Electronic supplementary material: Global regulatory burden for field testing of genetically modified trees

Tree Genetics and Genomes

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S1: Full Survey.

Global survey on regulatory requirements for field trials of genetically modified (GM) trees

The goal of this information gathering survey is to describe biotechnology scientists' understanding of the regulatory requirements to conducting field trials with genetically modified (genetically engineered) trees. For this purpose, we are contacting scientists that have had direct experience with field trials, or have direct knowledge of regulations concerning field trials. If you do not have such detailed knowledge or experience, please do not fill out this survey. However, please consider forwarding it to scientists that you know have such knowledge or experience.

Please note that we do not ask the views of your organization, company, or government; please comment as an individual scientist. For the purpose of this survey, genetically modified trees are produced using genetic transformation vectors such as *Agrobacterium* and biolistics ("gene gun"), followed by plant regeneration, regardless of the source or nature of the gene, or the trait imparted.

Our goal is to briefly publish the results in summary form in a scientific journal; however, your name, email address and company/organization will not be published. In addition, any comments you make, if quoted, will not be attributed to you by name. Please feel free to provide comments on any of the questions to help us understand your response or specific regulations / rules in your country. THANKS FOR TAKING THE TIME TO COMPLETE THE SURVEY! Please direct questions or concerns to Steve.Strauss@oregonstate.edu.

Basic Information

1. Name
2. Email address
3. URL of your own science-focused web site (English version if possible)
4. Position (e.g., professor, company research leader)
5. Brief description of main experience with field testing of GM trees
6. Highest degree or level of experience
   a. Bachelors

b. Masters
c. PhD
d. Postdoc

7. Are you interested in possibly helping to write and be a coauthor on this paper?

8. Country

9. University/Company/Organization you work in

10. Name of the department you work in

11. Tree genera you primarily work on (choose up to two; if other, please specify)
    a. *Populus*
    b. *Eucalyptus*
    c. *Citrus*
    d. *Acacia*
    e. *Pinus*
    f. *Malus*
    g. *Prunus*
    h. *Papaya*
    i. *Juglans*
    j. Other

12. Primary goals of your research (choose up to three areas; if other, please specify)
    a. Gene insertion methods
    b. Basic genomics
    c. Disease resistance
    d. Insect resistance
    e. Abiotic stresses
    f. Wood quality
    g. Flowering quality
    h. QTL analysis
    i. Association genetics
    j. In vitro culture methods
    k. Clonal propagation
    l. Conventional breeding
    m. Fruit quality
    n. Post harvest storage
    o. Yield
    p. Bioenergy
    q. Other

13. What percentage of research effort in your laboratory is spent in transferring genes to produce transgenic trees?

a. 0%
b. 1-10%
c. 11-25%
d. 26-50%
e. 51-75%
f. 76-100%

14. Number of regenerated transgenic lines with unique gene insertions created in your laboratory or a close collaborating laboratory in your career to date.
    a. 0
    b. 1-5
    c. 6-10
    d. 11-20
    e. 21-100
    f. 101-1,000
    g. >1,000

15. Number of field trial experiments that your laboratory or a close collaborating laboratory has conducted in your career to date.
    a. 0
    b. 1-5
    c. 6-10
    d. 11-20
    e. 21-100
    f. >100

Information about regulations in your country

16. URL (s) of the English version (if possible) of the main web site (s) for the Government regulatory agency in your country that controls field trials and commercialization of GM trees.

17. Specific field trial locations (that could allow members of the public to find the location of a precise trial) must be disclosed (made public) in your country.
    a. Yes
    b. No

18. When compared to GM crops, are there any special regulations/requirements for tests of GM trees or other perennial plant species? What are they? Please also specify any web site that describes them.

19. Are there any categories of GM trees or genes inserted (e.g., cisgenes, biopharma genes), that warrant greater or reduced regulatory oversight?
    a. Yes
    b. No
    c. Don’t know

20. If you answered "yes" to the above question, please explain/elaborate.

21. Are any kinds of GM trees exempt from field trial regulation?
    a. Yes
    b. No
    c. Don’t know

22. What scale of technical documentation is needed to obtain a permit for a field trial of a GM tree (single gene insertion)?
    a. One single spaced 12 point font page or less
    b. 2-5 single spaced 12 point font pages
    c. 6-10 single spaced 12 point font pages
    d. 11-20 single spaced 12 point font pages
    e. 21-50 single spaced 12 point font pages
    f. 51-100 single spaced 12 point font pages
    g. >100 single spaced 12 point font pages

