

**BRS-RD**  
TRANSMITTAL

TO: GLEN ROGAN  
FROM: VIRGIL MEIER  
FAX NUMBER: 314 694-3080  
DATE: 11/21/03  
SUBJECT: Alfalfa petition  
PAGES: Including cover sheet to 7

*Message:*

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**REGULATORY DIVISION**  
BIOTECHNOLOGY REGULATORY SERVICES  
4700 RIVER ROAD UNIT 147  
RIVERDALE, MD 20737  
TELEPHONE: (301) 734-5715 or (301) 734-7324  
**FAX: (301) 734-8669**

AR1879



## DRAFT

Mr. Glen Rogan  
Regulatory Affairs Manager  
Monsanto Company  
700 Chesterfield Pkwy North  
Chesterfield, MO 63198

**Subject:** Review for Technical Completeness of your petition numbered 03-127-01p for a Determination of Non-regulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163

Dear Mr. Rogan:

This letter is in reference to the Petition for Determination of Non-Regulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 submitted to the USDA, Animal and Plant Health Inspection Service/Biotechnology Regulatory Services (APHIS/BRS) on 7 May 2003. APHIS/BRS has assigned this petition the number 03-127-01p. After reviewing this petition APHIS/BRS has determined that there is a possible need for additional information and clarification before we issue a letter declaring more clearly and in more detail the deficiencies that APHIS/BRS has determined before this petition is declared technically complete. Enclosed is a table listing the entire list of possible agronomic deficiencies. Please respond to each of the points.

Sincerely,

Virgil Meier

Biotechnologist Reviewing 03-127-01p

RR Alfalfa Review- Agronomic issues only

Page	Comment
1	On the title page of CBI Deleted copy, need to indicate that this is "CBI Deleted " copy instead of "contains no confidential business information"
21	B. "tribe Trifolium" the correct term is Trifolieae
24	"putative hybrids with <i>M. lupulina</i> " Since <i>M. lupulina</i> , is a weed in the US, information needs to be provided on its hybridization with RR alfalfa.
25	Table II-1. <i>M. lupulina</i> -same comment as above.
26	F. information about <i>M. lupulina</i> - same comment as above.
106	Center of 1 <sup>st</sup> full paragraph – Please provide the selection procedure used for identifying, other than for the <i>cp4 epsps</i> transgene, the plants in the null segregating subset and in the positive segregating subset.
107	Missing word? In 1 <sup>st</sup> sentence in paragraph before B.3. 2, a word or words missing in "53 plants analyzed in this did not contain".
108	Top of page- Describe more completely the plants and procedures used for the seed increases under screen enclosures cages in 2001 and 2002.
110	Explain the presence of the two blots in lanes 33 and 34.
111	Reference to Figure 1?
114	Explain the selection procedures used to create the different populations and provide the number of plants in each population for each generation.
115	Stone et al. 1973. No such citation in References
115	Last paragraph. Both years RR seed substantially more dormant than checks, at least one more years worth of data required to help decide if dormancy is an issue.
119-125	Table headings need to be more complete. Need at least year of seed production.
121	"No trends for percentage abnormal germinated or dead seed were indicated . . ." ". . . due to random experimental error." No statistical analysis presented to indicate level of error term. Need to provide combined statistical analysis over years and temperature regimes as well as paired events. What is the trend for dormant seed?
123	C.2.a. Confirmatory data for the paired event population were not generated because of the lack of appropriate test and control seed. Please provide additional detail.
124-125	Table VI-4. Firm ungerminated. New category vs. 2001. Please explain the reason for the new category.
127	D. Please provide date of trial establishment, whether seeded or transplanted, age or size of transplants, date of each observation, and date of end of trial for the field trials. D.1. Only 1 year of data provided, whereas at least two years of data are needed.
128	Center paragraph. Null individuals were left in tested populations (around 50%). We agree that this will reduce precision of test. Considering that commercial seed would have null individuals as well, but at a rate less than 10%, the tests need to be conducted with "commercial type" seed or need to take out null individuals in tested populations.

137	In order to increase precision of the test results, need to combine data over all 4 locations and provide the statistical analysis.
138-141	Table VI-7: In the heading "2002-2002"? What does that mean? Why is reference data in Table VI-7 different from reference data in Table VI-5?
142	D.1.d. Need statistical analyses to determine if trends exist.
143	What is the seed source of reference varieties?
148	D.2.c "... no consistent trends ..." Please provide combined statistical analysis information.
157	"In general ..." Why only one reference variety? It seems to be difficult to generalize anything with only one reference population. Need to have a combined statistical analyses to provide more precision for any conclusions.
162	E. Why no data on stacked event? Since both events are critical for the commercialization of this product, data need to be submitted for the stacked event.
163, 167	Barnes, 1972. No such citation in References
168	Fig. VI-9 "Alfalfa Fower" ???
179	Statistical analyses needed for data in Table VI-21.
192	1 <sup>st</sup> line "identify" ???
193	Table VI-24. Why is seed yield so low for Control Set 3?
193, 194	G last paragraph "endemic diseases" Do you mean "typical" diseases?
194	2 <sup>nd</sup> to last paragraph "few observed differences" Which ones? Maybe a table showing only the observed differences would be helpful to explain this.
203	Table VI-26 Cysteine significance. Can this be explained? Is it of practical significance?
219	% DW no footnote 1 for DW
220	Why does the stacked event have more significant differences?
225	Minor amount used for ... sprouting purposes. Alfalfa seed is not used directly as a food or feed product. Please clarify this apparent contradiction.
227, 228	Page 227 "average stand-life is approximately 5 years" Page 228 "stand-life of a seed field is two to four years" Please clarify contradiction.
232	Sentence before B.8.iii: mustard ( <i>Brassica</i> spp.) listed as a weed in alfalfa. Will this lead to a problem of RR mustard in RR alfalfa?
234	Last paragraph notes a "nation-wide survey" Please provide reference.
236	D. paragraph 1 editorial comment inserted. Please provide appropriate remedy.
237	Spelling: <i>Solanum pythanthum</i> , <i>Polygonum pennsylvanicum</i>
239	Volunteer wheat is a serious weed in alfalfa. What will be the effect of RR wheat in RR alfalfa?
240	Annual bluegrass is a serious weed in creeping bentgrass as well. Explain why the release of both RR alfalfa and RR bentgrass should not be a major future problem in the development of Roundup resistant <i>Poa annua</i> .

