UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

24-August-1998

MEMORANDUM

Subject: PP# 2E04118 (formerly 2H05650) - Glyphosate tolerances on Imported Barley Grain, Barley Bran and Pearled Barley, Legume Vegetables (succulent and dried) Group (excluding soybeans), Canola Seed and Canola Meal. **Amendment of 9/29/93**
MRIDs: 438072-01 to -03, 438278-01 to -02 and 43845401
DP Barcodes: D221254, D221255 703-305-6017
Chemical #: 103601
Case #s: 284029, 283637
Submission #s: S497423, S497424

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Monsanto Company proposes to establish the following import tolerances for residues of the herbicide glyphosate (N-phosphonomethyl glycine) resulting from the preharvest application of the isopropylamine salt and/or the monoammonium salt of glyphosate.

Table 1: Proposed Import Tolerances

commodity	tolerance (ppm)
barley grain	20
barley bran and pearled barley	60
*grain crops (except wheat, corn, oats, grain sorghum, and barley)	0.1
canola seed	10
canola meal	25
legume vegetables (succulent & dried) group (except soybeans)	5

*Present tolerances are for "grain crops (except wheat, corn, oats and grain sorghum)" at 0.1ppm. This proposal is to add "except barley" to the above statement and to change the group to be consistent with EPA's proposal in 61FR:3349-33474.

This petition was supported by the following data (submitted 1-May-1992).

MRID 42312801, *Glyphosate residues in Roundup® Herbicide PreHarvest-Treated Cereals, Rapeseed, Beans, Peas, Grass, Hay and Silage, European Field Trials 1978-1984, Part A*

MRID 42312802, *Glyphosate Residues in Roundup® Herbicide Preharvest treated Cereals, Rapeseed, Beans, Peas, Grass, Hay and Silage, European Field Trials 1978-1984, Part B*

MRID 42312803, *Residue Analysis for Glyphosate and AMPA in Brassica Seedcrops and Processed Fractions Following Preharvest Roundup® Herbicide Treatments*

MRID 42312804, *Glyphosate and AMPA Residues in Canadian Field Peas and Lentils Following Preharvest Applications of Roundup Herbicide*

These studies were reviewed and a memo written identifying deficiencies (memo, D. Davis, 29-Sept-93). Monsanto submitted the following data to address these deficiencies (27-Sept-95).

MRID 43807201, *Glyphosate Residues in Peas Following Preharvest Application with Roundup Herbicide in Denmark and Belgium*

MRID 43807202, *Addendum to MSL-9458: Glyphosate Residues in Canadian Barley Grain and Straw Following Preharvest Application of Roundup® Herbicide*

MRID 43807203, *Glyphosate Residues in Canadian Canola Raw Agricultural Commodities and Processed Canola Fractions*

MRID 43827801, *Residues of Glyphosate/AMPA in Winter Oilseed Rape Following Applications of MON 52276, MON 44068, and Roundup® Herbicide Two Weeks Before Harvest. UK Field Trials 1992*

MRID 43827802, *Glyphosate Residues in Cereal Grain and Straw Following Preharvest Treatment with Roundup® Herbicide in the United Kingdom: 1982 Trials–Part 1*

MRID 43845401, *Glyphosate and AMPA Residues in Wheat and Barley Following Application of MON 52276, MON 44069 and Roundup® Herbicide One Week Before Crop Harvest: French Trials 1991*

The following document addresses Monsanto's response to HED's previous memo (memo, D. Davis, 29-Sept-93).

Executive Summary of Chemistry Deficiencies

- A revised Section F is required (conclusions 5 and 6).

Recommendations

Provided Section F is revised as specified in Conclusions 5 and 6, RAB1 concludes there are no residue chemistry data requirements that would preclude the establishment of the following permanent import tolerances for glyphosate; 20 ppm barley grain, 30 ppm barley bran, 0.1 ppm cereal grain groups (except wheat, corn, oats, grain sorghum, and barley), 10 ppm canola seed, 15 ppm canola meal and 5 ppm legume vegetables (succulent & dried) group (excluding soybeans). A human-health risk assessment will be prepared as a separate document.

Conclusions

1. The petitioner has indicated that the technical products used in Canada and most of those used in Europe are the same as the technical products registered in the US. The petitioner has indicated that the European application of glyphosate will involve two products not registered by the EPA, MON 52276 and MON 44068. The difference between these formulations and US registered products are the inert ingredients. The inert ingredients identified in these formulations are not List 1 or 2 compounds (see Deficiency-Conclusions 1b and 1d for further information).

2. The petitioner has provided a complete listing of all countries in which glyphosate will be applied to barley, rape, peas and lentils. Information regarding application rate, application frequency, time of application and PHI has also been submitted. The petitioner has provided copies of foreign labels with english translations of application rate, application timing and PHI (see Deficiency-Conclusion 2 for further information).

3. MRIDs 423128-01 & -02 summarized field trials conducted in Europe for the determination of glyphosate residues in/on barley grain and straw following preharvest application. This information was reviewed (memo, D. Davis, 29-Sept-93) and found to be lacking detailed information allowing the reviewer to assess the field and analytical procedures. The petitioner submitted MRID 43827802, which presented additional information concerning field, sampling and quantitative procedures for the UK portion of MRIDs 423128-01 & -02. Additional field data for barley grain and straw, can be found in MRID 43807202 and 43845401. These studies, conducted in Canada and France respectively, pertain to glyphosate residues in/on barley grain and straw following preharvest treatment.

The residue data generated and presented in MRID 423128-01 & -02 will now be considered valid for the following reasons, **(1)** the assumption that the field and analytical procedures presented in MRID 43827802 are representative of the procedures performed in the remainder of the European field trials, **(2)** the similar glyphosate residues generated in/on barley grain and straw for all studies, **(3)** confirmation that the analytical method used was US PAM Vol. II method I and **(4)** the study was conducted pre-GLP and the type of detailed information required under this regulation was not typically included in reports. HED concludes that the proposed import tolerance of 20 ppm on barley grain, as a result of the preharvest application of Roundup® as defined in this petition, is appropriate. HED also accepts the addition of "except barley" to the grain crops group for glyphosate (see Deficiency-Conclusion 7a for further information).

4. MRID 42312802 summarized field trials conducted in Europe for the determination of glyphosate residues in/on dried peas following preharvest application. This information was reviewed (memo, D. Davis, 29-Sept-93) and found to be lacking in detailed information allowing the reviewer to assess the field and analytical procedures. Since that time, the Agency has recommended increasing the tolerance on legume vegetables (except soybeans) to 5 ppm to harmonize with Codex MRLs (Glyphosate RED, September 1993). HED concludes that the proposed import tolerance of 5 ppm on legume vegetables group (except soybeans) is appropriate (see Deficiency-Conclusion 7b for further information).

5. MRID 42312803 summarized field trials conducted in Europe for the determination of glyphosate residues in/on canola seed and processed fractions following preharvest application. This information was reviewed (memo, D. Davis, 29-Sept-93) and found to be lacking detailed information allowing the reviewer to assess the field, processing and analytical procedures. The information needed to adequately assess MRID 42312803 is no longer available. In response the petitioner submitted a second study, MRID 43827801, which presented glyphosate residues in/on canola seed from field trials conducted in UK, 1992. This study reported all necessary field, sampling and analytical procedures necessary for validation. The residue data from MRID 42312803 will now be considered valid for the following reasons, **(1)** the similarity in the canola seed glyphosate residue data for MRIDs 42312803 and 43827801, **(2)** confirmation that the analytical method used was the US PAM Vol. II method I and **(3)** the study was conducted pre-GLP and the type of detailed information required under this regulation was not normally included in reports. MRID 42312803 demonstrates that glyphosate does not concentrate in canola crude or refined oil. The average glyphosate concentration factor for canola meal calculated from MRID 42312803 was 2.5. The maximum theoretical concentration factor for canola meal is 1.9. Using the theoretical concentration factor and the single highest glyphosate residue for canola seed of 6.3 ppm (Finland, 1981), HED concludes that an import tolerance of 15 ppm for canola meal and 10 ppm for canola seed, as a result of the preharvest application of Roundup® as defined in the petition, is appropriate. A revised Section F is required (see Deficiency-Conclusions 7c and 7e for further information).

agrees with proposed 11/30/98

6. The 3X processing concentration factor for barley milling fractions was derived from a wheat processing study (MRID 00150835) in which glyphosate and AMPA residues were combined. The Agency no longer considers AMPA of toxicological significance and it is no longer included in the tolerance expression for glyphosate. The average glyphosate concentration factor for wheat bran calculated from MRID 00150835 was 2.15. Using this average wheat bran concentration factor and the single highest glyphosate residue for barley grain of 14.0 ppm (UK, 1980), HED concludes that an import tolerance of 30 ppm on barley bran, as a result of the preharvest application of Roundup® as defined in this petition, is appropriate. As concentration in pearled barley is not expected, a tolerance on this commodity is not required. A revised Section F is required (see Deficiency-Conclusion 7f for further information).

7. The maximum glyphosate residue level in/on cereal straw was 210 ppm. This, combined with the tolerances on legume vegetables group (excluding soybeans), canola meal and barley grain, will not significantly increase the dietary burden on foreign animals as compared to the dietary burden of US animals resulting from registered domestic uses of glyphosate (see Deficiency-Conclusions 8a and 8b for further information).

