DOC B

Complete list of comments and other documents on glyphosate draft assessment report (Round 7)

from	Section ECCO 85 Overview Meeting	ECCO 76 Phys Chem Properties	ECCO 80 Fate and Behaviour	ECCO 84 Ecotoxico-logy	ECCO 78 Mammalian Toxicology	ECCO 82 Residues
Cheminova/ Monsanto Belguim		X			X	
Monsanto Belgium		X	X	X	X	X
BE					X	
DE					X	X
FI			X	X	X	
FR					X	X
GR					X	
NL			X	X	X	X
UK	X				X	X
European Commissio n Belgium				X		X
ECCO 76			X		X	
Mr Bruce UK				X		X
Mr Declercq France						X
Mr Bruno Germany	X					
Mr Flynn UK	X					

from	ECCO 85 Overview Meeting	ECCO 76 Phys Chem Properties	ECCO 80 Fate and Behaviour	ECCO 84 Ecotoxico-logy	ECCO 78 Mammalian Toxicology	ECCO 82 Residues
Mr Haenel		X				
Mr Solecki Germany					X	
Mr Sorzer Germany						X
Worldwide Fund for Nature				X		

DOCUMENTS ON GLYPHOSATE DRAFT ASSESSMENT REPORT

Section: Overview Meeting (ECCO 85)

Comments

NONE

Other documents

NONE

Additional information considered at the meeting but not included in this report

Date	Supplier	Content	ECCO.Ref.No.
October 1999-	Mr Bruno	Revised list of supported uses	6682/ECCO/PSD/99
October 1999	Mr Flynn	Recent UK press releases	6681/ECCO/PSD/99

DOCUMENTS ON GLYPHOSATE DRAFT ASSESSMENT REPORT

Section: Identity, Phys. Chem. Properties, Methods of Analysis (ECCO 76)

Comments

Date	Supplier	ECCO Ref No.
12 February 1999	Monsanto/Cheminova	6275/ECCO/PSD/99
4 March 1999	UK	6276/ECCO/PSD/99
4 March 1999	UK	6277/ECCO/PSD/99

Other documents

Date	Supplier	Content	ECCO Ref No.
March 1999	Ms. Gillespie	Glyphosate - A summary of the manufacturing routes	Not applicable as confidential
March 1999	Mr. Haenel	Glyphosate - Table C.1.2.2 Impurity profile from different manufacturers	Not applicable as confidential
March 1999	Mr. Haenel	Glyphosate - table showing completeness of the data package for each product	6310/ECCO/PSD/99

(76)

Monsanto Life Sciences
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium
Tel number: +32 2 776 41 99
Fax number: +32 2 776 48 69

Registration Department

Date : February 12, 1999

From : **Hilde Van Parijs**

FACSIMILE TRANSMISSION

To	Company name	Location	Fax number
	ECCO-TEAM PSD	York	+44 19 04 45 57 22
Dr. Bruno	ECCO-TEAM BBA	Braunsschweig	+49 5 31 2 99 30 03

This fax contains page(s) (including this one). Please call Sender +32 2 776 4199, if you do not receive all the pages.

P.S.D.
15 FEB 1999
I.D. No. 54854

URGENT MESSAGE:

Re: EC evaluation of Glyphosate (according to regulation EC Nr 3600/92 and concerning inclusion of the active substance Glyphosate in Annex I of Directive 91/414)

Dear Sirs,

Attached is a copy of the Monsanto/Cheminova comments on the second draft of the Monograph on Glyphosate.

We have sent as well full copies (relevant appendixes + separate confidential folder) of the comments
- 4 copies to BBA
- 1 copy to PSD

Yours sincerely,

Hilde Van Parijs
Registration Correspondent

6275/ECCO/PSD/99

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Monsanto Services International S.A./N.V.
Avenue de Tervuren 270-272
Tervurenlaan 270-272
Letter Box n°1
B - 1150 Brussels Belgium

☎ direct (+32) 2 776 4607
Fax direct (02) 776 4869
e-mail:USERID@Monsanto.com

Cheminoca Agro A/S
P.O. Box 9
DK-7620 Lemvig
Denmark

☎ (+45) 96 90 96 90
Fax (+45) 97 83 45 55
Telex 66514 CHEMV DK

ECCO-Team (BBA)
Biologische Bundesanstalt für Land- und Forstwirtschaft
Abteilung für Pflanzenschutzmittel und Anwendungstechnik
Messeweg 11/12
D-38104 Braunschweig

PSD ref.: PRD 3624
Our ref. : RPG/hvp

Brussels, February 11, 1999

URGENT

Dear Sirs,

Re: EC evaluation of Glyphosate (according to regulation EC Nr 3600/92 and concerning inclusion of the active substance Glyphosate in Annex I of Directive 91/414)

Please find enclosed our comments on the second draft of the Monograph on Glyphosate. The major point from our review are:

a) We do not believe that Glyphosate is explosive.
b) An anaerobic metabolism study is not needed as the use on rice is to bare soil, before planting the rice.
c) Beneficial insect laboratory studies are affected by the "sticky nature" of the dried deposit.
d) We have a disagreement on the impact of Glyphosate on aquatic organisms.