241	Goosegrass resistant to Roundup populations already exist. Explain how the release of RR alfalfa will not cause additional problems. Eluesine Spelling
245	Letuca Spelling Mustards: RR canola already exist. Explain how the release of RR alfalfa will not cause additional problems in the mustards.
246	Lolium RR plants already exist. Explain how the release of RR alfalfa will not cause additional problems in Lolium.
247	1 <sup>st</sup> full paragraph "seeding methods[reference]" A reference is needed. Doll, 2002: not in reference list
249	Last paragraph: "Roundup Ready technology will allow producers to treat and target weed problems as they arise during any point in the growing season." Does this imply repeated applications each year over multiple years and how does this affect the selection for RR weeds?
250	Doll, 2003 No citation in reference list
252	D.6 editorial comment in lines 8-10. Please apply appropriate remedy.  "research conducted by Monsanto has shown that once Roundup Ready alfalfa stands are established, they remain relatively weed free." Need data to document this. How can there be data to document this when the fields are expected to be around 5+ years and RR alfalfa testing was only started in 1999 with only a few plants?
253	"There are no weedy relatives of alfalfa occurring in North America" Does not agree with previous information on <i>M. lupulina</i> ?
255	Paragraph before E.3 Apparent contradictory statements made in the same paragraph. More explanation needed.
258	Paragraph before E.6. (USDA-APHIS 2000, . . . , USDA-ARS 2003) Citations not found in reference list
259	F.1. References to rotations with wheat, sugar beet, corn, soybeans, cotton. All have RR versions that have nonregulated status (or it has been requested). Need more detail on RR alfalfa in rotations with these crops.
261	Popcorn could also be RR. see above comment for page 259
265	CRP acres – Do not use abbreviation without explanation. <i>Limnonthes</i> – spelling
266	<i>Solanum tuberosum</i> L.O – punctuation <i>Tritium</i> – spelling
270	1 <sup>st</sup> paragraph: USDA-NASS 2003 – no citation in References 2 <sup>nd</sup> paragraph, last sentence: When citing rotation statistics on a national basis, what are these same type statistics on selected regional basis where the rotation is much more common?

271	<p>Sentence just above F.5: "... largely dependent upon diligent alfalfa stand take-out ..."</p> <p>1<sup>st</sup> bullet under F.5. "Diligent stand take-out"</p> <p>2<sup>nd</sup> bullet under <i>Plan for success</i></p> <p>Please expand on your explanations. The suggested procedures probably will not be followed many times. Explain what will happen in the worst case scenario if these suggested procedures are not followed.</p>
276	<p>Paragraph above F.7. dealing with volunteer alfalfa in fruit trees: "... control emphasis will change to aggressive alfalfa stand termination ..." – Please elaborate on the aggressive measures to be used.</p> <p>Last sentence at bottom of page about "catch crop" seed will not be allowed – This statement sounds good, but follow through is very difficult, especially once all proprietary rights are expired within 20 years. Explain what will happen in the worst case scenario if these suggested procedures are not followed.</p>
277	F.8. Technical Support – This whole section relies on the goodwill of Monsanto to do the "right thing". Once proprietary rights expire within 20 years, there is no economic incentive for Monsanto or any other commercial institution to do the "right thing". Under that situation, the corrective action falls on the shoulders of the US Government or state government. Explain in detail how Monsanto can be held accountable in the long term.
278	"Weed scientists consider the risk of weeds developing resistance to glyphosate as low." Why? Provide references and additional information.
280	Acharya et al - issue number needed
284	Little and Hills Title, etc. information stated correctly? McCloskey citation stated incorrectly?
290	Padgett et al – no citation in references
291	Top of page: "With alfalfa- <i>lupulina</i> hybrids appearing doubtful, no risk for Interspecific hybridization exists" – It appears this statement is not a very positive statement of no risk. It seems that a simple experiment conducted in the field could put this assumption to rest simply by placing several populations of <i>M. lupulina</i> in the center of an ongoing RR alfalfa seed increase nursery or field, harvesting its seeds and applying Roundup to the germinating seedlings to determine the rate of Roundup resistance. Please provide this type of data.
295	What is the level of RR protein in the dual event plant? Will that cause a problem?
296	Conclusion: "... greater than nine generations of crossing." Where is this described?
297	Clarify citations: Padgett et al. – no year and no blank line following citation Quiros and Bauch – no blank line before and different from repeat just below
309	<p>A. 2<sup>nd</sup> to the last sentence – Is a more recent reference than Malik et al, 1989 available?</p> <p>B. 1<sup>st</sup> sentence – "Today" and "Heap, 2002: is contradictory. 1 year difference, use more recent information.</p>

311	Figure 1 needs to be updated, after all this is 2003, not 2000 – maybe an even more pertinent graph would show the date of introduction of herbicide and the development of resistant weeds
312	C. 1 <sup>st</sup> paragraph – “four weeds resistant to glyphosate” Should be five weeds according to Heap. Elusine –spelling
316- 317	References are not in alphabetic order

Confirmation Report - Memory Send

Page : 001  
Date & Time: Nov-21-03 01:17pm  
Line 1 : 301-734-8669  
Machine ID : Biotechnology

Job number : 162  
Date : Nov-21 01:12pm  
To : 2913146943080  
Number of pages : 007  
Start time : Nov-21 01:12pm  
End time : Nov-21 01:17pm  
Pages sent : 007  
Status : OK

Job number : 162

\*\*\* SEND SUCCESSFUL \*\*\*

**BRS-RD**  
TRANSMITTAL

TO: GLEN ROGAN  
FROM: VIRGIL MEIER  
FAX NUMBER: 314 694-3080  
DATE: 11/21/03  
SUBJECT: Alfalfa petition

PAGES: Including cover sheet to 7

**Message:**

**REGULATORY DIVISION**  
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FAX: (301) 734-8669

AR1886



Virgil D Meier

12/10/2003 11:52 AM

To: Lena C Soileau/MD/APHIS/USDA@USDA

cc:

Subject: Meeting to discuss clarification of RR alfalfa agronomic data

Carmen,  
here is Glen's phone number: 314-694-6602  
Virgil

----- Forwarded by Virgil D Meier/MD/APHIS/USDA on 12/10/2003 11:51 AM -----



"ROGAN, GLENNON J  
[AG/1000]"  
<glennon.j.rogan@monsanto.com>

To: "Virgil.D.Meier@aphis.usda.gov" <Virgil.D.Meier@aphis.usda.gov>  
cc:  
Subject: Meeting to discuss clarification of RR alfalfa agronomic data

12/01/2003 11:50 AM

Virgil,

Can you please reply with available times next week (December 8-12) to review the draft letter of clarification.

I will work with these times to schedule a phone conference between Monsanto, FGI and APHIS.

I understand that the purpose of the call will be to make sure that we are clear on the request from APHIS. Is this correct?