Detailed Considerations

Deficiency - Conclusions 1b & 1d (memo D178843, D Davis 9/29/93)

1b. The petitioner is requested to verify that the technical products intended for foreign use are the same as the technicals used in this country. Provided, the same technicals are used for both domestic and foreign glyphosate formulation, no additional product chemistry data will be required to support this petition. However, should technical products which have not been reviewed by EPA be used in the production of foreign formulations, CBTS will require product chemistry data for those technical grade active ingredients.

1d. The isopropylamine salt of glyphosate is formulated into a soluble concentrate containing 480 g/liter (356 g acid equivalent (ae)/liter). The formulated product is known as MON-2139 Herbicide (EPA Reg. No. 524-308) and is manufactured by Monsanto Agricultural Company. Determination as to whether the inert ingredients in this formulation are cleared is under the purview of RD. The petitioner is requested to verify that foreign application of glyphosate will be restricted to use of EPA registered formulations. Should the petitioner intend to allow

application of formulations not registered in the U.S., CBTS will require information on the identity of the inerts in the unregistered end use products to verify that residues of concern will not result.

Petitioner's Response:

The glyphosate herbicide products sold in Canada for preharvest use on barley, canola, peas and lentils are registered in the US under the EPA Reg No 524-308, 524-424, 524-441, 524-442 and 524-477. Glyphosate herbicide products sold in Europe for preharvest use on barley, canola, peas and lentils under the brand name Roundup® Herbicide is identical to Roundup® Export Herbicide, EPA Reg. No.524-308. Two additional formulations of glyphosate are sold in Europe, MON 52276 and MON 44068, under a variety of brand names. All glyphosate technical products and manufacturer products produced by Monsanto around the world adhere to the exact same specifications. The certified limits for the active ingredient and all impurities are provided in the Confidential Statements of Formula, which have been submitted to the Agency to support the registrations of glyphosate (EPA Reg No.524-420), glyphosate Technical (EPA Reg No. 524-421), and the glyphosate isopropylamine Salt Technical Solution MON 0139, 62% (EPA Reg. No. 524-333). The difference between the two European formulations (MON 52276 & MON 44068) and US registered products are the inert ingredients.

HED's Conclusions:

The inert ingredients in the two European formulations are not List 1 or 2 compounds. The requested information has been provided and these deficiencies resolved.

Deficiency - Conclusion 2 (memo D178843, D Davis 9/29/93)

2. The description of proposed uses for glyphosate submitted with this petition is not sufficient to allow the Agency to adequately assess foreign glyphosate use impacting US imported commodities. The petitioner is requested to submit an amended Section II (Amount, Frequency and Time of Application) which provides a complete listing of all countries in which glyphosate will be applied to barley, rape, peas and lentils as well as current detailed information regarding specific rates and application instructions for all foreign uses of glyphosate. The petitioner should provide copies of all pertinent foreign labels with English translations as required.

Petitioner's Response:

A tabular summary of all countries where preharvest use of glyphosate on barley, rape, peas and lentils is presented in Tables 2 - 5. Only a single preharvest application is allowed in all cases. In addition, recent copies of representative foreign labels are presented, along with English translations of application rates and timing. A preharvest use in Sweden for oilseed rape was granted in July 1995. A label is not yet available but it will specify **(1)** use rates of 1.08 - 1.44 kg ae/ha **(2)** applications should be made at 30% or less grain moisture, and **(3)** a minimum of 14-21 days should be allowed between application and harvest. The tables below summarize international use rates and timings for the commodities of interest.

Table 2: barley

country	application rate (kg ae/ha)	preharvest interval (PHI, days)	seed moisture
UK	1.44	7	<30%
Ireland	0.72 - 1.44	7	<30%
Germany	1.08 - 1.80	14	<25%
Denmark	0.72 - 1.08	10	<30%
Netherlands	1.08 - 2.16	7	<30%
Belgium	1.08 - 1.44	7	<30%
France	1.08 - 2.16	7	<25%
Norway	1.08	7	5 days after yellowing of crop
Canada	0.90	7-14	<30%

Table 3: oil seed rape (canola)

country	application rate (kg ae/ha)	preharvest interval (PHI, days)	seed moisture
UK	≤1.44	14-21	<30%
Ireland	≤1.44	14-24	<30%
Canada	0.90	7-14	<30%
Sweden	≤1.44	14-21	<30%

Table 4: peas

country	application rate (kg ae/ha)	preharvest interval (PHI, days)	seed moisture
UK	≤1.44	7	<30%
Ireland	≤1.44	7	<30%
Denmark	1.44 - 2.16	7	<30%
Netherlands	≤2.16	7	<30%
Belgium	≤1.44	7	<30%
Canada	0.90	7-14	<30%

Table 5: lentils

country	application rate (kg ae/ha)	preharvest interval (PHI, days)	seed moisture
Canada	0.90	7-14	<30%

HED's Conclusion:

The requested information has been provided and the deficiencies resolved.

Deficiency - Conclusion 6a (memo D178843, D Davis 9/29/93)

6a. **Barley and Pea Method Validation** - The analytical methods used to collect residue data in/on barley grain and peas have not been adequately validated. Validation data must be submitted specific to each method, and matrix with supporting data as noted in the *Analytical Method - Data collection (MRID No. 423128-01, -02)* section of this review.

Petitioner's Response:

The information submitted previously in support of this petition (MRIDs 423128-01,-02, *Glyphosate residues in Roundup® Herbicide PreHarvest-Treated Cereals, Rapeseed, Beans, Peas, Grass, Hay and Silage, European Field Trials 1978-1984, Part A & B*) was a summary of European preharvest data and therefore not all details were included in the report. Representative residue reports on which this summary was based are now included in this submission. MRID 43827802 presents detailed information, including method validation data, pertaining to the UK barley grain and straw data summarized in MRID 423128-01, & -02. MRID 43807201 presents detailed information, including method validation data, pertaining to the Denmark and Belgium pea data summarized in MRID 423128-01 & -02.

Additional analytical method validation data for barley grain and straw, can be found in MRID 43807202 and 43845401. These studies, conducted in Canada and France respectively, pertain to glyphosate residues in/on barley following preharvest treatment.

The petitioner confirms that the method described as "new" in MRIDs 423128-01,-02 (chelation ion exchange with post-column o-phthalaldyhyde reaction detection) is US PAM Vol. II method I. Full descriptions of the analytical method were not provided in MRIDs 423128-01,-02 as they were summaries of several other studies. A description of the method is included in the full reports being submitted for MRIDs 43827802, 43845401, 43807202 and 43807201. Method validation data for peas, barley grain and barley straw from the most recent submissions is summarized below.

MRID 43827802, *Glyphosate Residues in Cereal Grain and Straw Following Preharvest Treatment with Roundup Herbicide in the United Kingdom: 1982 Trials-Part 1*

A summary of this study was initially submitted in the spring of 1992 (MRID 423128-01,-02). Upon review (memo, D. Davis, 27-Sept-93), more detailed information was requested to better evaluate the methods used to quantify glyphosate residues in/on barley grain and straw. Monsanto submitted this study which contains detailed information pertaining to the UK portion of MRID 423128-01,-02.

Untreated grain and straw samples were fortified with glyphosate. Residues of glyphosate were

recovered by aqueous extraction, charcoal and cation ion-exchange chromatography as clean-up steps followed by derivatization using a o-phthalaldehyde reactor coupled to a HPLC fluorescence detector. This method from here on will be referred to as US PAM Vol. II method I. Samples were analyzed at Monsanto Technical Center; Louvain-La-Neuve, Belgium.

Table 6: Method Validation Data, Grain

crop	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
grain	0.4	85	
	0.8	82	
	1.0	66	
	2.0	70, 76, 72, 67, 63	70 ± 5
	4.0	62, 73, 72, 71, 73, 62, 71, 69, 82	77 ± 6
	8.0	75	
average % recovery 72 ± 7			

Table 7; Method Validation Data, Straw

crop	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
straw	4.0	77	
	8.0	58, 61	60 ± 2
	16.0	76, 80	78 ± 3
	20.0	68, 81, 80, 62, 97	78 ± 13
	40.0	82, 60, 84, 76, 84	77 ± 10
	80.0	81	
average % recovery 75 ± 11			

MRID 43845401, ***Glyphosate and AMPA Residues in Wheat and Barley Following Application of MON52276, MON 44068 and Roundup® Herbicide One Week Before Crop Harvest: French Trials 1991***

This study was submitted in 27-Sept-95 as additional technical information regarding the establishment of a 20 ppm tolerance on barley grain.

Untreated barley grain and straw samples were fortified with glyphosate. Residues of glyphosate were recovered and quantified using US PAM Vol II method I. Samples were analyzed at MonsantoTechnical Center; Louvain-La-Neuve, Belgium.

Table 8: Method Validation Data, Grain

crop	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
grain	0.05	71, 79, 80, 81, 98, 103, 109, 117	92 ± 16
	0.1	112	
	0.2	76, 68, 73, 85, 92, 93, 93, 103, 109	89 ± 14
	0.5	60, 74, 76, 76, 77, 78, 99	77 ± 11
	1.0	72, 75	77 ± 2
	2.0	74	
	4.0	75	
	10.0	75	
average % recovery 85 ± 15			

Table 9: Method Validation Data; Straw

crop	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
straw	0.5	85	
	1.0	99, 66, 75, 93, 55	78 ± 18
	2.0	70	
	5.0	87, 89	88 ± 1
	10	65, 88	77 ± 16
	20	92, 94	93 ± 1
	50	81, 106	94 ± 18
	100	98	
average % recovery 84 ±14			

MRID 43807202, *Glyphosate Residues in Canadian Barley Grain and Straw Following Preharvest Application of Roundup® Herbicide*

This study was submitted in 27-Sept-95 as additional technical information regarding the establishment of a 20 ppm tolerance on barley grain.