We have done the best we can, within the time allocation for review, and look forward to further discussion on the data.

Yours sincerely,

Richard Garnett

R.P. Garnett
Registration Manager, Glyphosate

cc: ECCO-Team (PSD) - York

attachments

GENERAL COMMENTS

We suggest that the evaluation should establish a principle for the acceptance of data. Some pivotal studies are utilised where a company's compositional data shows incomplete analysis, i.e. unidentified impurities. The dosing levels for glyphosate studies are so high that slight variations in manufacturers impurity patterns may contribute to the variation in toxicological results which can be seen in the monograph. We would recommend that to be used for any critical endpoint the study concerned should be classified as "Acceptable" and the test material adequately defined, in terms of purity, impurities and description.

There are two main manufacturing routes for glyphosate, one called the Glycine process and the other the IDA process. Although they both produce >95% pure material the impurity profiles are different, and because the toxicological studies have been carried out at extremely high dose levels the significance of the impurities increases.

In a similar manner glyphosate formulations are available with a wide spectrum of Risk and Safety phrases because the major source of toxicological impact comes from the additional components, not glyphosate itself. It follows that critical endpoints for glyphosate which are based on formulation studies, such as ecotoxicological studies, should be considered by the Member States when they assess specific formulations, provided, for the purpose of Annex I listing it can be demonstrated that at least one formulation is within the acceptable limits.

We have given as many comments as possible in the limited time available but may not have covered all the items. We will continue to work on the document.

We are discussing with the rapporteur the most appropriate means of supplying additional data that have become available since the submission was first made - See Appendix I.

Volume 1, Level 1, Statement of Subject Matter and Purpose of Monograph

1.3.7 Manufacturer or manufacturers of the active substance

We believe that a number of the "Manufacturers" quoted in the list are in fact traders and have no manufacturing facility of their own. If they are just traders should they be included in the process? As a minimum we would suggest they have to declare their sources and the process.

We would like to add the following source of Monsanto material to the list of manufactory plant:

MONSANTO SAO JOSE DOS CAMPOS PLANT
AV. CARLOS MARCONDES, 1200
12241-420 SAO JOSE DOS CAMPOS-SP
BRAZIL

TEL : +55 123 327100
FAX : +55 123 327199

1.3.10 Identity of isomers, impurities and additives

In conjunction with FAO we have submitted new specifications to comply with the new requirements for the establishment of FAO specifications. These will be considered at their meeting of 29th June 1999. As a result of the batch analyses carried out on material from our manufacturing plants, there are some slight amendments to our original submission. The new levels are disclosed in CONFIDENTIAL Appendix A.

1.3.11 Analytical profile of batches

As mentioned in 1.3.10 we have carried out recent analyses of our material and the results are attached in CONFIDENTIAL Appendix A - see section "impurity profiles Monsanto glyphosate".

1.5.4-1 Information on the approvals in the EU

Information on the approval in EU for Cheminova's glyphosate products is missing. This is now provided in Appendix J.

The tables for Austria and Belgium were missing from our copy but we assume this is just a copying error as they were included in the original draft.

We submitted the data below for Denmark on a previous occasion and the compounds noted below for France all have 10 year registrations. The product concentrations for Sweden and Greece should be amended as indicated.

Denmark			
Roundup 2000	48-9	SL 400 g/l	1991-1999
Marvel	48-10	SL 120 g/l	1991-1999
Roundup 480	48-15	SL 480 g/l	1991-1998
Roundup Spray	48-19	SL 7.2 g/l	1994-1999

France
Roundup Geoforce, Roundup Bioforce, Roundup360, Hockey Pro, Spasor A, Aristo TS, Durano TX, Honcho TS, Roundup Acti, Nomix Agri 2000, Roundup Alphee, and Ragtime -- all have 10 year registrations in France.

