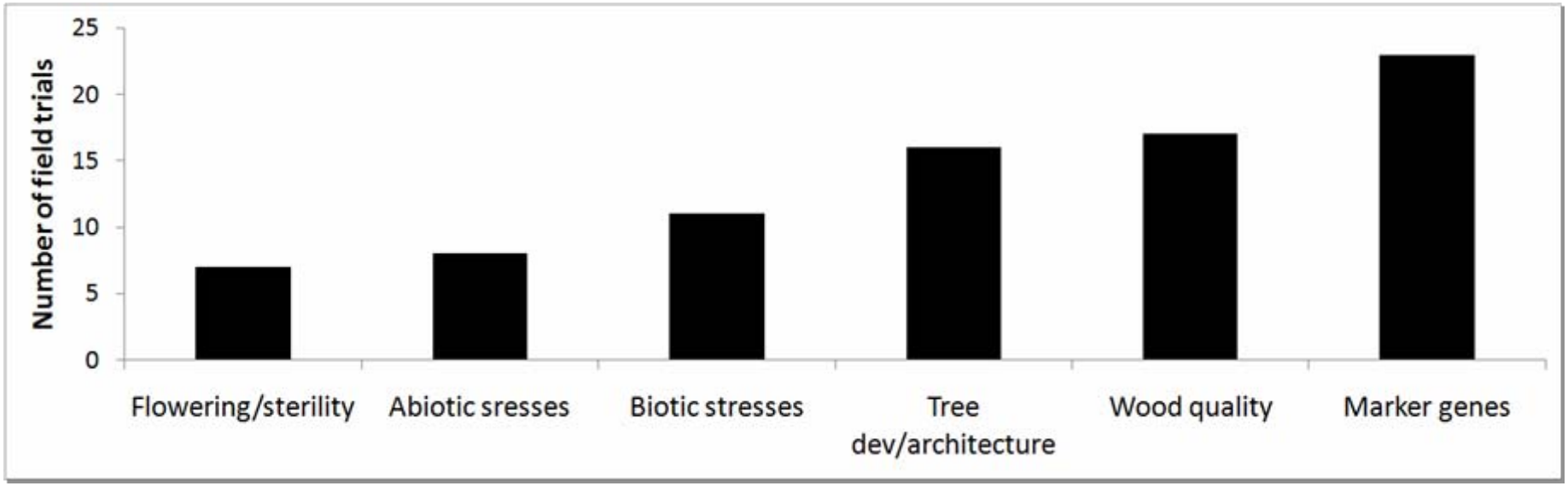
Populus alone accounted for one-third of all current field trials on the ground