Untreated barley grain and straw samples were fortified with glyphosate . Residues of glyphosate were recovered and quantified using US PAM Vol. II method I. Samples were analyzed by Enviro-Test Laboratories; Edmonton, Alberta.

Table 10: Method Validation Data; Barley Grain

crop	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
barley grain	0.05	106, 96	101 ± 7
	1.0	89, 76	83 ± 9
	5.0	79, 75	77 ± 3
	27	84, 70	77 ± 10
average % recovery 84 ± 12			

Table 11: Method Validation Data; Barley Straw

crop	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
barley straw	0.05	118, 70	94 ± 34
	1.0	77, 88	83 ± 8
	5.0	82, 77	79 ± 4
	25.0	96, 76	86 ± 14
average % recovery 85 ± 15			

MRID 43807201, ***Glyphosate Residues in Peas Following Preharvest Application with Roundup® Herbicide in Denmark and Belgium***

A summary of this study was initially submitted in the spring of 1992 (MRID 423128-01, & -02). Upon review (memo, D. Davis, 27-Sept-93), more detailed information was requested to better evaluate the methods used to quantify glyphosate residues in/on peas. Monsanto submitted this study, which contains detailed information pertaining to the Denmark and Belgium portion of MRID 423128-01, & -02.

Untreated pea samples were fortified with glyphosate at a single level, 0.5 ppm. Residues of glyphosate were recovered and quantified using US PAM Vol. II method I. Samples were analyzed at Monsanto Technical Center; Louvain-La-Neuve, Belgium.

Table 12: Method Validation Data; Peas

crop	fortification level (ppm)	glyphosate recovery (%)	avg % rev ± std dev
peas	0.5	95, 104, 86, 80, 69	87 ± 13

HED's Conclusions:

MRID 43827802, *Glyphosate Residues in Cereal Grain and Straw Following Preharvest Treatment with Roundup Herbicide in the United Kingdom: 1982 Trials-Part 1*, presented method validation data for grain and straw samples fortified with glyphosate from 0.4 - 8.0 ppm and 4.0 - 80.0 ppm, respectively (Tables 6 & 7). Chromatograms for control samples and treated samples along with their associated standards were presented. Sample weights, fortification levels, aliquot volumes and final volumes were also reported. No specification was made as to which grain and straw the method validation data pertains to. The lowest fortification level does not extend to the limit of quantification (LOQ), 0.05 ppm. This study will be considered validated despite these deficiencies due to the similarity in wheat, oat and barley grain and straw, and the glyphosate residue in/on treated grain and straw samples were all above 1.00 ppm. It will be assumed that the method validation procedures reported in this study are representative of the procedures performed in the remainder of European barley field trials in MRID 423128-01 & -02.

MRID 43845401, *Glyphosate and AMPA Residues in Wheat and Barley Following Application of MON52276, MON 44068 and Roundup® Herbicide One Week Before Crop Harvest: France 1991*, presented method validation data for grain and straw samples fortified from 0.05 - 27.0 ppm and 0.05 - 100.0 ppm, respectively (Tables 8 & 9). Chromatograms for control samples and treated samples along with their associated standards were presented. Sample weights, fortification levels, aliquot volumes and final volumes were also reported. No specification was made as to whether the validation data corresponds to wheat or barley grain and straw. However, due to the similarities in wheat and barley the analytical method has been properly validated

MRID 43807202, *Glyphosate Residues in Canadian Barley Grain and Straw Following Preharvest Application of Roundup® Herbicide*, presented method validation data for barley grain and straw samples fortified from 0.05 - 27.0 ppm and 0.05 - 25.0 ppm, respectively (Tables 10 & 11). Chromatograms for control samples and treated samples along with their associated standards were presented. Sample weights, fortification levels, aliquot volumes and final volumes were also reported. This study has been properly validated.

MRID 43807201, *Glyphosate Residues in Peas Following Preharvest Application with Roundup® Herbicide in Denmark and Belgium*, presented method validation data for pea samples fortified at 0.5 ppm (Table 12). Chromatograms for control samples and treated samples along with their associated standards were presented. Sample weights, fortification levels, aliquot volumes and final volumes were also reported. However, method validation data should present a minimum of two fortification levels, with one near the LOQ. This study will be considered validated despite these deficiencies since the glyphosate residue data for treated pea samples were generally not near the LOQ. It will be assumed that the method validation procedures reported in this study are representative of the procedures performed in the remainder of European pea field trials in MRID 423128-01 & -02.

The petitioner has submitted information necessary for the validation of MRID 423158-01 & -02 and therefore the deficiencies are resolved.

Deficiency - Conclusions 6b & 6c (memo D178843, D Davis 9/29/93)

6b. **Rapeseed and Rapeseed Meal Method Validation** - Provided the supporting information requested in the *Analytical Method - Data Collection (MRID No. 42312803)*section of this review is supplied, CBTS tentatively concludes that the data collection methods used for **glyphosate** residues in/on rapeseed and rape meal have been adequately validated and are satisfactory for collecting residues of glyphosate. However the petitioner has not adequately validated the methods employed for the detection of **AMPA** residues in/on rapeseed and rapeseed meal. All field trial residues are reported at or near the detection limit, however, no validation data at the detection limit

was generated for AMPA. Further, for the GC procedure, two of the three parameters were below a level considered acceptable by the Agency (<70%). Of the two validation samples submitted for rapeseed meal, one was below a level the Agency considers acceptable.

6c. **Rapeseed Oil Method Validation** - CTBS can not comment on the adequacy of the method used to analyze rape oil for residual **glyphosate** since an insufficient number of validation samples were reported. At a minimum validation data from two fortification levels should be reported. Validation for **AMPA** is not acceptable, as both recoveries reported are below a level considered acceptable by the Agency. Further, since the actual field trial residues reported for both glyphosate and AMPA were <0.05 ppm, validation data for both compounds at the limit of detection should be provided.

Petitioner's Response:

No additional details are available on the rapeseed and rape oil method validation samples for MRID 42312803. The supplemental information the reviewer requested was not typically included in the final report in the early 1980's (pre GLP), either in the US or Europe. Additional method validation data for rapeseed can be found in MRIDs 43827801 and 43807203. These studies, conducted in Canada and the UK, pertain to glyphosate residues in/on rapeseeds, rapeseed meal, rape crude oil and rape refined oil following preharvest application.

Analytical method validation for AMPA in/on rapeseed and rapeseed meal were not provided in MRID 42312803. In particular, no validation data were generated at the detection limits, recoveries on two of the three method validation samples for rapeseed were <70% using the GC method, and recovery of one of the two method validation samples for rapeseed meal was unacceptable. Monsanto notes that acceptable recoveries were obtained for AMPA in five of the seven fortified samples using the HPLC method and that, although the fortification levels were not exactly at the detection limit of 0.05 ppm, they were only 2-4 times greater. In addition, the Agency no longer considers AMPA of toxicological significance and is no longer included on the tolerance expression for glyphosate. Monsanto believes that no additional validation data should be required for AMPA since it is no longer included in the tolerance expression.

MRID 43827801, ***Residues of Glyphosate/AMPA in Winter Oilseed Rape Following Applications of MON 52276, MON 44068, and Roundup® Herbicide Two Weeks Before Harvest. UK Field Trials 1992***

Untreated winter oilseed rape samples were fortified with glyphosate at 0.05, 0.1, 0.5 and 1.0, 5.0, 20.0, 25.0 and 50.0 ppm. Residues of glyphosate were recovered and quantified using US PAM Vol. II method. Samples were analyzed at Monsanto Technical Center, Louvain-La-Neuve, Belgium.

Table 13; Method Validation Data; Oilseed Rape

crop	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
oilseed rape	0.05	84, 60	72 ± 17
	0.1	83	
	0.5	86, 72	79 ± 10
	1.0	79	
	5.0	69, 70, 74	71 ± 3
	20.0	79	
	25.0	71, 55	63 ± 11
	50.0	66, 76	71 ± 7
average % recovery 73 ± 9			

MRID 43807203; *Glyphosate Residues in Canadian Canola Raw Agricultural Commodities and Processed Canola Fractions*

Untreated canola seed and processed fractions were fortified with glyphosate and AMPA. Residues of glyphosate were recovered and quantified using US PAM Vol. II method I. Samples were analyzed by Monsanto St Louis, MO.

Table 14: Method Validation Data; Canola Seed, Meal, Crude Oil and Refined Oil

commodity	fortification level (ppm)	glyphosate recovery (%)	avg ± std dev
canola seed	0.05	67, 100	83 ± 23
	0.10	86, 96, 102	95 ± 8
	0.50	99	
	1.00	88, 87	87 ± 1
	5.00	83, 89	86 ± 4
average % recovery 82.87 ± 9.78			
canola meal	1.00	86, 88	87 ± 1
canola crude oil	0.50	83, 89	86 ± 4
canola refined oil	0.05	77, 83	80 ± 3

HED's Conclusions:

MRID 43827801, *Residues of Glyphosate/AMPA in Winter Oilseed Rape Following Application of MON 52276, MON 44068 and Roundup® Herbicide Two Weeks Before Harvest*, presented method validation data for winter oilseed rape samples fortified from 0.05 - 50.0 ppm (Table 13). Chromatograms for control samples and treated samples along with their associated standards were presented. Sample weights, fortification levels, aliquot volumes and final volumes were also reported. Area counts for the chromatograms were not included therefore the reviewer was not able to verify the results. Despite the missing information, the method will be considered validated.