Sweden	
Roundup Bio	SL 360 g/l
Roundup Garden	SL 120 g/l
Roundup Spray	AL 7.2 g/l

Greece	
Roundup Armada	SL 90 g/l

1.5.4-2 Approvals in the EU

The "Details of Intended Uses", Table 1.5.3-1, should be amended with the following uses which are approved in the countries indicated (see also annotated table Appendix B):

Citrus Fruit	Application rate: 0.54-4.32 kg as/ha
Pome and Stone Fruit	Application rate for Southern Europe: 0.54-4.32 kg as/ha
Almonds	Add use in Greece as indicated in Appendix B
Rape Seed	Pre harvest: application rate 1.08-1.44 kg as/ha Harvest Management: application rate 1.08-1.44 kg as/ha Add Germany to countries
Linseed	Pre-harvest: add Germany to countries Harvest Management: application rate 0.36-1.08 kg as/ha Add Germany to countries
Winter wheat, durum wheat, barley, oats	Add use as indicated in Appendix B
Maize	Delete Greece
Sugar Beet	Delete Greece
Annual spring crops	Application: add inter-row equipment Application rate: 0.54-3.6 kg as/ha Max application per season: 3.6 kg as/ha
Stubbles	Spring use: add UK to countries, delete Greece
Stubbles of various crops	Add cotton to list of crops (Greece only)
Conifer sites	Application after finish of shoot elongation: • add SG to first line • second line: application rate 0.54-1.08 kg as/ha, UK only

Home & Garden	- First line (all EU countries): water l/ha 400-700 - Insert second line for watering can application in all EU countries: water l/ha 1600-5000, otherwise as for sprayer Add watering can in same way for SG formulation Ready to Use Italy: 0.72 kg/hl
Railway	Application rate: 0.54-4.32 kg as/ha
Drains	Amend drains to "Drains - only when dry" Add Greece below Italy
Other non-crop land	Southern Europe: application rate 0.54-4.32 kg as/ha
Flower, poplar, shrub, ornamentals	Add all EU countries
Glyphosate tolerant crops:	
Maize	Growth stage 1-10 leaves for N and S Europe
Soya bean	Max/season 2.16 kg as/ha (ie 2 x 1.08 kg as/ha)

Volume 1, Level 2, Overall Conclusions

2.1 Identity

We note that several notifiers have not checked for N-nitrosoglyphosate in their technical active substance and in their plant protection products. Regulators may also wish to verify appropriate step are taken to ensure that specifications of raw materials used in the preparation of plant protection products eliminate the possibility of introduction of nitrosation agents.

The required information on propoxylation and ethoxylation is submitted in CONFIDENTIAL Appendix C.

2.2 Physical Chemical Properties

The statement: "The solubility is enhance by isopropylamine, NaOH, and NH_4OH" is not entirely correct. These basic substances react chemically with the acid moiety to form a more soluble salt.

We cannot accept the conclusion that glyphosate acid and isopropylamine salt are explosive.
The 62% isopropylamine salt is a viscous aqueous liquid, which if explosive would be a very unusual result considering the solid isopropylamine salt was not explosive in our tests. The author who obtained the strange result with the isopropylamine salt also carried out the work with Glyphosate acid which gave a positive result; was the salt made from the same technical batch, and what is the mystery unidentified 1% in the technical material of the notifier who sponsored this work? It is also noteworthy that the same author in testing the formulation of the notifier concluded "Glyphosan 360SL was found to be slightly sensitive to mechanical sensitivity with respect to shock". None of our formulations have shown this type of result.
All of the other explosivity tests on the salts gave negative results and from practical experience Monsanto, having made hundreds of thousands of tons of glyphosate acid, have never had an explosive event involving the product in its finished state.
We would suggest that the data be examined carefully to see if the result is correct. If it appears valid then we suggest that the impurities in the technical substance are the likely cause, and that each manufacturers material should be classified separately. If a manufacturer has no data available then it should be classed as a "Manufacturer's Data gap".

A long term storage stability study for MON 44068 and a dilution stability study for MON 52276 has been submitted - See Appendix H for details.

2.3.1 Statements to Application

page 5 paragraph 5.

In 1996 in Australia, it was reported that a biotype of annual rye-grass (*Lolium rigidum*) was surviving label recommended rates of glyphosate. After examination of greater than 500 samples, only two locations have been confirmed as having the resistant population, indicating the phenomenon is not wide spread. A large body of biochemical and molecular biology experiments indicate that the observed resistance is likely due to a combination of factors. Preliminary conclusions drawn to date are that the resistant biotype is easily controlled by conventional practices (tillage, other herbicides), and caused by a complex inheritance pattern, unlikely to occur across a wide range of other species. It should also be noted that glyphosate remains an effective weed management tool in the areas where this resistant population was identified for control of the many other species and cropping systems used there.