More than sixty field trials currently taking place



Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

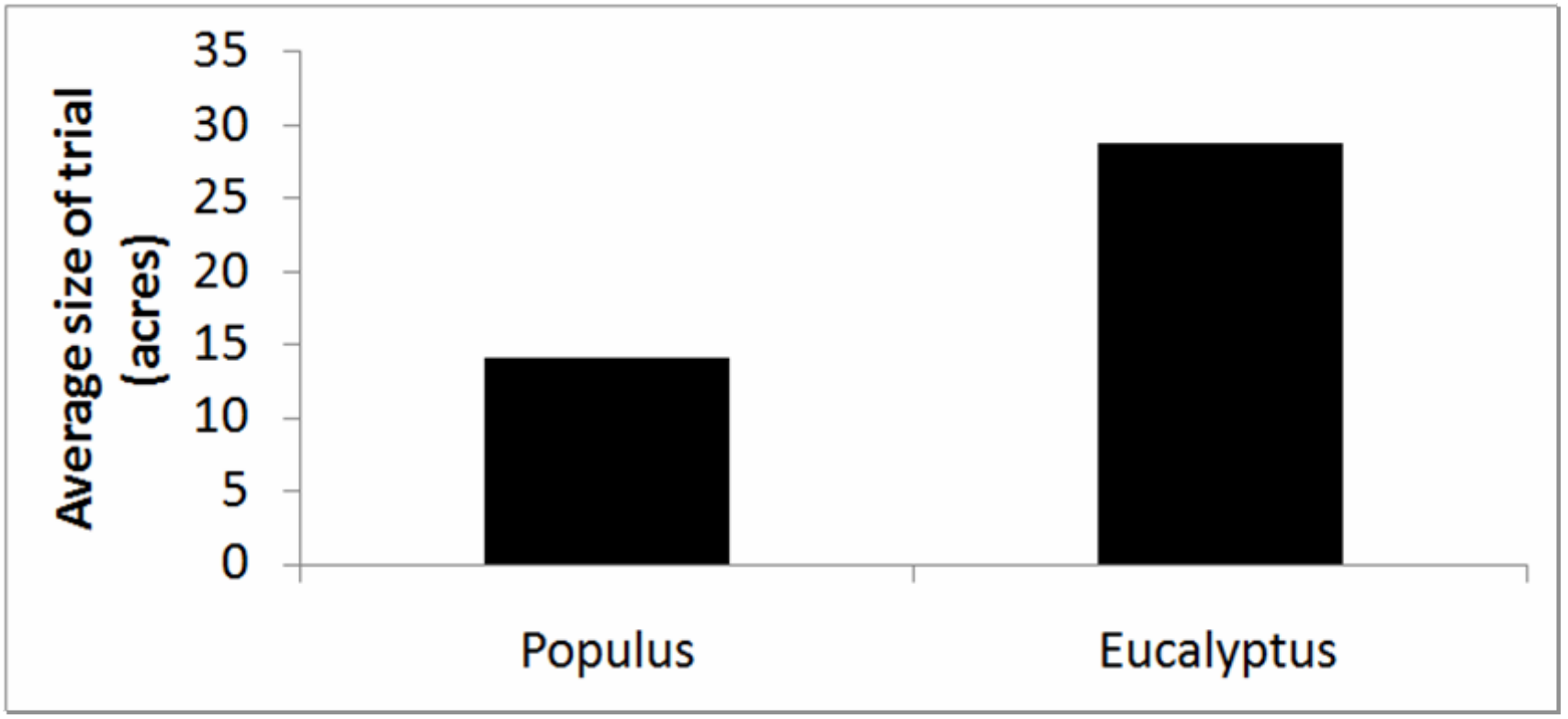
Marker genes and modification of wood quality were the two most important research objectives of current trials



Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

An activation tagged population during its first (top) and second (bottom) growing season in Oregon