MRID 43807203, *Glyphosate Residues in Canadian Canola Raw Agricultural Commodities and Processed Canola Fractions*, presented method validation data for canola seed and processed fractions (Table 14). Chromatograms for control samples and treated samples along with their associated standards were presented. Sample weights, fortification levels, aliquot volumes and final volumes were also reported. The study presented canola meal, crude oil and refined oil method validation data at only a single level. Validation data should have at least two fortification levels with one near the LOQ. Canola seed validation data contained several fortification levels with the lowest at the LOQ. Recoveries for canola seed samples fortified at 0.05 ppm (LOQ) were acceptable, thereby confirming that the HPLC was operating in a manner capable of detecting glyphosate at the LOQ. Therefore detection of 0.05 ppm levels in meal, crude oil and refined oil would be dependent on extraction efficiency and matrix effects. The recoveries of glyphosate from fortified canola meal, crude oil and refined oil, were acceptable and the chromatograms submitted showed a baseline devoid of interferences. It will be assumed that had the processed fractions been fortified at the LOQ, acceptable recoveries would have been attained. The analytical methods for canola seed, meal, crude oil and refined oil have been properly validated.

The petitioner has indicated that the supplemental information request to verify method validation data in MRID 42312803 is no longer available. This study predates GLP regulation, therefore detailed information such as injection volumes, aliquot volumes and chromatograms were not included in the report. The petitioner has indicated that the analytical method used in MRID 42312803 is US PAM Vol. II method I. The glyphosate residues reported in/on treated canola seed in the earlier study (MRID 42312803) and in MRID 43827801 are similar (see deficiency 7c, below). For these reasons, the canola seed and processing data presented in MRID 42312803 will be considered valid.

The Agency has determined that AMPA no longer needs to be regulated therefore residue data for this compound is no longer necessary. The petitioner has submitted the required information and the deficiencies have been resolved.

Deficiency - Conclusion 7a (memo D178843, D Davis 9/29/93)

7a. **Barley Field Trials** - Residue data was generated at Monsanto Technical Center, Louvain-La-Neuve, Belgium. Acceptance of the barley field trial data cited in Table 4 of this review is contingent upon the identification of the method employed to generate the specific data points cited, as well as, successful validation of the methods employed to generate residue levels reported. Additionally, acceptance of the cited residue data is contingent upon submission and acceptance of the supplemental information requested in the *Crop Field Trials General* section of this review. CBTS tentatively concludes that the geographic representation of this residue data is adequate. We further tentatively conclude that a tolerance of 20ppm for residues of glyphosate on barley grain as a result of the preharvest application of Roundup® as proposed in this petition is appropriate. These conditions are subject to revision if the petitioner is unable to supply the needed information or to successfully validate the analytical methods used to collect data. Further, if additional uses of glyphosate-based products are disclosed in response to deficiencies cited in the *Proposed Use* section of this review, additional data may be required to support these conclusions.

Petitioner's Response:

The petitioner confirms that the method described as "new" in MRIDs 423128-01, & -02 is US PAM Vol. II method I. MRID 43827802 presents detailed information pertaining to the UK portion of MRID 423128-01, & -02 (memo, D. Davis, 29-Sept-93). Additional field data for barley grain and straw, can be found in MRID 43807202 and 43845401. These studies, conducted in Canada and France respectively, pertain to glyphosate residues in/on barley grain and straw following preharvest treatment.

MRID 43827802, *Glyphosate Residues in Cereal Grain and Straw Following Preharvest Treatment with Roundup® Herbicide in the United Kingdom: 1982 Trials-Part I*

The original protocol for this study predates GLP standards and therefore is not in compliance. Field trials were supervised by Monsanto. Samples were analyzed at Monsanto Technical Center, Louvain-La-Neuve, Belgium.

Five trial sites were selected in the UK. Four test plots were established at each trial site: one untreated (control) and three treated plots. The test plots were a minimum of 100 square meters. The untreated test plot was located a minimum of 60 meters from the nearest treated test plot. At each trial site, Roundup® herbicide was applied to the treated test plots at a rate of 1.44 kg ae/ha. The herbicide was diluted in water and sprayed at 200 liters/ha when grain moisture was less than 25 %. At each test site 2 kg of grain and 0.5 kg of straw was randomly sampled 6 - 12 days after treatment using a farmer combine harvest. Samples were not frozen until they arrived at the analytical lab. The time from harvesting to arrival at the analytical lab extended to 6 days.

Barley grain was ground in an Ultracentrifugal mill and a subsample taken for analysis. Dry straw samples were powdered in a Brebender mill. The ground products were mixed and a 12.5 grams of grain or straw was sub-sampled and taken for analysis. Residues of glyphosate were recovered and quantified using US PAM Vol II method I. The time between collection of the samples and analysis extended to 5 months. The residue data is summarized below.

Table 15: Glyphosate Residues; Barley Grain and Straw

location	rate (kg ae/ha)	PHI (days)	grain (ppm)	straw (ppm)
E. Lothians	1.44	6	4.3	35.1
	1.44	6	4.2	39.4
	1.44	6	4.7	48.1
Cottenham	1.44	7	1.2	8.5
	1.44	7	1.5	17.4
	1.44	7	1.5	13.0
Bossal	1.44	8	10.7	29.5
	1.44	8	9.2	84.6
	1.44	8	12.8	71.8
Normanton	1.44	9	3.6	50.4
	1.44	9	4.7	57.0
	1.44	9	1.6	34.0

location	rate (kg ae/ha)	PHI (days)	grain (ppm)	straw (ppm)
Lechlade	1.44	12	1.7	10.6
	1.44	12	1.5	11.9
	1.44	12	1.7	18.0
barley grain average 4.3 ± 3.7 barley straw average 35.3 ± 23.4				

MRID 43807202, *Glyphosate Residues in Canadian Barley Grain and Straw Following Preharvest Application of Roundup® Herbicide*

The original protocol for this study predates GLP standards and therefore is not in compliance. Field trials were supervised by Monsanto. Samples were initially analyzed by Craven Laboratories. In response to allegations concerning the reliability of residue data generated by Craven, the samples were reanalyzed by Enviro-Test Laboratories; Edmonton, Alberta.

Nine trial sites were selected within the Provinces of Alberta and Manitoba. Five test plots were established at each trial site: one untreated (control) and a separate test plot for each application rate. The untreated test plot was located 2 to 300 meters from the nearest treated test plot. Treated test plots were separated by 1 to 30 meter buffer zone. Roundup® herbicide was applied to separate treated test plots at 0.67, 0.90 and 1.80 kg ae/ha. The herbicide was diluted in water and sprayed at a volume of 110 or 123 liters/ha. The test substance was applied as a single postemergence, broadcast spray treatment to barley in the hard dough stage of maturation (30% or less moisture content) 10-21 days prior to harvest. At one of the two 0.90 kg ae/ha applications at Minto (1), Minto (2) and Portage La Prairie, the test substance was applied at a 35% grain moisture content.

At each test site 10-12 kg of grain and 5-7 kg of straw were taken from each test plot. Barley was either swathed by hand or machine and threshed by stationary thresher or combined. All samples were frozen as soon as possible after harvest, shipped to Monsanto and maintained in frozen storage. Prior to analysis, subsamples from field composited samples from each test plot, were ground in the presence of dry ice, and again subsampled. These subsamples were shipped frozen to the analytical laboratory for glyphosate residue analysis.

Samples arrived at Enviro-Test on 12-May-92. The time between collection of the samples and analysis extended to 51 months (see deficiency 9, below). The samples arrived frozen and glyphosate residues were recovered and quantified using US PAM II method I. The time from extraction to analysis varied from 2 weeks to 6 months. Despite the long time between extraction and analysis, recoveries for fortified samples extracted and analyzed along with treated samples were acceptable. The residue data is summarized in Tables 16 & 17.

Table 16: Glyphosate Residues; Barley Grain and Straw

location	PHI (days)	rate (kg ai/ha)	grain (ppm)	straw (ppm)
Aubigny, MB	21	0.67	0.825	5.947
	21	0.90	1.166	9.646
	21	0.90	0.658	8.269
Beaumont, AB	17	0.67	1.539	10.931
	17	0.90	2.702	11.476
	17	0.90	1.424	9.064
Holden, AB	17	0.67	0.358	.690
	17	0.90	0.378	.672
	17	0.90	0.820	1.272
Kathryn, AB	13	0.67	2.095	9.069
	13	0.90	2.985	12.595
	13	1.80	5.349	12.337
Letherbridge, AB	13	0.67	1.894	14.140
	13	0.90	3.302	19.197
Minto (1), MB	10	0.67	0.422	3.210
	10	0.90	1.658	3.893
	14	0.90 (M)	1.903	2.875
	10	1.80	2.462	12.341
Minto (2), MB	10	0.67	0.721	4.197
	10	0.90	1.226	8.657
	14	0.90 (M)	4.198	7.388
	10	1.80	2.784	11.719
Olds, AB	13	0.67	0.831	6.112
	13	0.90	2.011	7.306
Portage La Prairie, MB	13	0.67	3.483	10.238
	13	0.90	3.945	15.122
	18	0.90 (M)	4.873	21.568
	13	1.80	3.723	16.228

(M) = preharvest treatment applied at 35% seed moisture content

Table 17: Average Glyphosate Residues; Barley Grain and Straw

	rate kg ae/ha					
	0.67		0.90		1.80	
	grain	straw	grain	straw	grain	straw
average	1.352	7.170	2.412	9.459	3.580	13.156
standard deviation	1.014	4.255	1.551	5.919	1.295	2.069

MRID 43845401,*Glyphosate and AMPA Residues in Wheat and Barley Following Application of MON 52276, MON 44068 and Roundup® Herbicide One Week Before Crop Harvest, French Trials 1991*

This study is not in compliance with GLP. Field trials were conducted by MBG-LANDIS Europe. Samples were analyzed at Monsanto Technical Center, Louvain-La-Neuve, Belgium.