We thoroughly investigated any alleged incidences of resistance.

page 5 paragraph 7 please amend to;
"An application for cotton was made in Spain in 1998."

2.4.3 AOEL

We find the process the Rapporteur has used to establish a systemic AOEL interesting and outside our normal experience. The resulting figure (0.22 mg/kg/day systemic) must then always be paired with a figure for the dermal penetration of a given preparation to assess acceptability. The key is to ensure that the concept of systemic exposure is tightly linked to this AOEL figure, and We are concerned that this may not always be scientifically understood and followed by all regulators who may rely on the EU monograph as the basis for their regulatory decisions. For instance, in Section 3.1 (Volume 1, Level 3), the AOEL figure is described by the Rapporteur as 0.2 mg/kg bw/day without any reference to the need for the dermal penetration calculation. Similarly, in Volume 3 (1 of 4) B.5.14.3, when the Rapporteur is comparing existing worker reentry exposure data to the AOEL, the dermal penetration correction was not employed, and it was concluded "The comparison with the systemic AOEL of 0.2 mg/kg bw/day, proposed by the Rapporteur, shows that this value would be exceeded for a worker entering crops after spraying for a full working day." Had the established upper estimate for dermal penetration (3%, Volume 1 Section 2.4.1) been included, the opposite conclusion that reentry does not exceed the AOEL would be reached. This example illustrates how incorrect conclusions can arise from use of the approach proposed by the Rapporteur.

We request that the Rapporteur include a more detailed discussion of the process that should be utilised by Member States and others so as to help guard against possible misinterpretations. The Rapporteur suggests that dermal penetration is 3%, allowing that dermal deposition of a glyphosate formulation during application would be acceptable if it were 7.5 mg/kg bw/day or less. Perhaps the monograph should cite both figures for added clarification.

2.5.3 Methods for Residue Analysis

We agree with the Rapporteur's position that "glyphosate" is the only residue of concern in the great majority of situation involving plants and animal products. Section 2.6.1 properly clarifies that glyphosate-tolerant plants to which an enzyme (GOX) has been intentionally added as a mechanism of providing glyphosate tolerance can also contain significant residues of AMPA, and that MRLs may be required in those situations. The phrase "containing the GOX plant enzyme" could be added to the last sentence on the 3rd paragraph of 2.5.3 to further clarify when the method needs to allow for AMPA residue determinations.

2.6.1 Residue Definition

We agree with the Rapporteur's position that "glyphosate" is the only residue of concern in the great majority of situation involving plants and animal products. In glyphosate-tolerant plants, there may be a need to establish MRLs for AMPA in situations where this is the prominent or exclusive residue, in order to monitor for Good Agricultural Practice. We do not understand reason for the comment that MRLs may be needed for animal products, since AMPA is not of toxicological concern, and there is no GAP to monitor in this case.

2.7.3 Compliance with existing MRLs

The open positions have been closed for olives, beans, peas and mustard seed in 98. We will submit the data again to comply with directive 91/414/EEC - see Appendix H "reference list of submitted reports".

We believe that for soybeans and cotton tolerant to glyphosate, there is sufficient residue of glyphosate "per se" present in treated commodities to conduct safety evaluations and to determine whether GAP has been followed. There is no need to establish separate MRLs for AMPA in these cases. The need for AMPA MRLs should be limited to cases where the GOX enzyme, or a similar glyphosate-degrading enzyme, has been intentionally introduced, thereby converting most or all of the residue into AMPA.

Volume 1, Level 4, Demand for Further Information

4.1 Data which are necessary for unrestricted inclusion in Annex I

Method of Analysis

A revised non-chloroform analytical method for glyphosate and AMPA in animal tissues has been completed and will be submitted - See Appendix I "Reference list of new reports to be submitted".

Residue data

Descriptions of intended uses

Berries and small fruit

- **selective in-crop treatments** for all crops listed: applications are based on selective application techniques. Weeds are treated in the inter-row only using a directed spray, drop boom or weed wiper.

Vegetables (bulb, stem and field)

- **pre-emergence** uses are self explanatory
- **post emergence** uses are based on selective application techniques using weed wipers. These allow precise placement of the herbicide on weeds growing between the rows of the crop, or on weeds which are significantly taller than the crop, without contacting the crop itself.
- **post harvest** use in asparagas: perennial weeds, particularly grasses, can be treated selectively when they are actively growing after harvesting the asparagas, when all surface growth of the crop has ceased and senesced.