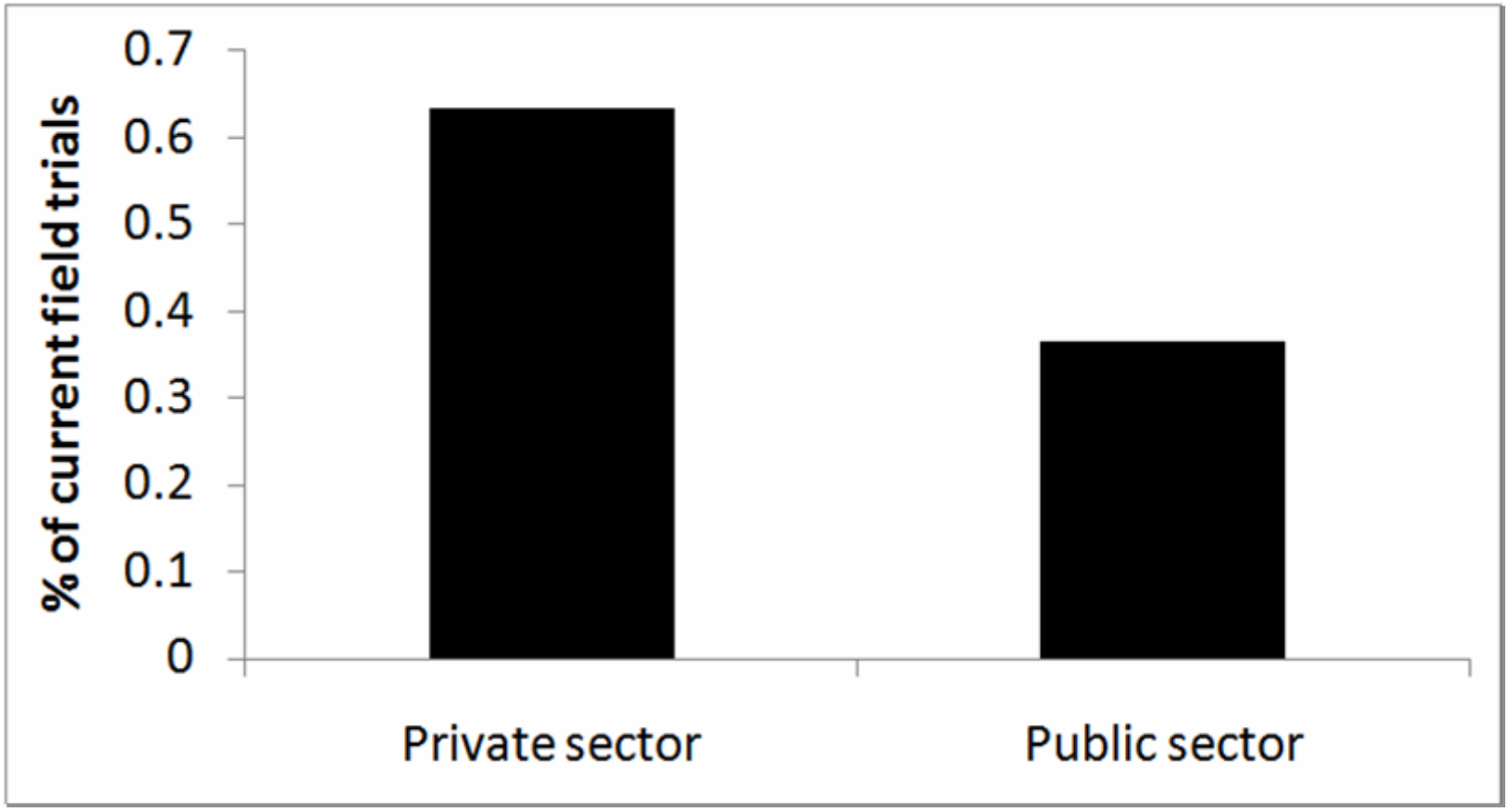
For field trials on the ground, the average size of an *Eucalyptus* trial was twice that of a *Populus* trial



The larger average field trial size for eucalypts is due to just two trials with a size of 197.2 acres and 130.5 acres respectively. The largest trial involving *Populus* was one with Eastern cottonwood on 74.75 acres.

Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Private sector organizations were conducting ~60% of all current field trials



ArborGen alone accounted for ~90% of the field trials being conducted by private companies!