Eight trial sites were selected in France. To each site, Roundup® herbicide was applied to winter and summer barley at a rate of 2.16 kg ae/ha and MON 52276 and MON 44068 (European glyphosate formulations) were applied to winter and summer barley at a rates of 1.08 kg ae/ha and 2.16 kg ae/ha (each formulation and rate replicated three times at each site). The size of the treated plots were 2 meters by 6 meters. The alleys between the treated plots was at least 6 meters. The untreated test plot was located up slope from the treated plots at a distance of at least 20 meters. The herbicide was diluted in water and sprayed at a volume of ~200 liters/ha. The compound was applied with standard spraying equipment that had been properly calibrated as a single postemergence spray 7-10 days prior to harvest.

Plant material was manually sampled. From each replicate and from the non-treated plot a minimum of 1 kg of grain and 0.5 kg of barley straw was sampled and placed in freezers as soon as possible. Samples were dispatched frozen to Monsanto Technical Center, Louvain-La-Neuve, Belgium and kept at -20°C until analysis. Ears were threshed prior to analysis and a composite sample of the three replicate samples were taken for analysis. Glyphosate residues were recovered and quantified using US PAM Vol II method I. Samples were collected in July 1991 and analysis was completed by the end of December 1991. The residue data is summarized in Table 18.

Table 18: Glyphosate Residues; Barley Grain and Straw

location	MON 52276				MON 44068				Roundup®	
	1.08 kg ae/ha		2.16 kg ae/ha		1.05 kg ae/ha		2.10 kg ae/ha		2.16 kg ae/ha	
	grain	straw	grain	straw	grain	straw	grain	straw	grain	straw
Vayres	1.0	9	1.8	15	0.1	0	2.8	8	1.6	9
Champ	1.2	8	1.6	17	1.1	4	2.2	16	3.3	12
Sept Sauly	4.3	61	5.4	140	3.2	49	4.4	72	7.2	140
Verneuil	4.4	70	5.9	160	2.8	30	4.0	140	9.6	120
avg	2.7	37	3.7	83	1.8	21	3.3	59	5.4	70
std dev	1.9	33	2.3	78	1.5	23	1.0	61	3.6	69

Champ = Champmptteux

The large variation in glyphosate residues is a result of rainfall occurring between application and harvest. Sites Vayres and Champotteux showed cumulative rainfall of 31mm and 15mm while Sept Sauly and Verneuil showed cumulative rainfall of 1mm and 2mm.

HED's Conclusions:

MRID 43827802, *Glyphosate Residues in Cereal Grain and Straw Following Preharvest Treatment with Roundup® Herbicide in the United Kingdom: 1982 Trials-Part 1*, presented additional information concerning field, sampling and quantitative procedures for the UK portion of MRID 423128-01 & -02. All quantitative data associated with samples, including sample weights, extraction volumes, aliquot volumes and final extract volumes were provided. Representative chromatograms were presented along with associated calibration standards.

MRID 43807202, *Glyphosate Residues in Canadian Barley Grain and Straw Following Preharvest Application of Roundup® Herbicide*, presented glyphosate residues on barley grain and straw following a preharvest application. All quantitative data associated with samples, including sample weights, extraction volumes, aliquot volumes and final extract volumes were provided. Representative chromatograms were presented along with associated calibration standards.

MRID 43845401,*Glyphosate and AMPA Residues in Wheat and Barley Following Application of MON 52276, MON 44068 and Roundup® Herbicide One Week Before Crop Harvest, French Trials 1991*, demonstrates that the European glyphosate formulations, MON 52276 and MON 44068, do not result in elevated glyphosate residues when compared to Roundup® Herbicide. All quantitative data associated with samples, including sample weights, extraction volumes, aliquot volumes and final extract volumes were provided. Representative chromatograms were presented along with associated calibration standards.

MRID 423128-01 & -02, *Glyphosate residues in Roundup® Herbicide Treated Cereals, Rapeseed, Beans, Grass, Hay and Silage, European Field Trials 1978-1984, Part A* (submitted 1-May-92), summarized field trials conducted in Finland, Norway, Sweden, Denmark, France, Germany, UK, and Belgium from 1978 - 1984. Glyphosate residues in/on barley grain and cereal straws treated shortly before harvest were presented. Plots received applications of Roundup® herbicide at rates ranging from 0.5 - 8.60 kg ae/ha. The herbicide was diluted in water and sprayed at volumes ranging from 200 - 600 liters/ha. Barley grain and straw were harvested at 1 to 29 days after treatment. Residual glyphosate was determined at the Monsanto Technical Center, Louvain-La-Neuve, Belgium. MRID 423128-01 & -02 reported glyphosate residue data for barley, wheat and oats. Grain data was presented individually but straw data was grouped as cereal straw. The information reported in MRID 423128-01 & -02 is a summary of these field trials. The data was reviewed (memo, D. Davis, 29-Sept-93) and found to be lacking detailed information which would allow the reviewer to adequately assess the field and quantitative procedures. In response, the petitioner submitted MRID 43827802 which presented additional information concerning field, sampling and quantitative procedures for the UK portion of MRID 423128-01& -02. It will be assumed that the field and analytical procedures reported in MRID 43827802 are representative of the procedures performed in the remainder of the European field trials in MRID 423128-01 & -02. Two additional studies were submitted (MRIDs 43845401, 43807202) which presented glyphosate residues in/on barley grain and straw following preharvest application.

The residue data reported in MRID 423128-01 & -02 will be accepted because **(1)** the assumption that the field and analytical procedures presented in MRID 43827802 are representative of the procedures performed in the remainder of the European field trials, **(2)** the similar glyphosate residues reported in/on barley grain and straw for all studies, **(3)** the confirmation that the analytical method used was US PAM Vol. II method I and **(4)** the study was conducted pre-GLP and the type of detailed information required under this regulation was not typically included in reports.

Glyphosate residue data in/on barley grain and cereal straw data from all the studies is summarized in Table 19. The data presented is limited to those data points which are representative of the maximum rate and minimum PHI for the country in which they were generated. HED concludes that the proposed tolerance of 20 ppm on barley grain, as a result of the preharvest application of Roundup® as defined in this petition, is appropriate. HED also accepts the addition of "except barley" to the grain crops group for glyphosate.

Table 19: Glyphosate residues MRIDs 423128-01 & -02, 43845401 and 4380720; Barley Grain & Cereal Straw

Grain

country	year	rate (kg ae/ha)	PHI (days)	glyphosate (ppm)
UK	1979	1.44	5	6.6
			7	3.6
	1980	1.44	7	2.8
			7	12.9
			7	12.5
			6	6.2
			6	2.6
			7	14.0
			7	4.5
	1982	1.44	7	1.4
France	1979	2.15	7	1.2
			7	2.4
	1981	2.15	9	4.0
			8	6.4
			9	11.0
	1991	2.16	7	5.4
			7	4.4
			7	7.2
			7	5.9
			7	4.0
			7	9.6
Germany	1980	1.80	14	0.4
			14	5.3
			14	2.0
			14	2.1
			14	6.3
	1981	1.80	14	1.2
	1982	1.82	14	7.0
			14	5.1

Cereal Straw

country	year	rate (kg ae/ha)	PHI (days)	glyphosate (ppm)
UK	1979	1.44	7	36
			7	58
			7	69
			7	210
	1980	1.44	7	24
			7	28
	1982	1.44	7	8
			8	9
			7	16
			8	22
			7	30
			7	43
			7	57
			7	57
			7	60
			8	76
France	1991	2.16	7	140
			7	72
			7	140
			7	160
			7	140
			7	120
Germany	1980	1.80	14	3.2
			14	8.7
			14	9.8
			14	12
			14	13
			14	15
			14	16

Grain

country	year	rate (kg ae/ha)	PHI (days)	glyphosate (ppm)
Belgium	1980	1.44	10	1.4
Denmark	1979	1.44	10	4.9
	1980	1.44	7	2.6.
			8	0.6
		2.16	7	1.3
			8	1.2
	1981	1.44	9	0.8
	1983	1.44	9	6.3
Finland	1978	1.44	7	3.3
	1980	1.44	7	1.8
	1981	1.44	7	12.0
Sweden	1978	2.15	7	3.0
	1979	1.44	7	5.2
				0.1
		2.16	7	4.1
				0.1
	1981	1.44	7	5.1
Norway	1979	2.00	8	4.5
			8	1.8
Canada	1988	0.90	10	1.7
			10	1.2
			13	3.0
			13	3.3
			13	2.0
			13	3.9
			14	4.2
			14	1.9