Forestry

Forestry can be divided into the following areas of use:

- **pre planting treatments**: either as spot applications or overall applications to clear weed growth prior to planting. This may be new land being prepared for forestry or preparation for re-planting old forestry areas.
- **post planting, over the top treatments**: tree species specified on the labels can be sprayed over the top during the dormant season; *i.e.* a selective in-crop treatment. The dormant season varies with location, climate and species, and is defined in the label recommendations.
- **post plant, directed applications**: all species of trees can be treated selectively by directing the herbicide onto weeds without treating the leaves or young shoots of the trees. This may be by directed sprays, drop booms or by placement using weed wipers.
- **forest management techniques**:
    - chemical thinning of standing trees or saplings: these can be removed selectively within a forest or woodland by injecting the herbicide into the trunk. This may be by a specific injection tool or by cutting into the stem with a hatchet and placing the herbicide into the cut.
    - chemical thinning by cut stump treatments: regrowth following felling can be prevented by treating the cut stump with herbicide soon after felling.

Maize

- In crop application directed spray between crop rows for the control of annual and perennial weeds at doses from 0.54-3.6 kg as/ha according to weeds species.
- Following harvests in stubble's and pre-plant.

Ecotoxicology

We will provided additional data and information to prove the limit value of Annex VI is not exceeded.

4.2 Documents which should be required by Member States for the assessment of plant protection product

Identity of the Plant Protection Product

CAS numbers are given in the CONFIDENTIAL Appendix F

Physical and Chemical properties

We will carry our studies on the solubility of the salts, although we do not think that is pivotal. The data on the acid already exists.

The MON 52276 dilution stability study has been submitted, for full details see Appendix H "reference list of submitted reports"

Environmental Fate and Behaviour

Annex II, Part A, Points 7.1.1.2 and 7.1.1.2.1
An anaerobic metabolism study in soil should not be needed since the use in rice cultures is only preemergent or after harvest. At these times, water is not present at the time of treatment, so the soil is not anaerobic. Information on the breakdown of glyphosate under anaerobic conditions in water / sediment conditions have been provided in Brightwell (1978) and in Kesterson and Jackson (1990) to account for processes that might occur in soil which is flooded after application. The results show that glyphosate conversion to AMPA and CO_2 occurs under both anaerobic and aerobic conditions, so there is no basis for concern that unusual conversion s might occur in rice culture.

The glyphosate applied to rice paddies prior to flooding is expected to bind tightly to soil, and there will be none in the water, so no PEC estimation is needed. (Annex III, Part A, Point 9).

Annex III, Part A, point 9
Rice culture: we will provide a report about PEC estimations for surface water.

Annex III Part A, point 9
Railway uses: we are attempting to obtain access to this data from the German Railway authority. We understand that this data is now directly available to the UBA and BBA.

Other Comments

Volume 2, Part A, Annex A, List of tests and studies
The Monsanto/Cheminova Joint dossier contains proprietary Monsanto and Cheminova studies.
In the reference list of the Joint dossier, the ownership status is for each study indicated by specifying the submitter (example from reference list is attached - see first page of Appendix K).
In the monograph reference list, most Cheminova studies are mistakenly specified as Monsanto studies.
We attached pages from the reference list to be corrected - see Appendix K.

Volume 3 (1 of 4) B.2.2.7.3 Storage Stability of MON 44068:
The storage stability on MON 44068 in representative packaging has been submitted, for full details see Appendix H "reference list of submitted reports".

Volume 3 (1 of 4) B.2.2.1 Appearance of MON 52276:
Since it is a water solution, the term "oily liquid" might be better replaced with "viscous liquid".

Volume 3 (1 of 4) B.2.2.8.4 Dilution Stability of MON 52276:
The MON 52276 dilution stability study has been submitted, for full details see Appendix H "reference list of submitted reports".

Volume 3 (1 of 4) B.5.1.1 Absorption, Distribution, and Excretion of Glyphosate
See Monsanto comments see Appendix G.

Volume 3 (1 of 4) B.5.6.1.2
Schroeder and Hogan (1981). The Rapporteur commented on p. 102 about the study referenced by Agrichem. We submitted the 3-generation study of Schroeder and Hogan study to EPA on 31-Jul-1981. This was almost certainly the one referenced by Agrichem.