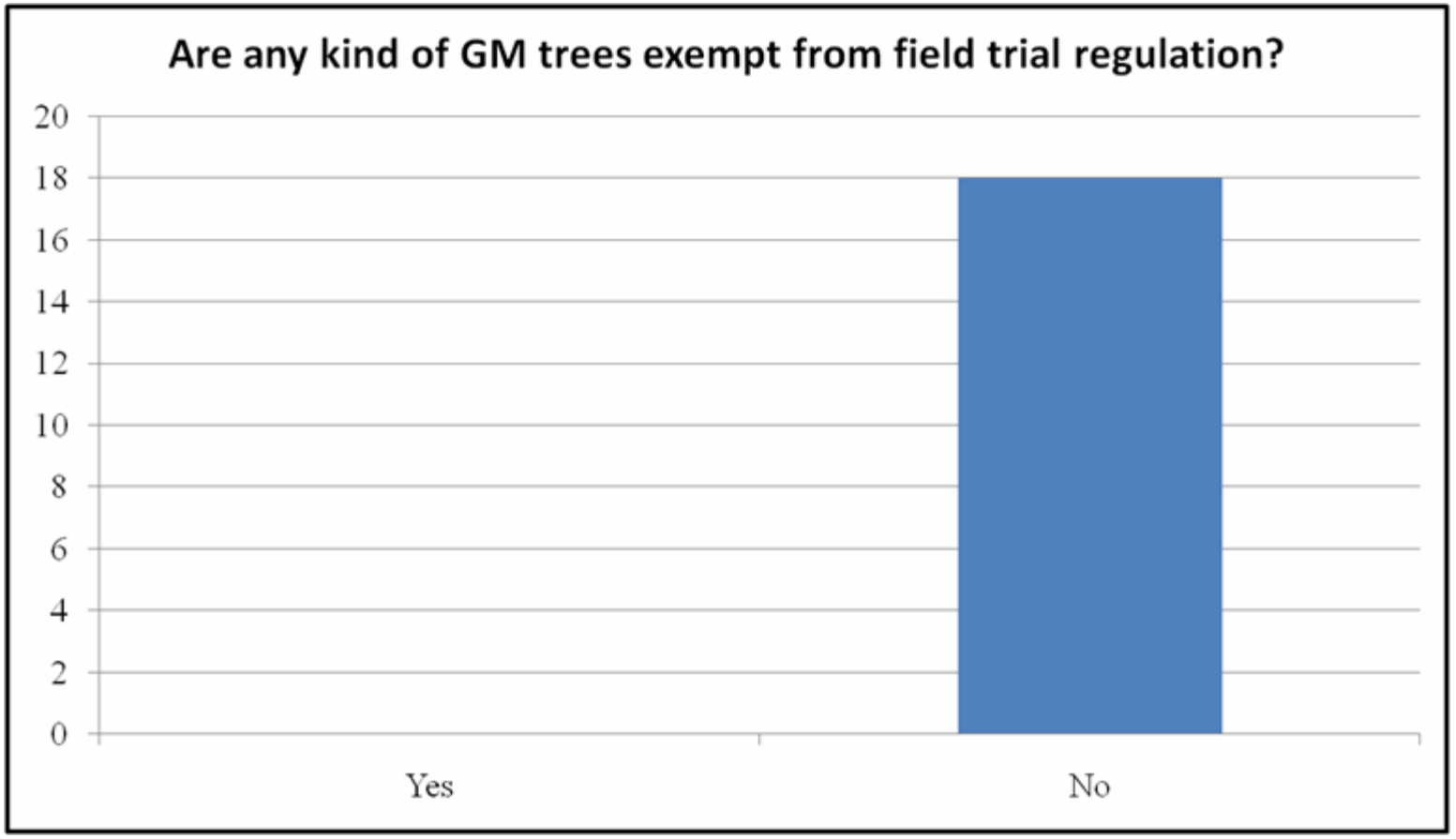
Source: Information Systems for Biotechnology (ISB), http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