23. What scale of technical documentation is needed to obtain a permit for a field trial of a FLOWERING GM tree (single gene insertion)?
    a. One single spaced 12 point font page or less
    b. 2-5 single spaced 12 point font pages
    c. 6-10 single spaced 12 point font pages
    d. 11-20 single spaced 12 point font pages
    e. 21-50 single spaced 12 point font pages
    f. 51-100 single spaced 12 point font pages
    g. >100 single spaced 12 point font pages

24. Is there an application processing fee?
    a. Yes
    b. No
    c. Don’t know

25. If you answered "yes" to the above question, how much does the fee approximately amount to (in US Dollars)?

26. Must the GM insertion be characterized for a field test permit to be approved?
    a. Yes
    b. No
    c. Don’t know

27. If you answered "yes" to the above question, what sort of characterization is required (check all that apply; if other, please specify)?
    a. PCR
    b. RNA gene expression
    c. Southern blot
    d. DNA sequence of insert

e. Protein analysis
f. Copy number
g. Chromosomal location
h. Other

28. Is fencing or trenching into the ground required around field trials of GM trees?
    a. Yes
    b. No
    c. Don’t know

29. If fencing or trenching into the ground around a field trial is needed, please describe its nature (height, depth, materials, electrification, and construction materials)?

30. Are monitoring and formal reporting about GM field trials required?
    a. Yes
    b. No
    c. Don’t know

31. If you answered "yes" to the above question, how frequently is reporting required?
    a. Less than or equal to once per year
    b. Twice per year
    c. More than two times per year
    d. Only when problems arise
    e. Only when the field trial research is completed

32. If you answered "yes" to question 30, how much detail is required in each report (assume one hectare field trial with twenty transgenic events)?
    a. One single spaced 12 point font page or less
    b. 2-5 single spaced 12 point font pages
    c. 6-10 single spaced 12 point font pages
    d. More than 10 single spaced 12 point font pages

33. If you answered "yes" to question 30, what data are you required to report (if other, please specify)?
    a. Soil quality
    b. Flowering
    c. Biodiversity effects
    d. Mycorrhizae effects
    e. Evidence of spread
    f. Other

34. Are separate approvals required for different field trial locations?
    a. Yes
    b. No
    c. Don’t know

35. Are separate approvals required for different constructs?
    a. Yes
    b. No
    c. Don’t know

36. Are separate approvals required for different tree species?
    a. Yes
    b. No
    c. Don’t know

37. Does each independent gene insertion, not just each kind of construct used, require a separate application (i.e., you cannot put several insertions into a single application for a field trial permit)?
    a. Yes
    b. No
    c. Don’t know

38. Is monitoring required after removal of the trees?
    a. Yes
    b. No
    c. Don’t know

39. If you answered "yes" to the above question, for how much time (years) after harvest is monitoring required?
    a. One year
    b. Two years
    c. More than two years
    d. At least until no more living sprouts or seeds can be detected from the site

40. How much time is required before a retired GE field site (a field site no longer under experiment) can be reused for other purposes?
    a. No preclusion
    b. One year
    c. Two years
    d. Three years
    e. More than three years
    f. Cannot be reused at all
    g. Only after no more living sprouts or seeds can be detected at the site
    h. Don’t know

41. Once all tree tissues are rendered inviable (dead), are special methods still required for disposition of their woody stem and/or root materials?
    a. Yes
    b. No
    c. Don’t know

42. If you answered "yes" to the above question, what methods are used (check all that apply; if other, please specify)?
    a. Autoclaving
    b. Burning
    c. Deep burial
    d. Excavation
    e. Fumigation of soil
    f. Other

43. If you answered "yes" to question 41, in what cases are special methods required for disposition of woody stem and/or root materials (please comment)?

Perception of effort to conduct field trials in your country

44. Has the stringency of the regulatory framework in your country led to a reduction or cessation of your interest in conducting field trials with GM trees?
    a. Yes
    b. No

45. The difficulty of complying with regulations in your country has been decreasing over time.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don’t know

46. Compared to a greenhouse study of non-GM trees, the amount of effort to conduct a greenhouse study of GM trees and then subsequently dispose off them is:
    a. Less demanding
    b. About the same
    c. Two-fold greater
    d. Three to ten-fold greater
    e. Eleven to hundred-fold greater
    f. >One-hundred-fold

47. The risk of vandalism to a field trial of GM trees is a significant concern in your country.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don’t know

48. Compared to a non-GM field trial, the amount of documentation required for a GM field trial (application, data, reports) is:
    a. Less demanding
    b. About the same

c. Two-fold greater
d. Three to ten-fold greater
e. Eleven to hundred-fold greater
f. >One-hundred-fold

The next eight questions are to determine which steps in the process of carrying out a GM field trial have the most amount of burden/cost associated with them (when compared to a field trial of non-GM trees).Please score them on a scale of 1-10, where 10 is maximum burden.