Best Regards,

Glen Rogan  
Regulatory Affairs Manager  
Monsanto Company

AR1912



Lena C Solleau

12/10/2003 03:01 PM

To: <glennon.j.rogan@monsanto.com>@INTER2@gw  
cc: Virgil D Meler/MD/APHIS/USDA@USDA  
Subject: Re: Roundup Ready alfalfa western blot

Dear Glen,

I will write up all my comments and send these to you before the final letter for completeness goes out. Most comments are typo's. I am hosting Madame Li Ming from China Thurs and Friday this week. She is the second in command for China Biotechnology. She is suppose to be here all day, both days so I don't know when I'll be free.

The question I have is about lanes 5 and 6 on both westerns. There appears to be a faint band at approximately 20 KDa. Is this an artifact of the photocopy or is there actually a band in these lanes?

I'll be in the office until 4 PM today (eastern time) and in and out of the office on Thurs and Friday. I'll know a better schedule when I meet with Li Ming tomorrow. If I have free time tomorrow I will email you. Call or email me anytime.  
Carmen

L. Carmen Solleau, Ph. D.  
USDA/APHIS/BRS  
4700 River Road, Unit 147  
Riverdale, MD 20737  
301-734-5301 Office  
301-734-8669 Fax

<glennon.j.rogan@monsanto.com>



<glennon.j.rogan@monsanto.com>

12/10/2003 02:41 PM

To: Lena C Solleau/MD/APHIS/USDA@USDA  
cc:  
Subject: Roundup Ready alfalfa western blot

Carmen,

Thanks for attending the Roundup Ready alfalfa conference call this morning. I understand that you have a question on one of the western blots in the petition.

I would be happy to discuss this with you at a convenient time.

I am available all afternoon tomorrow and Friday (Dec 11 and 12).

I can call you. Please let me know if this will work for you.

Best Regards,

Glen

AR1913



<glennon.j.rogan@monsanto.com>

12/10/2003 03:50 PM

To: Lena C Soileau/MD/APHIS/USDA@USDA,  
glennon.j.rogan@monsanto.com@INTER2@gw  
cc: Virgil D Meier/MD/APHIS/USDA@USDA  
Subject: RE: Roundup Ready alfalfa western blot

Carmen,

I will forward this to our protein biochemist. Do you want me to address now or would you like the response in the combined final response?

Regards,

Glen

-----Original Message-----

From: Lena C Soileau [mailto:Lena.C.Soileau@usda.gov]  
Sent: Wednesday, December 10, 2003 2:01 PM  
To: glennon.j.rogan@monsanto.com  
Cc: Virgil.D.Meier@usda.gov  
Subject: Re: Roundup Ready alfalfa western blot

Dear Glen,

I will write up all my comments and send these to you before the final letter for completeness goes out. Most comments are typo's. I am hosting Madame Li Ming from ChinaThurs and Friday this week. She is the second in command for China Biotechnology. She is suppose to be here all day, both days so I don't know when I'll be free.

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Carmen

L.Carmen Soileau, Ph. D.  
USDA/APHIS/BRS  
4700 River Road, Unit 147  
Riverdale, MD 20737  
301-734-5301 Office  
301-734-8669 Fax

<glennon.j.rogan@monsanto.com>  
12/10/2003 02:41 PM

To: Lena C Soileau/MD/APHIS/USDA@USDA  
cc:  
Subject: Roundup Ready alfalfa western blot

Carmen,

AR1914

Thanks for attending the Roundup Ready alfalfa conference call this morning.  
I understand that you have a question on one of the western blots in the  
petition.

I would be happy to discuss this with you at a convenient time.

I am available all afternoon tomorrow and Friday (Dec 11 and 12).


I can call you. Please let me know if this will work for you.

Best Regards,

Glen

AR1915

Virgil D Meier  
01/13/2004 08:21 AM

To: Virgil D Meier/MD/APHIS/USDA@USDA  
cc: Bruce MacBryde/MD/APHIS/USDA@USDA, James L  
White/MD/APHIS/USDA@USDA, Lena C  
Soileau/MD/APHIS/USDA@USDA, Levis W  
Subject: Re: Alfalfa deficiency letter 

And here is the letter



Review letter-alfalfa.doc  
Virgil D Meier

Virgil D Meier  
01/13/2004 07:31 AM

To: James L White/MD/APHIS/USDA, Levis W Handley/MD/APHIS/USDA,  
Shirley P Ingebritsen/MD/APHIS/USDA, Bruce  
MacBryde/MD/APHIS/USDA, Lena C Soileau/MD/APHIS/USDA  
cc:  
Subject: Alfalfa deficiency letter

Here is my proposed draft RR alfalfa deficiency letter. Please review.

It will be sent as a draft so that they can review each of the points and have a chance at suggesting improvements. One major point that I added to the previous draft deficiency letter was the need to have data for symbionts.

I will fax this to Monsanto after I hear from you.

Virgil

AR1921

## DRAFT

Dr. Glen Rogan  
Regulatory Affairs Manager  
Monsanto Company  
700 Chesterfield Pkwy North  
Chesterfield, MO 63198

**Subject:** Review for Technical Completeness of your petition numbered 03-127-01p for a Determination of Non-regulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163

Dear Dr. Rogan:

This letter is in reference to the Petition for Determination of Non-Regulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 submitted to the USDA, Animal and Plant Health Inspection Service/Biotechnology Regulatory Services (APHIS/BRS) on 7 May 2003. APHIS/BRS has assigned this petition the number 03-127-01p. After reviewing this petition, APHIS/BRS has determined that there is a need for additional information and clarification before we can declare this petition technically complete. Please respond to each of the 92 points listed below in the form of an addendum that will then be considered part of the petition. These points are listed under the relevant heading as they appear in the petition.

**Page 1 Title page**

1. For the copy of the petition that has the Confidential Business Information deleted, instead of stating "CONTAINS NO CONFIDENTIAL BUSINESS INFORMATION", it should state "CONTAINS CONFIDENTIAL BUSINESS INFORMATION DELETED". In addition, it would be helpful if each page stated on the top or bottom of the page "CBI Deleted" or "Confidential Business Information Deleted". For the copy of the petition that has the Confidential Business Information, it would be helpful if each page stated on the top or bottom of the page "CBI" or "Confidential Business Information".

**Page 11 Table of Contents**

2. Table II-1. What is the meaning of the superscript 1?

**Page 12 Table of Contents**

3. Tables VI-1, VI-8, VI-9. What is the meaning of the superscript 1?

**Page 21 Section II.B. Taxonomy and Genetics of Alfalfa**

4. "tribe Trifolium" The correct term is "Trifolieae".

**Page 23 Section II.E. Related Species**

5. "in thier review" Incorrect spelling.

AR1922

**Page 24 Section II.E. Related Species**

6. "putative hybrids with *M. lupulina*" Since *M. lupulina* has been noted as a weed in the US, clarification is needed on the probability of its hybridization with alfalfa or RR alfalfa. Provide data on actual attempts to hybridize these two species and/or provide information and references on the success rate of these hybridization attempts.