Global survey of regulations on GM trees: Experience & perception of burden

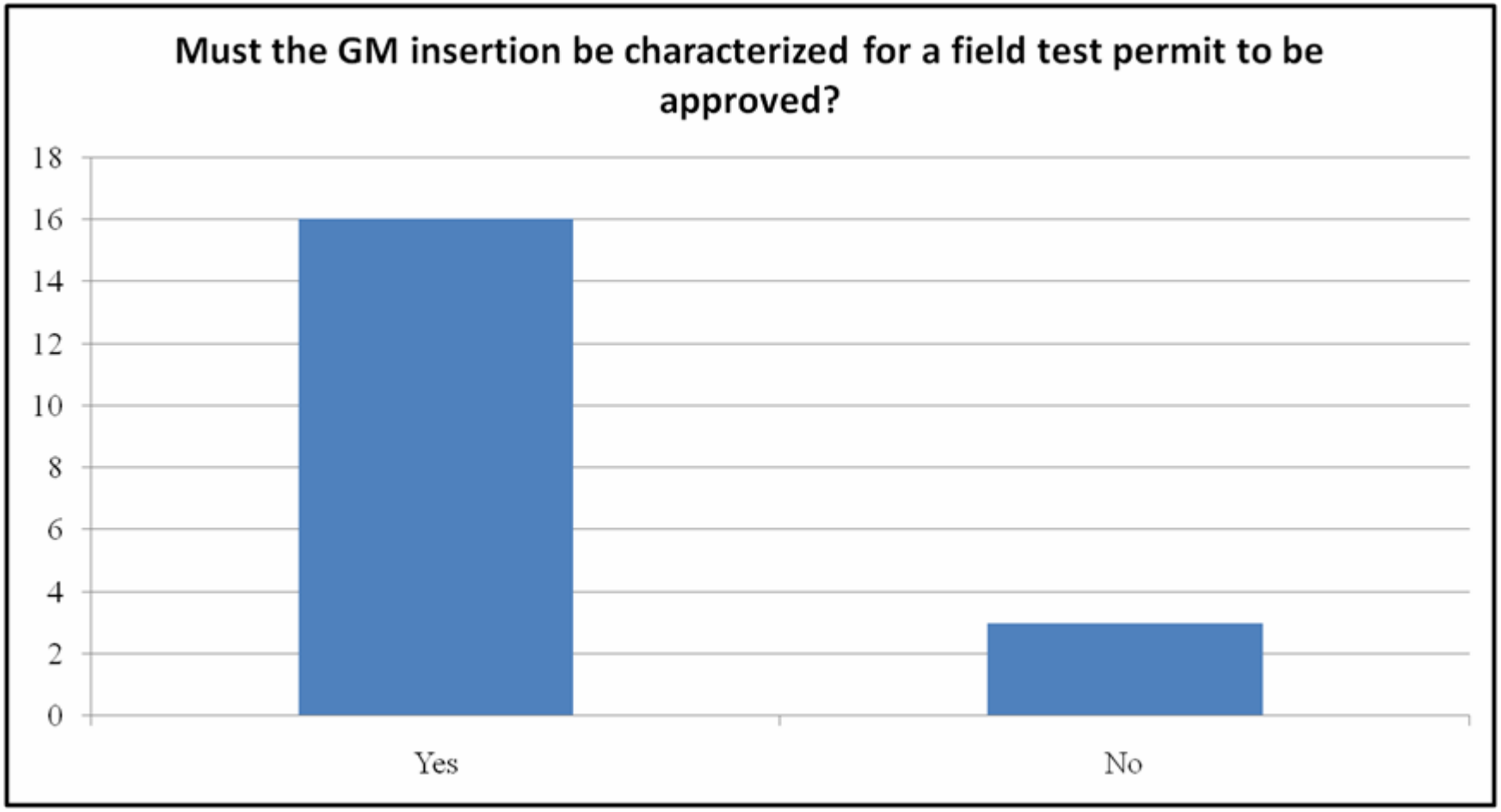
- Sent to 100 scientists from different parts of the globe who have direct experience with regulatory compliance for transgenic trees (or relevant crop species)
- 36 scientists, representing 20 different countries, responded to the survey

Austria	Chile	India (2)	New Zealand
Belgium (2)	Finland	Italy	Nigeria
Brazil	France	Jamaica	Spain (2)
Canada (2)	Germany (2)	Japan (2)	United States of America (10)
China (2)	Hungary	Netherlands	Sweden