49. Initial application

50. The required physical safeguards, such as cameras and fences

51. The extra workload

52. Prevention of flowering

53. Staff costs

54. Reporting costs

55. Field test devitalization (killing and certification of the death of all test trees and roots)

56. Special disposal of woody materials

57. I am concerned about my personal safety or reputation, or that of my family, workers or laboratory, due to public awareness of my GM tree field trials as a result of regulatory disclosure requirements.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don’t know

58. What is your estimated likelihood of at least one vandalism event (in %) occurring during a two year trial of GM trees?
    a. 0%
    b. 1-10%
    c. 11-50%
    d. >50%

59. What is your estimated likelihood of at least one vandalism event (in %) occurring during a two year trial of conventionally bred trees?
    a. 0%
    e. 1-10%
    f. 11-50%
    b. >50%

60. What is the estimated total annual cost (in US Dollars) for regulatory compliance for a one hectare trial (i.e., above a non-GM field trial, including permits, labor, monitoring, fences/ security, disposal, data, reports, containment of pollen/seeds, removal from site)?
    a. <$100
    b. $100-$1,000
    c. $1,001-$10,000
    d. >$10,000

61. With respect to its effect on your ability to conduct needed field studies, I am satisfied with the regulatory framework that is currently in place for conducting a field trial with GE trees in my country.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know

62. With respect to its effect on your ability to conduct needed field studies, I am frustrated with the regulatory framework that is currently in place for conducting a field trial with GE trees in my country.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know

63. Is the decision to approve a field trial of GM trees explicitly political (i.e.) require public consultations, politician approval, or significant non- scientist influences?
    a. Yes
    b. No
    c. Don't know

64. If you answered "yes" to the above question, please comment.

65. Please briefly describe the general nature of regulations in your country as it pertains to GM trees (please keep response below 100 words).

66. Please describe any regulatory changes you would like to see in order to facilitate your ability to conduct needed, safe field trials with GM trees (please keep response below 100 words).

67. Are there any comments/insights you wish to share (please keep response below 200 words)?

68. Can you suggest others that we should send this survey to who know the regulations that pertain to GM trees, and/or have undertaken field trials of GM trees themselves (names and emails)?

THANKS VERY MUCH FOR TAKING PART IN THIS SURVEY!

If there are any documents that you wish to share which would help us better understand your response (s), please email them to Steve.Strauss@oregonstate.edu

S2: Number and percentage of responses for questions 17-42 in the survey. The numbers are based on 20 responses that best represent the country's regulations. Questions 27, 31, 33, 39 and 42 have multiple responses.

Question number	Choice a	Choice b	Choice c	Choice d	Choice e	Choice f	Choice g	Choice h
17	Yes (15/75%)	No (5/25%)						
19	Yes (4/20%)	No (16/80%)	Don't know (0/0%)					
21	Yes (0/0%)	No (19/95%)	Don't know (0/0%)					
22	One ss page (0/0%)	2-5 ss pages (1/5%)	6-10 ss pages (7/35%)	11-20 ss pages (8/40%)	21-50 ss pages (4/20%)	51-100 ss pages (0/0%)	>100 ss pages (0/0%)	
23	One ss page (0/0%)	2-5 ss pages (1/5.6%)	6-10 ss pages (6/33.3%)	11-20 ss pages (6/33.3%)	21-50 ss pages (2/11.1%)	51-100 ss pages (0/0%)	>100 ss pages (3/16.7%)	
24	Yes (11/55%)	No (7/35%)	Don't know (2/10%)					
26	Yes (16/80%)	No (4/20%)	Don't know (0/0%)					
27	PCR (12/75%)	Gene expression (6/37.5%)	Southern blot (12/75%)	Sequence of insert (10/62.5%)	Protein analysis (6/37.5%)	Copy number (11/68.8%)	Chromosomal location (3/18.8%)	Other (3/18.8%)
28	Yes (12/60%)	No (7/35%)	Don't know (1/5%)					
30	Yes (20/100%)	No (0/0%)	Don't know (0/0%)					
31	Maximum of once per year (11/55%)	Twice per year (2/10%)	More than two times per year (7/35%)	Only when problems arise (3/15%)	After completion of trial (3/15%)			
32	One ss page (4/22.2%)	2-5 ss pages (7/38.9%)	6-10 ss pages (3/16.7%)	More than 10 ss pages (4/22.2%)				
33	Soil quality (4/20%)	Flowering (11/55%)	Biodiversity effects (7/35%)	Mycorrhizae effects (4/20%)	Evidence of spread (8/40%)			
34	Yes (14/70%)	No (4/20%)	Don't know (2/10%)					
35	Yes (15/75%)	No (4/20%)	Don't know (1/5%)					
36	Yes (16/80%)	No (2/10%)	Don't know (2/10%)					
37	Yes (4/20%)	No (11/55%)	Don't know (5/25%)					
38	Yes (18/90%)	No (1/5%)	Don't know (1/5%)					
39	One year (4/22.2%)	Two years (4/22.2%)	More than two years (4/22.2%)	Until no detection of living sprouts (9/50%)				
40	No preclusion (1/5%)	One year (2/10%)	Two years (2/10%)	Three years (1/5%)	More than three years (1/5%)	Cannot be reused (0/0%)	Until no detection of living sprouts (13/65%)	Don't know (0/0%)
41	Yes (5/25%)	No (6/30%)	Don't know (9/45%)					
42	Autoclaving (2/40%)	Burning (5/100%)	Deep burial (1/20%)	Excavation (2/40%)	Fumigation (1/20%)	Other (2/40%)		