**Page 25 Table II-1**

7. *M. lupulina*: Same as Point 6 above.

**Page 26 Section II.F. Geographic Location of Compatible Species**

8. "With alfalfa-*lupulina* hybrids . . .": Same as Point 6 above.

**Page 28 Section III.A. Description of the Transformation System**

9. "binary strain (ABI)" Is this a proprietary or registered strain?

**Page 31 Section IV.B. The *cp4 epsps* Gene and CP4 EPSPS Protein**

10. "47.6 kea protein" Incorrect spelling?

**Page 34 Table IV-1**

11. Citation for HSP70 not present in table.

**Pages 52-58, 62-68 Figures V-2 to V-8, V-12 to V-18**

12. Figure legends state "stained with ethidium", should say "stained with ethidium bromide".

**Page 72 Figure V-22**

13. "Syn 1 line is in bold font" Bold font is missing.

**Pages 76, 87 C. Characterization of the CP4 EPSPS Protein Produced by Event J101**

14. "BCS total protein assay" "BCA" not defined.

**Pages 78, 88 Tables V-2, V-5**

15. Are there alignment problems of the amino acids?

**Pages 82, 93 Figures V-25, V-29**

16. Western Blot data. What is the band that migrates at approximately 20 kDa?

**Pages 83, 94 Tables V-4, V-7**

17. "(shown in bold values)" Bold font is missing.

**Page 98 Section V.E. CP\$ EPSPS Levels in Roundup Ready Alfalfa**

18. ELISA methodology, sample preparation, antibody or antiserum purity and specificity, positive and negative controls are not described fully in text. Please provide a more complete description.

**Page 106 Section VI.B.1. Development and Characterization of Near Isogenic Control Population**

19. Please provide the selection procedure used for identifying, other than for the *cp4 epsps* transgene, the plants in the null segregating subset and in the positive segregating subset.

**Page 107 Section VI.B.2. Development and Characterization of Null Segregant Progenitors**

20. A word or words missing in "53 plants analyzed in this did not contain".

**Page 108 Section VI.B.3. Creation of MBC3 Negative Control Seed Lots**

21. Describe more completely the plants and procedures used for the seed increases "under screen enclosure cages in 2001 and 2002".

**Page 110 Figure VI-4**

22. Explain the presence of the two blots in lanes 33 and 34.

**Page 111 Figure VI-5**

23. "blot from figure 1" No figure 1 could be found.

**Page 114 Figure VI-8**

24. Explain the selection procedures used to create the different populations and provide the number of plants in each population for each generation.

**Page 115 Section VI.C. Dormancy and Germination Evaluations**

25. "Stone et al. 1973" No such citation in References

26. Data from 2001 indicated that the Roundup Ready events had a significantly higher level of dormancy than the controls and reference variety populations, whereas the data from 2002 indicated that the Roundup Ready events had a significantly lower level of dormancy than the controls and for the reference variety populations the significance level varied. Data from an additional year of testing is needed to help determine whether dormancy level has increased for the Roundup ready events or explain why the additional data are not necessary. Please provide information from the statistical analysis for tests noted in the petition and provide references for the explanations.

**Page 116 Section VI.C.1. Dormancy and Germination; 2001 Seed**

27. Are the four reference varieties for the single events the same as the four reference varieties for the paired-event? If they are the same, why are the data for the reference varieties in Tables VI-2 and VI-3 different? If they are different, why did you choose different varieties?

**Page 116 Section VI.C.1.a. Test, control and reference materials**

28. "A progeny map describing the test, control and reference materials is presented in Figure VI-8." Since Figure VI-8 does not contain any information on reference materials, please provide information on the reference materials.

**Pages 119, 122, 124 Tables VI-2, VI-3, VI-4**



29. Table headings need to be more complete. Need at least year of seed production.

**Page 121 Section VI.C.1.d. Results**

30. "No trends for percentage abnormal germinated or dead seed were indicated . . . due to random experimental error." Need to provide indication of the level of experimental error, such as lsd or similar statistic. Statistical analysis over years and temperature regimes is needed to detect trends. This same type of analysis for paired events would be helpful.

**Page 123 Section VI.C.2.a. Test, control and reference materials and methods**

31. "Confirmatory data for the paired event population were not generated because of the lack of appropriate test and control seed." Please explain in more detail.

**Pages 124 Tables VI-4**

32. "Firm Ungerminated" is a new category vs. 2001. Please explain the reason for the new category. It would be best to have the data from 2001 and 2002 presented in the same categories.

**Page 127 Section VI.D. Phenotypic Comparative Studies**

33. For these types of field trials, please provide date of trial establishment, whether seeded or transplanted, age or size of plants if transplanted, date of trial ending, and names and descriptions of the reference populations or varieties.

**Page 128 Section VI.D.1.a. Materials and methods**

34. Null individuals were left in the tested populations at around 50%. We agree that this will reduce the precision of this test. Considering that commercial seed would have null individuals as well, but at a rate less than 10%, the tests need to be conducted with "commercial type" seed or need to take out null individuals in tested populations. Another possibility would be to determine the proportion of null and Roundup Ready plants in these tests at the end of the trial to help determine if Roundup Ready plants are more competitive. As is, this trial provides little, if any, information useful for making a decision 'for' or 'against' this petition.

**Page 137 Section VI.D.1.c. Results and discussion**

35. In order to increase precision of the test results, need to combine data over all 4 locations and provide the statistical analysis.

**Pages 138-141 Table VI-7**

36. In the heading, "2002-2002"? Please correct.

37. Since the data presented in this table appears to have been obtained from the same test that was the source of the data in Table VI-5, why is the reference data in Table VI-7 different from reference data in Table VI-5?

**Page 142 Section VI.D.1.c. Results and discussion**

38. In order to increase precision of the test results, need to combine data over all 4 locations and provide the statistical analysis. In addition, since the data presented in this table appears to have been obtained from the same test that was the source of the data in Table VI-5, it would be

best that all data for the single events and paired events be included in the same statistical analysis.

**Pages 142, 143 Section VI.D.1.d. Fall growth habit, Tables VI-8,9**

39. Need statistical analysis to help determine if trends exist. It would be best that all data for the single events and paired events be included in the same statistical analysis.

**Pages 148-152 Section VI.D.2.c. Results and discussion, Tables VI-11,12**

40. Need combined statistical analysis over locations and years to help determine if any trends exist.

**Pages 162 Section VI.E. Reproductive Characteristics**

41. Why no data on stacked event? Since both events are critical for the commercialization of this product, data need to be submitted for the stacked event.

**Pages 163, 165, 167 Section VI.E.1.b. Results and discussion**

42. Barnes, 1972. No such citation in References

**Page 168 Figure VI-9**

43. "Afalfa Fower" spelling.