No category of GM tree is exempt from field trial regulation

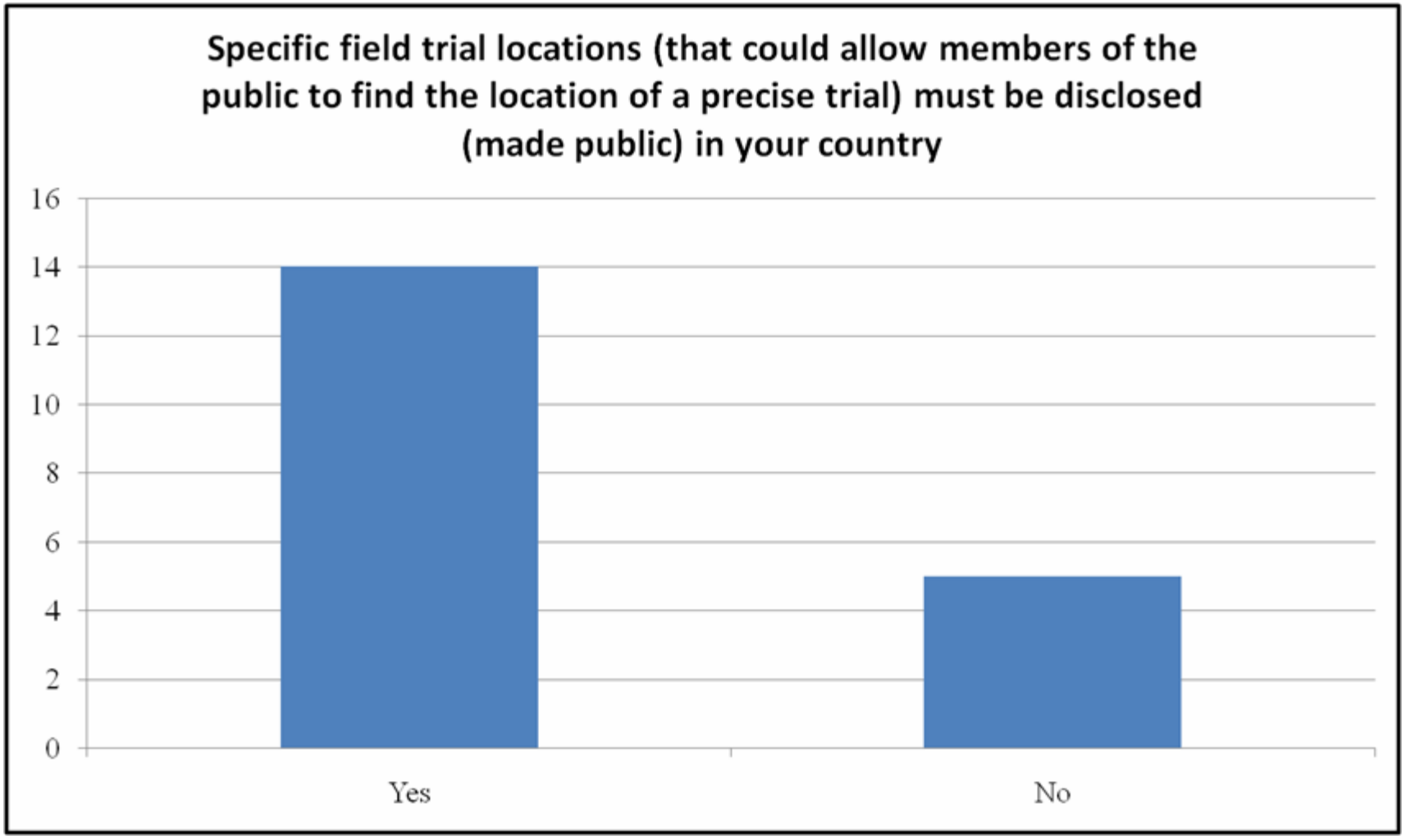


Inserts must be characterized for field trial