Volume 3 (1 of 4) B.5.6.2.2.2 Further Teratogenicity Studies in Rabbits
See our comments under point 2.4.2 ADI of this document.

Volume 3 (2 of 4) B.6.14.1.2 Calculation of TMDI
Some entries in Tables B.6.14-1 and B.6.14-2 appear to be erroneous or inconsistent:
Table B.6.14-1

1. (v) Berries and Small fruits. Entry for "other" under column "raw" should be 2.9 rather than 3.9 in order to sum with 6.1 to get 9.0.
1. (vi) Miscellaneous fruit. Entry for "others" under column "raw" should contain 21.3 in order to sum to 24.6.
8. Cereals. The figures under the column "processed" in the rows "bran, "flour" and "farinaceous pastes" sum to 100.7 not 101.7 as shown. Perhaps the entry for flour should be 92.7 rather than 91.7 in order to obtain the sum as shown.

Table B.6.14-2

1. (I) Citrus Fruits. The MRL proposed by the Rapporteur is 0.5 rather than 0.1. In order to make a comparable calculation, the higher value should be used.
2. (I) Vegetables - root and tuber vegetables was omitted. Comparison to Table B.6.14-1 suggests an entry should exist for this group.

Volume 3 (2 of 4) Section B.6.12 Proposed MRLs
Cotton (non-tolerant to glyphosate)
The submitted data for import tolerances for non-tolerant cotton should be considered, and a tolerance sufficient to cover both the tolerant and non-tolerant cotton established.

Volume 3 (3 of 4) Section B.7.1 Route and Rate of Degradation, p. 26
Error in summary table (rate of degradation) at top of page -
Soil #8 DT50 should be 180a)
Soil #9 DT50 should be <7

Volume 3 (3 of 4) Section B.7.2 Adsorption, Desorption and Mobility in Soil, p. 80
First line in table should be 'Total number of determinations made for glyphosate' (rather than total number with glyphosate >0.1 µg/L)

Volume 3 (3of 4) Table B.7.1.1
For the column labeled 'Sandy Loam (35 DAT)', change % glyphosate from 6.6 to 59.5, and % AMPA from ** to 6.6.

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List of appendixes

Appendix #
Referenced under
Confidentiality claim
Content

Appendix A
Volume 1, Level 1, Point 1.3.10 Identity of isomers, impurities and additives
Volume 1, Level 1, Point 1.3.11 Analytical profile of batches
CONFIDENTIAL
FAO specifications (dated January 1999)

Appendix B
Volume 1, Level 1, Point 1.5.4-2 Approvals in the EU
Non confidential
"Details of Intended Uses", Table 1.5.3-1 - annotated copy of the original table

Appendix C
Volume 1, Level 2, Point 2.1 Identity
CONFIDENTIAL
Information on propoxylation and ethoxylation

Appendix D
Volume 1, Level 2, Point 2.9.2 Effects on aquatic organisms
Non confidential
Presentation of a more detailed assessment of glyphosate effects on aquatic organisms

Appendix E
Volume 1, Level 2, Point 2.9.3.2 Effects on other arthorpods
Non confidential
Data package relevant to beneficial arthorpods toxicity of the formulation MON 52276 (Annex II Tier III format)

Appendix F
Volume 1, Level 4, Point 4.2 Documents which should be required by Member States for the assessment of plant protection product
CONFIDENTIAL
Identity of the Plant Protection Product - CAS numbers

Appendix G
Volume 3 (1 of 4) B.5.1.1 Absorption, Distribution, and Excretion of Glyphosate
Non confidential
An assessment of the relevance of Glyphosate bone localisation observation in the rat metabolism study.

Appendix H
Volume 1, Level 2, Point 2.2 Physical Chemical Properties
Non confidential
Reference list of submitted reports - (containing cross reference numbers)

Appendix I
Volume 1, Level 4, Point 4.1 Data which are necessary for unrestricted inclusion in Annex I
CONFIDENTIAL
Reference list of new reports to be submitted

Appendix #	
Referenced under	
Confidentiality claim	
Content	

Appendix J

Volume 1, Level 1, Point 1.5.4-2 Approvals in the EU
Non confidential
Information on the approvals in the EU for Cheminovas glyphosate products.

Appendix K

Volume 2, Part A, Annex A List of test and studies
Non confidential
Reference list - containing corrections with regards to the data ownership.