Cereal Straw

country	year	rate (kg ae/ha)	PHI (days)	glyphosate (ppm)
Germany	1980	1.80	14	22
			14	28
			14	29
			14	30
			14	64
Belgium	1978	1.44	14	16
			10	22
	1980	1.44	13	16
Denmark	1979	1.44	8	9
			6	14
			10	42
	1980	1.44	6	8
			8	12
			7	86
	1983	1.44	9	89
			9	110
Norway	1979	1.0	8	2.8
			12	10
			7	12
			10	24
Canada	1988	0.9	10	3.9
			10	8.7
			13	12.6
			13	19.2
			13	7.3
			13	15.1
			14	2.9
			14	7.4

-shaded data = France, MRID 43845401 (Sept Sauly & Verneuil data only); Canada, MRID 43807202

Deficiency - Conclusion 7b (memo D178843, D Davis 9/29/93)

7b. **Pea Field Trials** - Residue data was generated at the Monsanto Technical Center, Louvain-La-Neuve, Belgium. CBTS is unable to conclude that the proposed tolerance of 5 ppm for peas is appropriate based on the data submitted. Since the petitioner is requesting an import tolerance for peas, we are inclined to believe that the petitioner wishes a tolerance for dried peas. The petitioner is asked to indicate if the requested tolerance is for dry peas, succulent peas or for both commodities. In addition, field pea trial from Canada cannot be used since the analytical portion of this study was conducted by Craven Laboratories. Due to recent allegations concerning validity of the data generated by Craven Laboratories, the Agency will not rely on Craven data for regulatory decisions. Additional field trials from Canada will be required to support an import tolerance based on the proposed Canadian use of glyphosate on peas. CBTS cannot specifically delineate the number of additional field trials needed until the petitioner has more precisely defined the requested tolerance and has completely identified the RACs used in the studies cited in Table 5 of this review. However as a general guideline, we would suggest that for each commodity (dried or succulent peas), four field trials from each country for which there is a registered use would be appropriate. Provided the supporting data requested are supplied for the field trials cited in Table 5, and further provided those field trials were conducted on an appropriate commodity, the results may serve to partially fulfill the data requirements for pea field trials.

Petitioner's Response:

The Agency is correct in concluding that the proposed tolerance of 5 ppm for peas is for dried peas. The Agency also notes that some of the residue data submitted in support of this request were conducted by Craven Laboratories (MRID 42312804). Monsanto believes that the European residue data submitted in MRIDs 423128-01& -02, and in more detail in this submission (MRID 43807201), are adequate to establish an import tolerance for glyphosate on dried peas. The climatological and soil conditions in the European and Canadian regions where these peas are grown are similar, and although the Craven data cannot be used to establish a tolerance, Monsanto believes that they do provide some support in that they do not contradict the European results. In addition, it should be noted that the maximum use rate in Canada is well below that approved in European countries, and therefore lower residues would be expected.

Finally, we note that the Agency recently recommended increasing the tolerance for glyphosate on legume vegetables (except soybeans) to 5 ppm to harmonize with Codex MRLs (Glyphosate Reregistration Eligibility Decision (RED) document, September 1993, page 68, EPA 738-R93-014). In light of this determination Monsanto believes that no additional residue data on peas should be required.

MRID 43807201; *Glyphosate Residues in Peas Following Preharvest Application with Roundup Herbicide in Denmark and Belgium*

The original protocol for this study predates GLP standards and therefore is not in compliance. This data was initially submitted as part of European field Trials (MRIDs 423128-01, -02). This submission presents additional information for the Denmark and Belgium portions of the earlier submission. Field trials for this study were supervised by Monsanto. Samples were analyzed at Monsanto Technical Center, Louvain-La-Neuve, Belgium.

Sites were chosen in Denmark and Belgium for application of Roundup® herbicide at rates of 0.72, 1.08, 1.44 and 1.80 kg ae/ha. The herbicide was diluted in water and sprayed at volumes ranging from 200 - 1000 liters/ha. The compound was applied as a single postemergence spray 4-17 days prior to harvest. Dried peas were randomly sampled by hand and threshed prior to deep freezing. Upon arrival to the laboratory, the pea samples were powered using an ultra-centrifugal mill. Sub samples were stored at -20°C. Glyphosate residues were recovered and quantified using US PAM Vol. II method I. The residue data for dried peas is summarized in Table 20.

Table 20: Glyphosate Residues; Dried Peas

location	PHI (days)	rate (kg ae/ha)	glyphosate (ppm)
Gothab Denmark	6	1.44	0.5
Alborg, Denmark	4	1.44	1.8
Torrins-Jutland, Denmark	12	0.72	0.8
	12	1.08	1.7
	12	1.80	2.5
Veurne, Belgium	17	1.08	0.6
	17	1.08	0.9
UK	5	1.44	0.9
	7	1.44	<0.05

1.44 kg ae/ha × 0.453592 kg/lb × 1 ac/2.471 ha
1.285 lb ae/A

HED's Conclusions:

MRID 42312802 summarized field trials conducted in Europe for the determination of glyphosate residues in/on dried peas following preharvest application. This information was reviewed (memo, D. Davis, 29-Sept-93) and found to be lacking in detailed information allowing the reviewer to assess the field and analytical procedures. Since that time, the Agency has recommended increasing the tolerance on legume vegetables group (except soybeans) to 5 ppm to harmonize with Codex MRLs (Glyphosate RED, September 1993). HED concludes that the proposed import tolerance of 5 ppm on the legume vegetables (succulent & dried) group (except soybeans) is appropriate.

Deficiency - Conclusion 7c (memo D178843, D Davis 9/29/93)

7c. **Rapeseed Field Trials** - Residue data were generated at the Monsanto Technical Center, Louvain-La-Neuve, Belgium. The petitioner is requested to supply the supporting data requested under *Magnitude of the Residue - Plant Crop Field Trials; Rapeseed* section of this review. Further the methods used to generate the residue data cited in Table 6 of this review must be adequately validated as noted in the *Analytical Method - Data Collection* section of this review. CBTS tentatively concludes that the geographic representation of this residue data is adequate for the establishment of an import tolerance on rapeseed. We further tentatively conclude that residues of glyphosate and AMPA metabolite are not likely to exceed 10ppm as a result of the preharvest use proposed in this petition, consequently the proposed tolerance of 10ppm is appropriate and supported by adequate residue data. These conclusions are subjected revision if the rape field trials cited in Table 6 of this review are found to be inadequate due to missing supporting data or insufficient validation data. Further, if additional uses of glyphosate-based products are reported in response to deficiencies cited in *Proposed Use* section of this review, resulting in additional field trial requirements, these conclusions are subject to revision.

Petitioner's Response:

The additional data requested by the reviewer is no longer available. This type of information was not included in reports prior to GLP regulation. Glyphosate residues were recovered and quantified using US PAM Vol. II method I. The following study is being submitted as representative of the earlier study.

MRID 43827801; *Residues of Glyphosate/AMPA in Winter Oilseed Rape Following Applications of MON 52276, MON 44068, and Roundup® Herbicide Two Weeks Before Harvest. UK Field Trials 1992*

The study was not conducted according to GLP standards. Field trials were conducted by Agrisearch UK Ltd; Wilson, Melbourne. Samples were analyzed at Monsanto Technical Center, Louvain-La-Neuve, Belgium.

Four trial sites were selected within the UK. Seven test plots were established at each trial site: one untreated (control) and a separate test plot for each application rate. The untreated test plot was located 30 meters from the nearest treated test plot. Treated test plots were 90 square meters and separated by a 3 meter buffer zone. At each test site, Roundup® herbicide and MON52276 were applied to separate treated test plots at 1.44 and 2.88 kg ae/ha and MON 44068 was applied at 1.47 and 2.97 kg ae/ha. The test substance was diluted in water and applied at 200 liters/ha as a single postemergence spray when grain moisture was less than 30%. The oilseed rape was harvested 14 days after application.

Three subplots were established within each test plot. Oilseed was collected from various locations within each subplot and field composited. A minimum of 0.5 kg of oilseed was collected at each plot and threshed using a machine. Samples were frozen as soon as possible after harvest or sent to Monsanto Technical Center, Louvain-La-Neuve, Belgium where they were maintained in frozen storage until analysis.

Glyphosate residues were recovered and quantified using US PAM Vol. II method I. All samples were analyzed within 4 months of collection. The glyphosate residue data is summarized in Table 21.

Table 21: Glyphosate Residues; Oilseed Rape

	PHI	MON 52276		MON 44068		Roundup®	
		1.44	2.88	1.47	2.94	1.44	2.88
Wilson, Derbyshire	14	1.3	2.4	1.2	3.5	1.3	3.4
Wintringham, Yorks	14	0.6	1.5	1.0	1.4	0.6	1.8
Terling, Essex	14	0.9	1.3	0.8	0.9	1.3	0.7
Burnham, Essex	14	0.6	0.4	0.6	1.4	0.4	1.6
avg		0.9	1.4	0.9	1.8	0.9	1.9
std dev		0.3	0.8	0.3	1.2	0.5	1.1

HED's Conclusions:

MRID 43827801; *Residues of Glyphosate/AMPA in Winter Oilseed Rape Following Applications of MON 52276, MON 44068, and Roundup® Herbicide Two Weeks Before Harvest. UK Field Trials 1992* presented all quantitative data associated with samples, including sample weights, extraction volumes, aliquot volumes and final extract volumes. Representative chromatograms were given along with associated calibration standards. The area counts for these chromatograms were not given, thereby not allowing the reviewer to independently verify the results. The resulting glyphosate residues demonstrates that the European glyphosate formulations, MON 52276 and MON 44068, do not result in elevated glyphosate residues when compared to Roundup® Herbicide.