permits in most countries

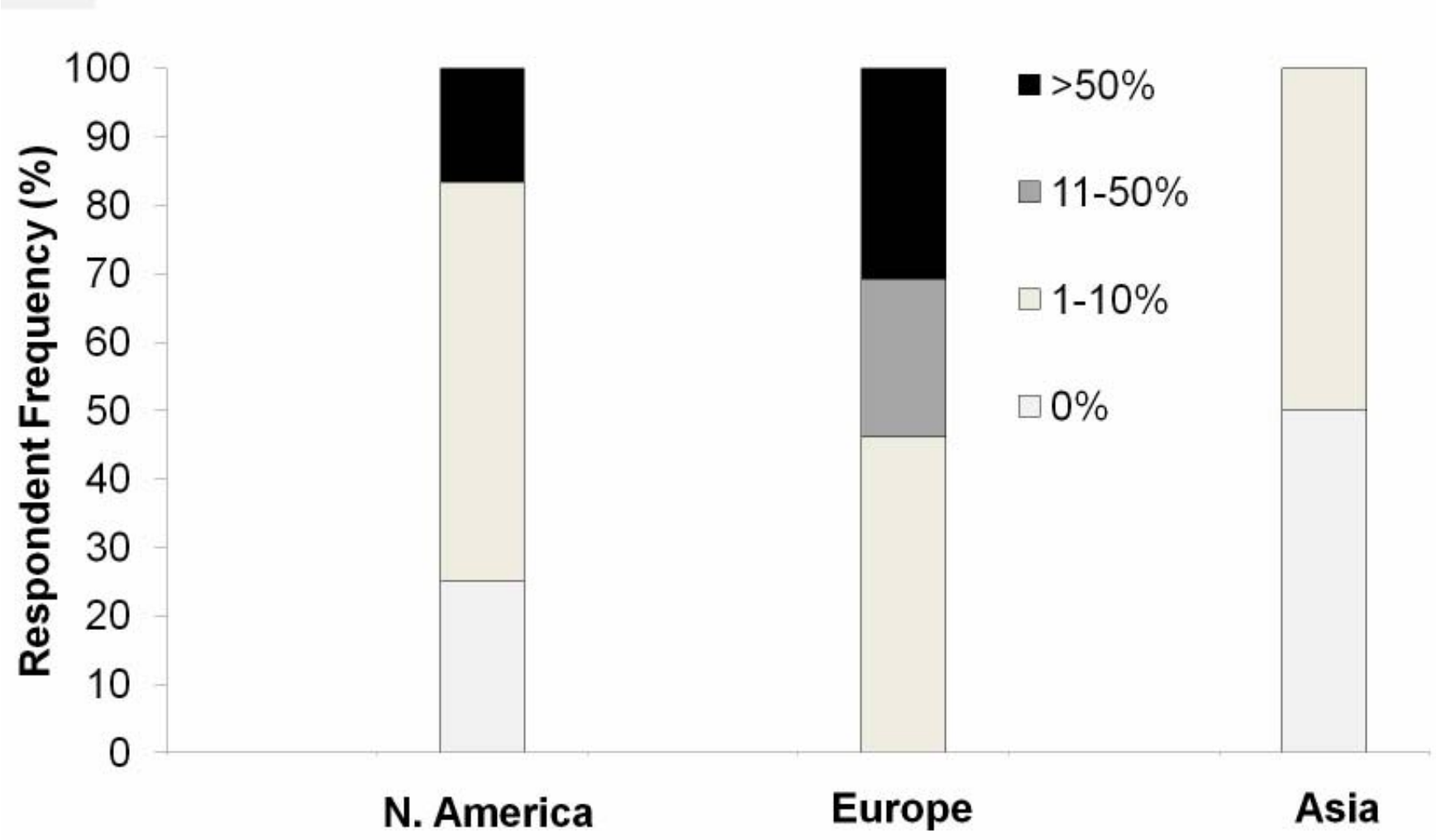


Need to study many inserts due to position effects, driving costs up dramatically