Appendix A

Volume 1, Level 1, Point 1.3.10 Identity of isomers, impurities and additives
Volume 1, Level 1, Point 1.3.11 Analytical profile of batches
CONFIDENTIAL
FAO specifications (dated January 1999)

Data not submitted here but separately as confidential data

Appendix B

Volume 1, Level 1, Point 1.5.4-2 Approvals in the EU
Non confidential
"Details of Intended Uses", Table 1.5.3-1 - annotated copy of the original table

Appendix C

Volume 1, Level 2, Point 2.1 Identity
CONFIDENTIAL
Information on propoxylation and ethoxylation

Data not submitted here but separately as confidential data

Appendix D

Volume 1, Level 2, Point 2.9.2 Effects on aquatic organisms
Non confidential
Presentation of a more detailed assessment of glyphosate effects on aquatic organisms

APPENDIX H

Reference list of submitted reports

Dossier file no.	Author(s)	Title, Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file no. of submitting company Date of report For publications : reference	GLP GEP	Published or not
Data submitted 04/95				
MON 52276 - Annex III, Part A, Section 1, Point				
2.8.4 (2.1/01 - resubm. 12/95)	Toussaint, M.	Dilution stability of MON 52276 : a water soluble concentrate (SL) of Glyphosate. Generated by : Monsanto LLN Submitted by : Monsanto Company Report number : F-95-52276-01 Date : november 1995	yes	no
Data submitted 04/95				
MON 44068 - Annex III, Part A, Section 1, Point				
2.1 /02	Campbell, C.N. Calierno, A.	MON 44068. Long-term storage stability of MON 44068 (metallised sachet). Generated by : Inveresk Research International Submitted by : Monsanto Company Report no. : 10499 Date : March 7, 1997	yes	no
	Campbell, C.N. Calierno, A.	MON 44068. Long-term storage stability of MON 44068 (cardboard box and polyester/SiO_2/PE foil liner). Generated by : Inveresk Research International Submitted by : Monsanto Company Report no. : 10498 Date : March 7, 1997	yes	no
Data submitted 04/95				
Glyphosate - Annex II, Part A, Section 4, Point				
6.3 /08	Michaux, M.	CP 67573 : Determination of crop residues in salads, onions, carrots, peas and beans. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : Agricultural Research Report A 16 Date : October 1977	no	no
6.3 /09	Michaux, M.	CP 67573 : Determination of crops residues in olives and olive oil. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : Agricultural Research Report A 20-II Date : February 8, 1978	no	no

Dossier file no.	Author(s)	Title, Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file no. of submitting company Date of report For publications : reference	GLP GEP	Published or not
6.3 /27	Mestdagh, P.	Glyphosate residues in peas following preharvest application with Roundup herbicide in the U.K. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.081 Date : June 2, 1982	yes	no
6.3 /35	Mestdagh, P.	Glyphosate residues in beans following Roundup herbicide preharvest applications. UK 1980/1982 and Denmark 1982 trials. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.109 Date : July 29, 1983	yes	no
6.3 /39	Mestdagh, P.	Glyphosate residues in peas following preharvest application with Roundup herbicide in Denmark and Belgium. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.131 Date : June 22, 1984	yes	no
6.3 /44	Reding, M.A.	Residual Glyphosate and AMPA in oilseedrape, beans and peas following application of MON 8762 - MON 8795 and Roundup herbicide. UK 1986 field trials. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.180 Date : January, 1987	yes	no
6.3 /46	Mestdagh, P.	Glyphosate and AMPA residues in oilseedrape and peas following preharvest Roundup herbicide applications. 1986-1987 field trials Fed. Rep. of Germany. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.204 Date : March 7, 1988	yes	no
6.3 /48	Reding, M.A.	Residue determination of Glyphosate and aminomethylphosphonic acid in various crops following different Roundup, or Glyphosate based formulation, applications. 1978-1987 trial period. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.206 Date : April 1988	yes	no