MRID 42312803, *Residue Analysis for Glyphosate and AMPA in Brassica Seedcrops and Processed Fractions Following Preharvest Roundup® Herbicide Treatments*, summarized European field trials (Denmark, UK and Finland from 1978 - 1984) conducted to determine residues of glyphosate on rapeseed and

processed fractions as a result of preharvest treatment. For each field trial, a single foliar application of Roundup® was applied to the crop preharvest. The herbicide was diluted in water and sprayed at volumes ranging from 200 - 600 liter/ha. Plots received applications of Roundup® at rates ranging from 0.72 - 2.88kg ae/ha. Rapeseed was harvested 2 and 34 DAT and analyzed for residues of glyphosate. Glyphosate residue data was generated at the Monsanto Technical Center, Louvain-La-Neuve, Belgium. The data were reviewed (memo, D. Davis, 29-Sept-93) and found to be lacking detailed information concerning field, sampling and quantitative procedure. In response, the petitioner submitted an additional study, MRID 43827801, which presented UK field trials conducted to determine glyphosate residues in/on rapeseed following a preharvest application. The canola seed glyphosate residue data reported in MRID 42312803 will now be considered valid for the following reasons, **(1)** the similarity in the reported canola seed glyphosate residue data in MRIDs 42312803 & 43827801, **(2)** confirmation that the analytical method used to generate the glyphosate residue was US PAM Vol. II method I and **(3)** the study was conducted pre-GLP and the type of detailed information required under this regulation was not normally included in reports.

Table 22 summarizes data from both studies. According to the proposed use section of this submission, Roundup® is not used in Finland. This data will be cited as translatable to Sweden. Only data representative of the maximum rate allowed in the country and minimum PHI is presented. HED concludes that the proposed tolerance of 10 ppm on canola seed, as a result of the preharvest application of Roundup® as defined in this petition, is appropriate.

Table 22: Glyphosate Residues; Oilseed Rape

country	year	rate kg ae/ha	PHI (days)	glyphosate (ppm)
Finland	1981	1.45	7	6.3
Sweden	1981	1.45	10	0.4
	1983	1.44	8	6.3
	1983	1.44	5	0.7
UK	1980	1.44	7	0.7
	1980	1.44	11	0.8
	1982	1.40	14	0.2
	1982	1.40	14	2.0
	1982	1.40	14	4.1
UK	1992	1.44	14	1.3
	1992	1.44	14	0.6
	1992	1.44	14	0.7
	1992	1.44	14	0.4

shaded data = MRID 43827801, the remaining data from MRIDs 42312803

Deficiency - Conclusion 7e (memo D178843, D Davis 9/29/93)

7e. **Rapeseed Processing Study** - The rapeseed processing study is not acceptable as submitted. Additional details on the study as outlined in the *Magnitude of the Residue - Plants, Processing Study* section of this review are required before the adequacy of the study can be determined. Based solely on preliminary results, a feed additive tolerance for rape meal appears necessary and as a result, a food additive petition should be filed.

Petitioner's Response:

The Agency notes that the rapeseed processing study submitted previously is not acceptable. Monsanto believes that the processing study on Roundup-tolerant canola (oilseed rape) enclosed in this submission (MRID 42807203) will be acceptable. Although the actual residue levels seen for this use are lower than those from the preharvest use, the residence segregation is the same upon processing. This study is consistent with numerous other processing studies conducted on glyphosate and AMPA; no concentration occurs in the oil fraction due to the polar nature of the molecules but some concentration is observed in the meal fraction

The Agency noted that in addition to a feed additive tolerance, a food additive tolerance on rape meal is necessary. This tolerance has been requested in the revised Section F.

MRID 43807203; ***Glyphosate Residues in Canadian Canola Raw Agricultural Products and Processed Canola Fractions***

This study was not conducted or reported in compliance with the US EPA GLP standards. The field trials were supervised by Monsanto and analysis of samples was performed by Monsanto Co. St. Louis MO. Processing Canola seed was performed by Texas A&M University; Bryan, TX.

Eight trial sites were selected within Canada encompassing a variety of geography, soils and climates. Eight test plots were established at each trial site: 2 untreated (control) and 6 treated. Two proprietary Roundup® tolerant canola lines were planted at each location and identified by the code numbers RT-73 and RT-200. One untreated plot and three treated plots were planted for each canola line at each trial site. Roundup® (EPA Reg # 524-308) was ground applied as a broadcast treatment to separate plots at target rates of 0.45 kg ae/ha postemergence, 0.90 kg ae/ha late postemergence and 1.8 kg ae/ha preemergence + 0.90 kg ae/ha early postemergence + 0.90 kg ae/ha late postemergence. Spray volumes ranged from 61.5 - 113.8 l/ha. Plot sizes ranged from 90-111 square meters. The untreated test plot was located 60 meters from the nearest treated test plot. Fifteen meters separated treated test of different application rates.

Canola seed samples were collected by harvesting whole plots (minimum of 6kg) and freezing immediately. Canola seeds collected from test plots at each location were separately analyzed for glyphosate residues. The canola seed used for processing was a composite of seed from each location with similar treatment rates. A subsample of this composite was taken prior to shipment to the processor and analyzed. Just prior to processing, another subsample of unmilled canola seed was taken and returned to Monsanto for analysis.

Canola seed was processed to simulate commercial practice. Canola seed was dried and cleaned (aspiration and screening). The kernels were flaked, heat conditioned, and pressed in an expeller for the purpose of liberating a majority of the crude oil. The residual crude oil remaining in the solid material (presscake) exiting the expeller was later extracted with hexane. The solvent extracted presscake (meal if ground to a finer size) was desolventized. The crude oil recovered from the expeller and solvent extraction was combined and refined.

Glyphosate residues were recovered and quantified using US PAM Vol II method I. For the analysis of the raw agricultural commodity and processed fractions, seed from only one untreated check and two treated plots (0.45 & 0.90 kg ae/ha) were analyzed. The seed from the Roundup® tolerant canola line RT-73 was selected since it possessed the best combination of tolerance and agronomic traits. Due to suspected contamination of the 0.45 kg ae/ha treated seed during the initial processing step, the processed fractions from this seed were not analyzed. The glyphosate residue data is summarized in Table 23.

Table 23: Glyphosate Residues; Canola Processing Fractions

commodity	application rate (kg ae/ha)	glyphosate (ppm)	concentration factor
canola seed	0.45 0.90	not found 0.016	-
unmilled canola seed	0.90	0.032	2.0
canola meal	0.90	0.030	1.9
canola crude oil	0.90	not found	-
canola refined oil	0.90	not found	-

During the metabolism study a second metabolite of glyphosate was identified in canola seed, N-glyceryl-AMPA. This compound was present in canola seed at a ratio of approximately 2:1 AMPA to N-glyceryl-AMPA. The metabolism study also indicated that there is no N-glyceryl-AMPA present in the oil fractions. Based on the 2:1 ratio and absence of N-glyceryl-AMPA in the oil fraction, N-glyceryl-AMPA theoretical concentration in canola meal would be 0.24ppm at a treatment of 0.90 kg ae/ha.

HED's Response:

MRID 43807203; *Glyphosate Residues in Canadian Canola Raw Agricultural Products and Processed Canola Fractions* presented all quantitative data associated with samples, including sample weights, extraction volume, aliquot volumes and final extract volumes. Representative chromatograms were given along with associated calibration standards. This study involved the use of Roundup® tolerant canola. Preharvest intervals ranged from 87 - 111 days. As a result, glyphosate residues in/on canola seed and canola milling fractions were all below the LOQ.

MRID 42312803, *Residue Analysis for Glyphosate and AMPA in Brassica Seedcrops and Processed Fractions Following Preharvest Roundup® Herbicide Treatments*, summarized European studies conducted to determine glyphosate residue in/on canola seed and processing commodities. The data was reviewed (memo D. Davis, 29-Sept-93) and found to be lacking information allowing the reviewer to adequately assess the field, sampling, processing and quantitative procedures. The data presented in MRID 42312803 will now be considered valid for the following reasons, **(1)** the similarity in the reported canola seed glyphosate residues in MRIDs 42312803 & 43827801, **(2)** confirmation that the analytical method used was US PAM Vol. II method I and **(3)** the study was conducted pre-GLP and the type of detailed information required under this regulation was not normally included in reports. The processing data for MRID 42312803 is summarized in Table 24.