**Pages 179 Table VI-21**

44. Statistical analyses needed for data in Table VI-21.

**Pages 185 Section VI.F. Seed Yield**

45. "variables could more highly controlled" One or more words missing.

**Pages 189 Section VI.F.2.a. Test, control and reference populations**

46. "comprised of four conventional . . . varieties (DK134 and Sutter)" Please list the other two varieties.

**Page 192 Section VI.F.3.a. Test and control/reference materials**

43. "plants were identifie" spelling.

44. "63 Syn 0", "93 control subpopulations", "93 Syn 0 subpopulations", "93 Syn 1". Are all of these numbers correct?

**Pages 193 Table VI-24**

45. Please explain why the seed yield so low for Control Set 3?

**Page 193, 194 Section VI.G. Field Testing and USDA-APHIS Reports**

46. "endemic diseases", "diseases that are endemic", and "insects that are endemic". "typical" is probably a better choice of words than "endemic".

**Pages 198 Table VI-25**

47. Please change the USDA Notification numbers "03-346-15n, 03-346-17n, 03-346-18n" to correspond to USDA-APHIS permanent record numbers "02-346-15n, 02-346-17n, 02-346-18n"

**Pages 219 Table VI-26**

47. "Analyte (% DW<sup>1</sup>)" no footnote 1 shown for DW

**Page 225 VII.B.1. Overview**

48. "Minor amount used for . . . sprouting purposes. Alfalfa seed is not used directly as a food or feed product." Please clarify this apparent contradiction.

**Page 227-228 VII.B.3. Establishment of Alfalfa for Seed Production, B.5. Alfalfa Seed Production**

49. Page 227 "average stand-life is approximately 5 years"

Page 228 "stand-life of a seed field is two to four years"

Please clarify apparent contradiction.

**Page 232 VII.B.8.ii. North Central Region (Northern Corn and Dairy Belt)**

50. Mustard (*Brassica* spp.) is listed as a weed in alfalfa. Since Roundup Ready canola has already been deregulated and since canola is sexually compatible with most *Brassica* spp. with some glyphosate resistant *Brassica* spp. plants having been reported in North America, will the general release of Roundup Ready alfalfa accentuate and accelerate the development of glyphosate tolerant weedy *Brassica* spp.?

**Page 234 VII.C. Impact of Weeds in Alfalfa Forage and Seed Production**

51. "In a nation-wide survey, 81 species" Please provide a reference for this survey.

**Page 236 VII.D. Agronomic and Economic Impact of Roundup Ready Alfalfa**

52. "[Delete or move the previous two sentences to another part of the document – they don't fit here.]" An apparent editorial comment that is not suitable for this document. Please provide appropriate remedy.

**Page 237 VII.D.1. Current Herbicide Options for Seedling Establishment of Alfalfa**

53. "*Solanum pythanthum*", "*Polygonum pennsylvanicum*" Please correct these misspellings.

**Page 239 VII.D.2. Impact of Roundup Ready Alfalfa on Seedling Establishment Practices**

54. "For those growers who seed alfalfa following winter wheat (*Triticum aestivum* L.) harvest, volunteer wheat is often the most serious weed present." Since APHIS has received a petition to deregulate Roundup Ready wheat, will glyphosate resistant wheat volunteers become a major problem in Roundup Ready alfalfa? If so, how do you plan to mitigate this potential problem.

**Page 240 VII.D.2. Impact of Roundup Ready Alfalfa on Seedling Establishment Practices**

55. Annual bluegrass is noted as a problem grassy weed in alfalfa. Annual bluegrass is a serious grassy weed for creeping bentgrass as well. Roundup Ready Creeping bentgrass has been petitioned to be deregulated by APHIS as well. Explain why the release of both Roundup Ready

alfalfa and Roundup Ready creeping bentgrass should not be a future major problem in the development of glyphosate resistant *Poa annua*.

**Page 241 Table VII-3**

56. Goosegrass is noted as an annual weed of alfalfa. Since glyphosate tolerant goosegrass plants have been noted in the USA and in Asia, explain why the release of Roundup Ready alfalfa should not accelerate the development of glyphosate resistant goosegrass as a serious weed for all Roundup Ready crops.

57. "*Ehuesine indica*" Please correct spelling.

**Page 245 Table VII-5**

58. "*Letuca serriola*" Please correct spelling.

**Page 246 Table VII-5**

59. Italian ryegrass (*Lolium multiflorum*) and ryegrasses (*Lolium* L. spp.) are noted as winter annual weeds in alfalfa. Since glyphosate tolerant *Lolium* spp. plants have been noted in the USA and in Australia, explain why the release of Roundup Ready alfalfa should not accelerate the development of glyphosate resistant *Lolium* spp. as a serious weed for all Roundup Ready crops.

**Page 247 VII.D.2. Impact of Roundup Ready Alfalfa on Seedling Establishment Practices**

60. "Roundup Ready soybean varieties have increased the number of acres established using no-till seeding methods" A reference needs to be cited.

61. "[reference]" Appears it should be deleted.

62. "(Doll, 2000)" No such citation listed in References

**Page 249 VII.D.4. Impact of Roundup Ready Alfalfa on Established Stands**

63. "Roundup Ready technology will allow producers to treat and target weed problems as they arise during any point in the growing season." Does this imply repeated applications each year over multiple years and how does this repeated use of glyphosate affect the selection for glyphosate tolerant weeds?

**Page 250 VII.D.4. Impact of Roundup Ready Alfalfa on Established Stands**

64. "(Doll, 2003)" No such citation listed in References

**Page 252 VII.D.6. Impact of Roundup Ready Alfalfa on Herbicide Use in Alfalfa**

65. "[all of the other herbicide rates are in ai; maybe we should change the glyphosate from ae to ai.]" An apparent editorial comment that is not suitable for this document. Please provide appropriate remedy.

66. "research conducted by Monsanto has shown that once Roundup Ready alfalfa stands are established, they remain relatively weed free." Need to present data to document this. How can

there be data to document this when the fields are expected to be around 5+ years and Roundup Ready alfalfa testing was only started in 1999 with only a few plants?

**Page 253 VII.E. Gene Flow**

67. "There are no weedy relatives of alfalfa occurring in North America" Does not agree with previous information on *M. lupulina*. All parts of this petition that provide contradictory information must explain in detail the reasons for these contradictions.

**Page 255 VII.E.2. Gene Flow During Commercial Seed Production**

68. "Information obtained from these studies confirms that the spatial isolation distances already utilized by the alfalfa industry are an effective means to maintain the purity of both conventional and Roundup Ready alfalfa varieties. This information will be provided to alfalfa seed producers and members of the alfalfa seed industry community so that they can determine appropriate isolation distances needed to meet the varietal purity requirements of different seed markets." These two statements made in the same paragraph appear contradictory. More explanation needed.