S3: Number and percentage of responses for questions 6, 13-15, 44-48, and 57-63. The numbers are based on all responses received. Questions 1-12 with personal data are excluded, with the exception of question 6.

Question number	Choice a	Choice b	Choice c	Choice d	Choice e	Choice f	Choice g	Choice h
6	Bachelors (0/0%)	Masters (3/8.3%)	PhD (12/33.3%)	Postdoc (21/58.4%)				
13	0% (2/5.6%)	1-10% (9/25%)	11-25% (11/30.6%)	26-50% (4/11.1%)	51-75% (6/16.7%)	76-100% (4/11%)		
14	0 (3/8.3%)	1-5 (1/2.8%)	6-10 (4/11.1%)	11-20 (5/13.9%)	21-100 (6/16.7%)	101-1,000 (9/25%)	>1,000 (8/22.2%)	
15	0 (7/19.4%)	1-5 (17/47.2%)	6-10 (7/19.4%)	11-20 (0/0%)	21-100 (3/8.3%)	>100 (2/5.7%)		
44	Yes (17/47.2%)	No (19/52.8%)						
45	Strongly agree (2/5.6%)	Agree (5/13.9%)	Disagree (15/41.7%)	Strongly disagree (10/27.8%)	Don't know (4/11%)			
46	Less demanding (2/5.6%)	About the same (4/11.1%)	Two-fold greater (8/22.2%)	Three to ten-fold greater (14/38.9%)	Eleven to hundred-fold greater (4/11.1%)	>One-hundred fold (4/11.1%)		
47	Strongly agree (11/30.6%)	Agree (13/36.1%)	Disagree (10/27.8%)	Strongly disagree (1/2.8%)	Don't know (1/2.7%)			
48	Less demanding (1/2.8%)	About the same (0/0%)	Two-fold greater (2/5.6%)	Three to ten-fold greater (11/30.6%)	Eleven to hundred-fold greater (16/44.4%)	>One-hundred fold (6/16.6%)		
57	Strongly agree (4/11.1%)	Agree (12/33.3%)	Disagree (16/44.4%)	Strongly disagree (3/8.3%)	Don't know (1/2.9%)			
58	0% (6/16.7%)	1-10% (20/55.6%)	11-50% (4/11.1%)	>50% (6/16.6%)				
59	0% (28/77.8%)	1-10% (6/16.7%)	11-50% (1/2.8%)	>50% (1/2.7%)				
60	<$100 (0/0%)	$100-$1,000 (7/19.4%)	$1,001-$10,000 (15/41.7%)	>$10,000 (14/38.9%)				
61	Strongly agree (0/0%)	Agree (12/33.3%)	Disagree (12/33.3%)	Strongly disagree (10/27.8%)	Don't know (2/5.6%)			
62	Strongly agree (9/25%)	Agree (15/41.7%)	Disagree (10/27.8%)	Strongly disagree (0/0%)	Don't know (2/5.5%)			
63	Yes (13/52%)	No (11/44%)	Don't know (1/4%)					

S4: Responses to questions 49-56 on the difficulty of executing a field trial of GM trees, on a scale of 1 (least difficult) to 10 (most difficult). The number of answers in a score category are indicated, with question numbers given in parentheses. More than 40% of the respondents gave a score of 7 or more for all of the eight questions.

Score	Application (49)	Physical safeguards (50)	Extra workload (51)	Prevention of flowering (52)	Staff costs (53)	Reporting costs (54)	Devitalization (55)	Disposal (56)
1	1	3	0	4	1	1	3	3
2	2	3	1	2	3	4	2	6
3	2	2	1	0	4	3	2	3
4	1	2	2	2	5	2	2	2
5	1	6	8	5	3	8	1	1
6	0	2	3	6	0	3	2	3
7	1	3	3	2	2	1	6	3
8	10	8	8	2	5	5	7	4
9	4	0	4	1	2	2	2	2
10	14	7	6	11	11	7	9	8