Table 24: Glyphosate Residues; Canola Processing Fractions

sample ID	rate (kg ae/ha)	grain (ppm)	meal		crude oil (ppm)	refined oil (ppm)
			ppm	conc. factor		
UK-Bottisham 1982/15 Rp	1.44	0.16	0.34	2.1	<0.05	<0.05
	2.88	0.48	3.37	7.0	<0.05	<0.05
UK-Easton Cambs 1982/15 site 1	1.44	1.48	1.74	1.2	<0.05	<0.05
	2.88	3.20	4.87	1.5	<0.05	<0.05
UK-Easton Cambs 1982/15 site 2	1.44	2.74	3.07	1.1	<0.05	<0.05
	2.88	3.98	8.88	2.2	<0.05	<0.05

No concentration of glyphosate was noted during the processing to crude or refined oil. The average concentration factor for canola meal was 2.5. The maximum theoretical concentration factor for canola meal is 1.9 (OPPTS Test Guidelines; 860.1520). Using the theoretical concentration factor and the single highest glyphosate residue for canola seed of 6.3 ppm (Finland, 1981), HED concludes that an import tolerance of 15 ppm, as a result of the preharvest application of Roundup® as defined in the petition, is appropriate. A revised Section F is required.

Deficiency - Conclusion 7f (memo D178843, D Davis 9/29/93)

7f. **Barley Processing Study** - CBTS concludes that it is appropriate to translate data from a wheat processing study to barley milling fractions. We further concur that a 3X concentration factor for barley milling fractions (exec. flour) is appropriate. Provided the petitioner is able to support a tolerance for barley grain of 20ppm, we tentatively conclude that a tolerance of 60 ppm for barley milling fractions (excluding flour) is appropriate. If the final tolerance expression for barley grain is amended, the corresponding processed commodity tolerance is subject to revision.

Petitioner's Response: none

HED's Conclusions:

The 3X processing concentration factor for barley milling fractions was derived from a wheat processing study (MRID 00150835) in which glyphosate and AMPA residues were combined. The Agency no longer considers AMPA of toxicological significance and it is no longer included in the tolerance expression for glyphosate. The glyphosate residues and concentrations factors from MRID 00150835 are presented in Table 25.

Table 25: Glyphosate Residues; Wheat Milling Fractions

location (rate)/fraction	glyphosate (ppm)	concentration factor
Tennessee (1.90 kg ae/ha)	-	-
whole grain	0.67	-
wheat bran	1.66	2.48
break flour	0.14	0.21
reduction flour	0.12	0.18
shorts	1.20	1.79
Missouri (16.30 kg ae/ha)	-	-
whole grain	66.6	-
wheat bran	121.2	1.82
break flour	22.8	0.34
reduction flour	22.8	0.34
shorts	94.7	1.42

No concentration of glyphosate was noted in the wheat flour milling fractions. The average concentration factor for wheat bran was 2.15. Using this concentration factor and applying it to the highest single glyphosate residue for barley grain of 14.0 ppm (UK, 1980, trial agric. inst.), HED concludes that an import tolerance of 30 ppm for barley bran, as a result of the preharvest application of Roundup® as defined in the petition, is appropriate. As concentration in pearled barley is not expected, a tolerance on this commodity is not required. A revised Section F is required.

Deficiency - Conclusions 8a & 8b (memo D178843, D Davis 9/29/93)

8a Provided the petitioner is able to support tolerances for barley grain, rape meal and peas at the levels proposed in this petition (barley grain at 20 ppm, rape meal at 25 ppm and peas at 5 ppm), CBTS tentatively concludes that the existing tolerances for poultry kidney and liver and swine kidney and liver are adequate to cover the secondary residues of glyphosate likely to occur in poultry and swine as a result of this use. However, if the final tolerances are established at levels higher that currently proposed, this conclusion is subject to revision.

8b CBTS concludes that, given the potential increase in dietary burden for livestock grazing on glyphosate treated crops, the existing ruminant tolerances may not be adequate to cover secondary residues of glyphosate in animal commodities. The petitioner is advised that this deficiency may be addressed by 1) including restrictions prohibiting grazing and feeding of the treated commodities, 2) demonstrating that treatment of the crops renders them unfit for livestock consumption, 3) conducting a decline study to determine the residues present in/on forage, vines, straw or hay from treated crops and their respective rates of decline, and incorporating feeding or grazing restriction intervals to prevent grazing of the treated crop parts until residues have fallen off to the extent that their ingestion will not likely increase the dietary burden or 4) determining the residues present in/on forage, vines, straw or hay from treated crops, and , in lieu of additional feeding or grazing restrictions, conducting a new feeding study at the appropriate level and proposing increased tolerance levels and/or new tolerances based on the study results. (See the *Meat, Milk, Poultry and Eggs* section of this review for additional details.)

Petitioner's Response:

The Agency concluded that existing ruminant tolerances may not be adequate to cover secondary tolerances on animal feed commodities since they are used on-farm and it would be extremely unlikely that they will enter channels of trade in the US. For the same reason, Monsanto believes that secondary residues in animal commodities should not be of concern for an import tolerance since it is very unlikely that meat products will be imported into the US.

In addition, Monsanto has conducted animal feeding studies at levels up to 400ppm (MRIDs 40532001-3), which is above the maximum residue level expected in animal feeds. We have also petitioned the Agency to increase the tolerances on cattle, goat, hog, sheep and horse kidney to 4ppm (Pesticide Petition No 4F312); to increase the tolerances on poultry liver and kidney liver to 1ppm (PP No. 8F3673). We believe these increased tolerances adequately address any concerns the Agency may have had about secondary residues in animals.

HED's Conclusions:

The maximum glyphosate residue level in/on cereal straw was 210 ppm. This, combined with the tolerances on legume vegetables group (excluding soybeans), canola meal and barley grain, will not significantly increase the dietary burden on foreign animals as compared to the dietary burden of US animals resulting from registered domestic uses of glyphosate. This deficiency has been resolved.

Deficiency - Conclusion 9 (memo D178843, D Davis 9/29/93)

9. The Residue Chemistry Chapter of the RED indicates that residues of glyphosate and its metabolite, AMPA are stable under frozen (-20°C) storage conditions in or on plant commodities for a period of 1 year and in animal commodities for two years. Provided the requested sample storage dates and conditions are provided and samples were not stored in excess of the time period indicated above for stability, no further storage stability is required for this petition. However, if samples were stored under different conditions, or for longer intervals, either additional storage stability data or new field trials may be required.

Petitioner's Response:

Although the RED stated that the residues of glyphosate are stable under frozen conditions for 1 year in plant commodities, the Agency has more recently concluded that glyphosate residues are stable for at least 2.5 years under frozen storage and perhaps for several years beyond. A copy of the EPA memorandum is attached (C. Eiden, 17-Nov-94). A review of the detailed residue data enclosed with this submission demonstrates that the samples were analyzed within this time frame and therefore no additional storage stability data should be required.

HED's Conclusions:

The following is a summary of C. Eiden memo, 17-Nov-94.

> Date submitted to the Agency for the establishment of tolerances of glyphosate on plums, grapes and sugar beets, was initially analyzed by Craven Laboratories and then reanalyzed 48-63 months later. To support this long storage time, Monsanto provided a storage stability study on glyphosate in five different crops (corn, sorghum straw, clover, tomato and soybean forage) using fortified samples placed in frozen storage at -18°C. The samples were analyzed at periods ranging from 0 to 31 months. The results indicated the glyphosate did not degrade or degraded very slowly over time under the conditions of storage. Remaining glyphosate residues were

between 105% and 72% of the initial fortification level on the various crops at the end of 31 months time.

To further clarify this point, linear regression analysis were performed on the fortified sample residue data for glyphosate on several crops. The results show that the variation in the percent recovery values for the crops tested cannot be explained fully by a relationship with time. It is likely that instrument, analytical and operator errors may be causing the variation in the percent recoveries for glyphosate residues over time. The data indicate that the glyphosate residues in theses frozen fortified samples are stable or degrading slowly within 31 month's time. Extrapolations to the 60 month time point indicate that even after five years, glyphosate is stable or degradation is occurring very slowly.

Although there is no definitive study tracking the decline or stability of glyphosate (weathered or fortified) in crops over a five year period there is a body of evidence that glyphosate residues persist for several years on several crops under frozen storage.

MRID 42807202 barley grain and straw was initially analyzed by Craven Laboratories and then 51 months later by Enviro-Test Laboratories. Residue data from both laboratories were presented. Enviro-Test glyphosate residues in/on barley grain was consistently less and averaged 80.22% ±12.97 of that determined by Craven. Enviro-Test glyphosate residues in/on barley straw was nearly the same and averaged 98.23 ±19.42 of that measured by Craven. The consistency of the Enviro-Test data relative to the Craven Data as well as the C. Eiden memo leads to the conclusion that the samples did not experience any significant degradation during the 51 months from harvest to analysis. The requested information has been provided and this deficiency resolved.

Deficiency - Conclusion 10 (memo D178843, D Davis 9/29/93)

10. Codex limits are established for glyphosate *per se* on barley at 20 ppm and rapeseed at 10 ppm. HED metabolism committee has decided that the AMPA metabolite does not need to be regulated, however, the current tolerance expression includes both the parent compound, as well as the AMPA metabolite. In addition the petitioner has expressed a desire to retain the AMPA metabolite in the tolerance expression. Issues surrounding the inclusion of AMPA in the tolerance expression will have to be resolved prior to a final conclusion on Codex harmonization for barley and rapeseed. There are no Codex limits for peas or lentils, so harmonization is not an issue for those commodities

Petitioner's Response:

At the time the Agency's letter was written, there were still some issues surrounding the inclusion of AMPA in the tolerance expression for glyphosate. Since that time, however, Monsanto has agreed with the Agency's position to remove AMPA from the tolerance expression.

HED's Conclusions:

This deficiency has been addressed and resolved.

cc: PP# 2E04118, PP# 2H05650, T. Bloem (RAB1)
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