**Page 258 VII.E.5. Six State Survey of Feral Alfalfa Populations**

69. "(USDA-APHIS 2000, USDA-APHIS 2002, USDA-NRCS 2003, USDA-ARS 2003)" No such citations listed in References.

**Page 265 Table VII-9**

70. "CRP Areas" – Do not use abbreviation without explanation.

71. "*Limnonthes*" – Correct spelling needed.

**Page 266 Table VII-9**

72. "Potatoes (*Solanum tuberosum* L.O)" - Correct punctuation needed.

73. "*Tritium*" – Correct spelling needed in four places

**Page 270 VII.F.4. Impact of Roundup Ready Alfalfa on Current Crop Rotation Practices**

74. "USDA-NASS, 2003" – No such citation in References

75. "(Table VI-13)" was noted several times. Should it be "(Table VII-13)"?

**Page 276 VII.F.6. Control Options for Feral Alfalfa**

76. "... control emphasis will change to aggressive alfalfa stand termination ..." – Please elaborate on the type aggressive measures that might be used.

**Page 276 VII.F.7. Management of Gene Flow During Alfalfa Seed and Forage Production**

77. "Forage growers will not be allowed to produce "catch crop" seed." – Please define the term "catch crop". This statement sounds good, but follow through is very difficult, especially once all proprietary rights are expired within 20 years. Explain what will probably happen in the worst case scenario if these suggested procedures are not followed.

**Page 277 VII.F.8. Technical Support**

78. "If feral alfalfa containing the Roundup Ready trait were to create a management challenge in any of these markets, local Monsanto field scientists will assist in developing practices tailored to address the specific circumstances." This statement relies on the goodwill of Monsanto to do the "right thing". Once proprietary rights expire within 20 years, there is no economic incentive for Monsanto or any other commercial institution to do the "right thing". Under that situation, the corrective action, if any is required, falls on the shoulders of the US Government or state government. Explain in detail how Monsanto can be held accountable in the long term.

**Page 278 VII.G. Weed Resistance**

79. "Weed scientists consider the risk of weeds developing resistance to glyphosate as low." Why? Provide references and additional information.

**Page 280 References**

80. Acharya et al – Volume number needed

**Page 284 References**

81. "Little and Hills" Is the Title information stated correctly?

82. "McCloskey" Is this citation stated incorrectly?

**Page 290 Appendix 1 Introduction and Statement of Purpose**

83. "Padgett et al., 1996" – no citation in Literature Cited for Padgett for 1996

**Page 296 Appendix 1 Conclusion**

84. "... greater than nine generations of crossing." The petition appears to describe fewer than nine generations? Please provide information to justify using this number.

**Page 297 Appendix 1 Literature Cited**

85. Padgett et al. – no year and no blank line following citation.

86. Quiros and Bauchan– no blank line before this citation and slightly different from what appears to be a repeat immediately following this citation. Please correct.

**Page 309 Appendix 2 B. Characteristics Related to Resistance**

87. "Today . . . Heap, 2002" Appears contradictory since today more information is available. Please update the information.

**Page 311 Appendix 2 Figure 1**

88. Figure 1 needs to be updated, after all this petition was submitted in 2003, not 2000 – maybe an even more pertinent graph would show the date of introduction of each herbicide class in relation to the development of resistant weeds.

**Page 312 Appendix 2 C. Weeds Resistant to Glyphosate**

JANUARY 2004

89. "four weed species resistant to glyphosate" Should be five weeds according to Heap. Please provide information on the fifth weed.

90. "Elusine" Please correct spelling.

**Page 316 Appendix 2 References**

91. It would be helpful if all references are in alphabetic order.

92. The petition was reviewed to determine whether it contained all of the appropriate information for environmental assessments as noted in Appendix II: Environmental Characterization Data for Transgenic Plants Intended for Unconfined Release. One area that was not covered in this petition was "Symbionts". Since alfalfa is generally regarded as a nitrogen fixing species because of its close symbiotic relationship with *Rhizobia* bacteria, information must be supplied on the effect of this transgenic event on the symbiotic relationship.

Please contact us if you need to discuss further the status of these petition submissions or any questions you may have about the content of this letter.

Sincerely,

Virgil Meier  
Biotechnologist Reviewing 03-127-01p  
APHIS, Biotechnology Regulatory Service

AR193<sup>101</sup>

Virgil D Meier  
01/21/2004 07:27 AM

To: <glennon.j.rogan@monsanto.com>@INTER2@gw  
cc: raymond.c.dobert@monsanto.com, sfitzpatrick@foragegenetics.com,  
sheila.a.schuette@monsanto.com  
Subject: Re: Draft questions for Roundup Ready alfalfa

Glen,  
Just wanted to let you know that I received your input. We would like to get a letter to you soon.

Virgil  
<glennon.j.rogan@monsanto.com>



<glennon.j.rogan@monsanto.com>  
01/15/2004 03:57 PM

To: Virgil D Meier/MD/APHIS/USDA@USDA  
cc: sfitzpatrick@foragegenetics.com@INTER2@gw,  
sheila.a.schuette@monsanto.com@INTER2@gw,  
raymond.c.dobert@monsanto.com@INTER2@gw  
Subject: Draft questions for Roundup Ready alfalfa

Virgil,

Please find attached suggested wording on a sub-set of the draft questions.

Note that we have no concerns with the wording for the rest of the questions included in the draft list received from you and Carmen Soileau.

I look forward to working with you to get a final list of questions and to work through the process for withdrawal and re-submission of the petition for Roundup Ready alfalfa.