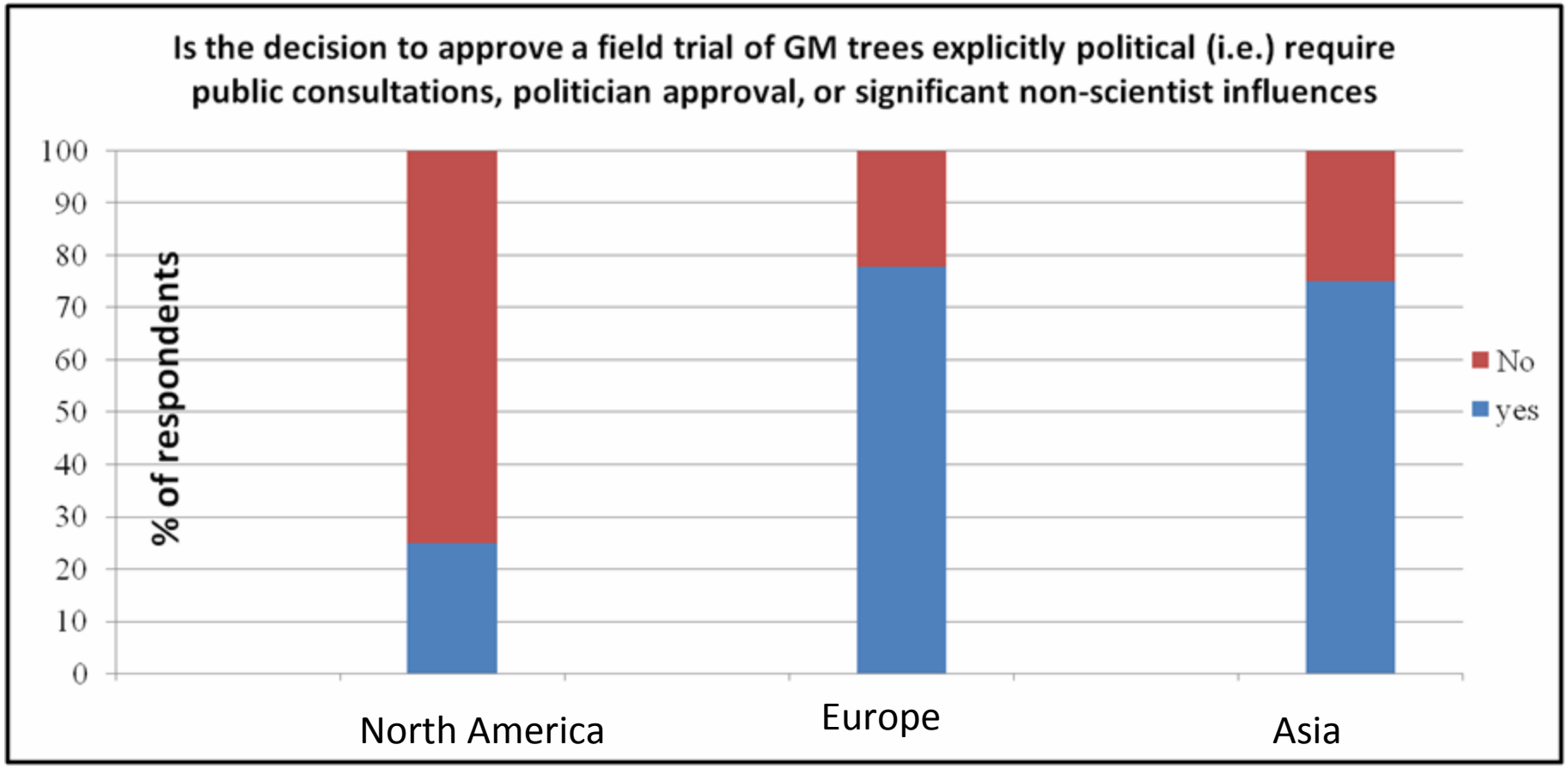
Field sites must be made public in most countries



Likelihood of at least one vandalism event occurring during a two year trial of GM trees



A majority in Europe and Asia felt the decision making process to approve a field trial is highly political



Effect of regulations on deterrence of field research

The proportion of scientists that felt the stringent regulations in their country deterred field research on GM trees was higher in Europe and Asia compared with North America.