Best Regards,

Glen Rogan  
Regulatory Affairs Manager  
Roundup Ready Alfalfa

<<Roundup Ready alfalfa USDA questions.fn1.doc>>

AR1932





Roundup Ready alfalfa USDA questions.fnl.doc

AR1933

Roundup Ready Alfalfa Agronomic issues only

Page Number	Original question posed by USDA with suggested re-wording or clarification below in italics
24	'putative hybrids with <i>M. lupulina</i> '. Since <i>M. lupulina</i> is a weed in the US, information needs to be provided on its hybridization with RR alfalfa.
24	<i>'putative hybrids with M. lupulina'. Since M. lupulina is a weed in the US, information needs to be provided on its possible natural hybridization with alfalfa.</i>
115	Last paragraph, both years RR seed substantially more dormant than checks; at least one more year worth of data required to help decide if dormancy is an issue.
115	<i>We believe that data from the two experiments were mis-interpreted. First year seed (Table VI-2 and Table VI-3) showed significantly higher dormancy for plants containing the Roundup Ready alfalfa events. Second year seed (Table VI-4) showed significantly lower dormancy. Please review these data to determine whether this question still needs to be asked.</i>
127	D. Please provide date of trial establishment, whether seeded or transplanted, age or size of transplants, date of each observation, and date of end of trial for the field trials. D.1. Only 1 year of data provided, whereas at least two years of data are needed
127	<i>It was our understanding that the agency would discuss this question internally and determine whether there were sufficient data in the petition to address the need for multiple years of data. Multiple years of phenotypic data were provided in the second and third study. Suggested re-wording of question: D.1. Only 1 year of data provided, multiple years of data for alfalfa would strengthen the petition.</i>
123	C.2.a. Confirmatory data for the paired event population were not generated because of a lack of appropriate test and control seed. Please provide additional detail.
123	<i>It is our understanding that APHIS does not regulate events combined by traditional breeding. Therefore, it would not be appropriate to request data for the paired events. Preferred re-wording would be: Confirmatory seed dormancy data on commercial breeding populations would strengthen the petition.</i>
128	Center paragraph. Null individuals were left in tested populations (around 50%). We agree that this will reduce precision of the test. Considering that commercial seed would have null individuals as well, but at a rate less than 10%, the tests need to be conducted with "commercial type" seed or need to take out null individuals in tested populations
128	<i>We believe that APHIS has mis-interpreted event purity for the test populations used in this experiment. Suggested reword: Please clarify event purity for each of the test populations used in this experiment.</i>
162	E. Why no data on stacked event? Since both events are critical for the commercialization of this product, data need to be submitted for the stacked event
162	<i>It is our understanding that APHIS does not regulate "stacked" products produced through conventional breeding. The focus of the determination should be on single events. Suggest that the question is removed or rephrased to request additional information on the paired event population.</i>
220	Why does the stacked event have more significant differences?
220	<i>It is our understanding that APHIS does not regulate "stacked" products produced through conventional breeding. The focus of the determination should be on single events. Same comment as 162 above.</i>

Roundup Ready Alfalfa Agronomic issues only

232	Sentence before B.8.iii: mustard ( <i>Brassica</i> spp.) listed as a weed in alfalfa. Will this lead to a problem of RR mustard in RR alfalfa.
232	<i>Sentence before B.8.iii: mustard (Brassica spp.) listed as a weed in alfalfa. Will the introduction of the Roundup Ready alfalfa weed control system lead to glyphosate tolerant mustard in Roundup Ready alfalfa?</i>
239	Volunteer wheat is a serious weed in alfalfa. What will be the effect of RR wheat in RR alfalfa?
239	<i>It was our understanding from discussions with USDA that the crop rotation data submitted to USDA would be re-reviewed to determine whether the information submitted was adequate to address this question. Crop rotation data for wheat were provided (see Section F.4., pages 270-271 and Table VII-13, page 272-274 and the topic of glyphosate tolerant weeds was specifically addressed in Section G, page 277 and in Appendix 2). If this information is not sufficient, suggested rewording is: "Volunteer wheat may be the most serious weed in newly-established, fall seeded alfalfa planted following winter wheat. What will be the effect of RR wheat in RR alfalfa?". This rewording is suggested because the statement to which APHIS refers to on page 239 regarding wheat as a serious weed in alfalfa is specific to the case of ... "late season establishment...for growers who seed alfalfa following winter wheat..." so the question should be more narrowly focused.</i>
240	Annual bluegrass is a serious weed in creeping bentgrass as well. Explain why the release of both RR alfalfa and RR bentgrass should not be a major future problem in the development of Roundup resistant <i>Poa annua</i> .
240	<i>Annual bluegrass is listed as a weed in alfalfa. Will the introduction of the Roundup Ready alfalfa weed control system lead to glyphosate tolerant Poa annua in Roundup Ready alfalfa?</i>
241	Goosegrass resistant to Roundup populations already exist. Explain how the release of RR alfalfa will not cause additional problems.
241	<i>The issue of glyphosate tolerant goosegrass was addressed in Appendix 2, Section C., page 312-313, with stewardship actions proposed on page 314. If APHIS needs additional information the following rewording of the question is proposed: "Goosegrass populations tolerant to glyphosate already exists. Please address the impact of the Roundup Ready weed control system on glyphosate tolerant goosegrass".</i>
245	Mustards: RR canola already exist. Explain how the release of RR alfalfa will not cause additional problems in the mustards.
245	<i>It is not clear from the question whether this deals with gene flow from Roundup Ready canola to other related relatives of canola, volunteer canola or Roundup Ready canola in Roundup Ready alfalfa fields or gene flow from alfalfa to the mustard family. We request that USDA rephrase the question.</i>

246	Lolium RR plants already exist. Explain how the release of RR alfalfa will not cause additional problems in Lolium.
246	<i>The issue of glyphosate tolerant Lolium (ryegrass) was addressed in Appendix 2, Section C., page 312, with stewardship actions proposed on page 314 and some discussion of ryegrass tolerance at the bottom of page 311. Additional stewardship discussions and issues related to weed resistance appear in VII Section G., page 277-278 and in Appendix 2. If APHIS needs additional information the following rewording of the question is proposed: "Lolium populations tolerant to glyphosate already exist. Please address the impact of the Roundup Ready weed control system on glyphosate tolerant Lolium".</i>
259	F.1. Reference to rotations with wheat, sugar beet, corn, soybeans, cotton. All have RR versions that have nonregulated status (or it has been requested). Need more detail on RR alfalfa in rotations with these crops.
259	<i>It was our understanding from discussions with USDA that the crop rotation data submitted to USDA would be re-reviewed to determine whether the information submitted was adequate to address this question. Crop rotation data by region and potential acres impacted for all Roundup Ready crops were provided (see Section F.4., pages 270-271 and Table VII-13, page 272-274).</i>
261	Popcorn could also be RR. See above comment for page 259
261	<i>Same as 259 above.</i>
271	Sentence just above F.5: "...largely dependent upon diligent alfalfa stand takeout..." 1 <sup>st</sup> bullet under F.5: "Diligent stand take-out" 2 <sup>nd</sup> bullet under Plan for success Please expand on you explanations. The suggested procedures probably will not be followed many times. Explain what will happen in the worst case scenario if these suggested procedures are not followed.
271	<i>In the event that a grower is not successful in taking out a Roundup Ready alfalfa stand, please provide additional information on the recommendations that may be provided to the grower.</i>
276	Last sentence at bottom of page about "catch crop" seed will not be allowed - This statement sounds good, but follow through is very difficult, especially once all of the proprietary rights are expired within 20 years. Explain what will happen in the worst case scenario if these suggested procedures are not followed.
276	<i>Last sentence at bottom of page about "catch crop" seed - Please elaborate on information that has been developed that could be shared with the alfalfa seed and forage growing community regarding appropriate stewardship of the Roundup Ready alfalfa weed control system.</i>
277	F.8. Technical Support – This whole section relies on the goodwill of Monsanto to do the "right thing". Once proprietary rights expire within 20 years, there is no economic incentive for Monsanto or any other commercial institution to do the "right thing". Under that situation, the corrective action falls on the shoulders of the US government or state government. Explain how Monsanto can be held accountable in the long term.
277	<i>F.8. Technical Support - Please provide additional information in this section describing on-going product support efforts that have/will be established to support crops improved through the use of biotechnology.</i>

Roundup Ready Alfalfa Agronomic issues only

291	Top of page: "With alfalfa-lupulina hybrids appearing doubtful....
291	<i>It is our understanding from discussions with USDA that literature data along with expert testimony would be sufficient to address this question. Suggested re-wording: We request additional information on the potential natural hybridization between Medicago sativa and Medicago lupulina</i>
295	What is the level of RR protein in the dual event plant? Will that cause a problem?
295	<i>This information was provided in the petition (see page 99 for data and, page 20 for information on EPA's establishment of an exemption from the requirement for tolerance for the CP4 EPSPS protein in raw agricultural commodities ). We request the question be removed from the list.</i>

Draft Document

Virgil D Meier  
02/09/2004 09:16 AM

To: James L. White/MD/APHIS/USDA@USDA, Levis W  
Handley/MD/APHIS/USDA@USDA, Lena C  
Soileau/MD/APHIS/USDA@USDA, bmacbryde@netscape.net  
cc:  
Subject: Call-in number for this mornings phone conference

This is a reminder for the conference call on the Monsanto alfalfa petition at 11 am today in Jim's office.

Virgil

----- Forwarded by Virgil D Meier/MD/APHIS/USDA on 02/09/2004 09:11 AM -----



<glennon.j.rogan@monsanto.com>  
02/09/2004 09:00 AM

To: Virgil D Meier/MD/APHIS/USDA@USDA  
cc: sfitzpatrick@foragegenetics.com@INTER2@gw  
Subject: Call-in number for this mornings phone conference

Virgil,

You can use the following number:

888-390-3405 / 16051# passcode

Looking forward to discussing the questions with you at 11 am EST.

Best regards,

Glen

-----Original Message-----

From: Virgil D Meier [mailto:Virgil.D.Meier@usda.gov]  
Sent: Monday, February 09, 2004 5:37 AM  
To: glennon.j.rogan@monsanto.com  
Subject: RE: Draft questions for Roundup Ready alfalfa

Glen,

Just a reminder, what number do we call for our 11 am (EST) conference call? Bruce MacBryde will be calling from a different phone than the rest of the APHIS review team.  
Virgil

<glennon.j.rogan@monsanto.com>  
02/05/2004 02:37 PM

To: Virgil D Meier/MD/APHIS/USDA@USDA  
cc:  
Subject: RE: Draft questions for Roundup Ready alfalfa

Virgil,

Thanks,

I will review and get back to you. Our server was out yesterday, so, I am just now receiving this.

Best regards,

AR1959

Glen

-----Original Message-----

From: Virgil D Meier [mailto:Virgil.D.Meier@usda.gov]

Sent: Wednesday, February 04, 2004 8:59 AM

To: glennon.j.rogan@monsanto.com

Cc:

/S=raymond.c.dobert@monsanto.com/OU=APHISNOTES/O=APHIS/P=GOV+USDA/A=ATTM  
AIL/C=US/; sfitzpatrick@foragegenetics.com%aphisn1;

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MAIL/C=US/; James.L.White2@usda.gov; Bruce.Macbryde@usda.gov;

Lena.C.Soileau@usda.gov; Levis.W.Handley@usda.gov;

Shirley.P.Ingebritsen@usda.gov

Subject: Re: Draft questions for Roundup Ready alfalfa

Glen,

After reviewing some of your concerns on the draft letter for completeness, we are to ready to send the official version.

As we agreed earlier, I am attaching a draft of the final letter. I would like to send out the official letter late this week or early next week. If you have any concerns, please let me know as soon as possible.

Virgil Meier, Ph.D.

USDA Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road Unit 147 5B45

Riverdale, MD 20737

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virgil.d.meier@aphis.usda.gov

www.aphis.usda.gov/brs

AR1960

alfalfa update

Virgil,

We would be willing to provide you with a soft copy of the petition provided that it is used for review and other purposes within the USDA only and not distributed outside of your organization. It would also not be allowed to be posted as a word file on the website.

We are also willing to help draft the initial version of the EA. Can we meet to discuss assistance with the EA? I request that we have your boss involved because this is precedent setting.

Finally, I heard that you had accepted a new position within USDA. Is this true and if so, congratulations! Will you be able to finish the EA for RR alfalfa or will it be assigned to someone else.

Best Regards,

Glen

-----Original Message-----

From: Virgil D Meier [mailto:Virgil.D.Meier@usda.gov]  
Sent: Monday, May 17, 2004 1:07 PM  
To: glennon.j.rogan@monsanto.com  
Cc: sfitzpatrick@foragegenetics.com%aphisn1  
Subject: Re: Roundup Ready alfalfa update

Glen,

I have to admit that we have not yet had a chance to review the new parts.

I'm the one that will supposedly write the EA since I am the lead on this petition. If you are willing to provide assistance with the EA, I would appreciate it. At this time, no one has voiced a concern with this so I am assuming that there is no problem. In a related manner, because I am supposed to write the EA, I would appreciate receiving an electronic copy of the petition (Word?) so I can do cut and paste which I think will speed the completion of the EA. Do you have a problem with either request?

Virgil Meier, Ph.D.  
USDA Animal and Plant Health Inspection Service  
Biotechnology Regulatory Services  
4700 River Road Unit 147 5B45  
Riverdale, MD 20737

Tel. 301-734-3363  
Fax 301-734-8669  
virgil.d.meier@aphis.usda.gov  
www.aphis.usda.gov/brs

<glennon.j.rogan@monsanto.com>  
05/17/2004 09:41 AM

AR2371



To: Virgil D Meier/MD/APHIS/USDA@USDA  
cc: sfitzpatrick@foragegenetics.com@INTER2@gw  
Subject: Roundup Ready alfalfa update

Virgil,

Hope all is well with you. I thought I would send you a note to follow up on our conversation regarding petition number 04-110-01p.

During our discussion, Bruce McBride had mentioned the possibility of the applicant providing assistance with the EA. I had assumed that you would be following up with your group to determine whether there was internal support for this. Have you discussed this idea further?

I would also like to know whether you have had a chance to review the new parts of the petition and if so, does the new information adequately address your concerns.

Should you have any questions on the petition or the EA, FGI and Monsanto would be readily available to meet with you and your team at any time that is convenient for the agency.

Best regards,

Glen

Document was scanned by USDA-APHIS Antivirus

AR2372