Dossier file no.	Author(s)	Title, Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file no. of submitting company Date of report For publications : reference	GLP GEP	Published or not
6.3 /51	Losseau, F.	Glyphosate and AMPA residues in oilseedrape (OSR), peas and beans following preharvest applications of MON 14478 with Ammonium sulfate (AS) in comparison to Roundup or Roundup 480 herbicide applications. 1988 UK field trials. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.223 Date : February 24, 1989	yes	no
6.3 /56	Hontis, A.M.	Residues of Glyphosate/AMPA in olives and olive oil following use of Sting SE - Spanish field trials 1990/1992. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.297 Date : June 5, 1992	yes	no
6.3 /57	Hontis, A.M.	Residues of Glyphosate and AMPA in olives and olive oil, following a soil treatment with MON 65040 herbicide. Italian field trials 1993. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30.319 Date : September 1993	yes	no
Data submitted 04/97 Glyphosate - Annex II, Part A, Section 4, Point				
6.3 (# not mentioned when submitted)	Hontis, A.M.	Residues of Glyphosate and AMPA in field beans (Vicia Faba) treated preharvest with MON 52276 herbicide. UK and Belgian field trial, 1995. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30463 Date : May, 1996	yes	no
6.3 (# not mentioned when submitted)	Hontis, A.M.	Residues of Glyphosate and AMPA in peas treated preharvest with MON 52276 herbicide. UK and Belgian trials, 1995. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30464 Date : May, 1996	yes	no
6.3 6.5 (# not mentioned when submitted)	Hontis, A.M.	Residues of Glyphosate and AMPA in olives and olive oil, following a soil treatment with Roundup® herbicide. Spanish field trials 1995. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30469 Date : May, 1996	yes	no

Dossier file no.	Author(s)	Title, Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file no. of submitting company Date of report For publications : reference	GLP GEP	Published or not
Data submitted 01/98				
Glyphosate - Annex II, Part A, Section 4, Point				
6.3.5/01	Hontis, M.A.	Residues of Glyphosate and AMPA in cotton containing Roundup Ready® genes, after multiple treatment with MON 52276 herbicide. Spanish field trials, 1997. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30762 Date : January, 1998	yes	no

APPENDIX I

Reference list of new reports to be submitted

Dossier file no.	Author(s)	Title, Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file no. of submitting company Date of report For publications : reference	GLP GEP	Published or not
Glyphosate - Annex II, Part A, Section 2, Point				
4.1	-	Analytical method for glyphosate and AMPA in cow tissues, raw cow milk and chicken eggs. Generated by : Monsanto Company Submitted by : Monsanto Company Report number : ES-ME-0073-01 Date : November 1998	yes	no
Glyphosate - Annex II, Part A, Section 4, Point				
6.3	Hontis, M.A.	Residues of Glyphosate and AMPA in cotton treated preharvest with Roundup® (MON 2139), Roundup® Plus (MON 60612) and MON 52276 herbicide. Spanish field trials, 1996. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30611 Date : June, 1997	yes	no
6.3	Hontis, M.A.	Residues of Glyphosate and AMPA in cotton treated preharvest with Roundup® (MON 2139), Roundup® Plus (MON 60612) and MON 52276 herbicide. Spanish field trials, 1997. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30763 Date : February, 1998	yes	no
6.3	Hontis, M.A.	Residues of Glyphosate and AMPA in sugar beet, *beta vulgaris spp.*, containing Roundup Ready® genes, after multiple treatment with MON 52276 herbicide. Belgian field trial, 1998. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30919 Date : January, 1999	yes	no
6.3	Hontis, M.A.	Residues of Glyphosate and AMPA in sugar beet, *beta vulgaris spp.*, containing Roundup Ready® genes, after multiple treatment with MON 52276 herbicide. UK and French field trial, 1998. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30918 Date : January, 1999	yes	no

Dossier file no.	Author(s)	Title, Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file no. of submitting company Date of report For publications : reference	GLP GEP	Published or not
6.3	Hontis, M.A.	Generation samples of soybean, containing Roundup Ready® genes, after multiple treatment with MON 52276 herbicide for protein expression and compositional analysis evaluations. French and Italian field trials, 1998. Generated by : Monsanto Company Submitted by : Monsanto Company Report no. : MLL 30914 Date : December, 1998	yes	no
Glyphosate - Annex II, Part A, Section 5, Point				
7.2	Palmer, R.C. Holman, I.P.	Soil and hydrogeological investigation of the water supply source of Llanthony, Gwent, UK.. Generated by : Soil Survey and Land Research Centre Submitted by : Monsanto Company Report no. : CON 82/4132 Date : August, 1997		
7.2	Kreuter, U.A. Kußmaul, H.	Verification and evaluation of glyphosate findings published 1994 in the Greenpeace Report "Pestizide im Grundwasser". Generated by : Institut Fresensius Gruppe Submitted by : Monsanto Company Report no. : Date : October, 1997		
MON 52276 - Annex III, Part A, Section 6, Point				
10.5.1	Kleiner, R.	MON 52276: (Final report 98 10 48 066) Testing toxicity to beneficial arthorpods Cereal aphid parasitoid - *Aphidius rhopalosiphi* (Destefani-Perez) (extended laboratory test) following the IOBC Guideline proposal (Mead-Briggs 1994). Generated by : BioChem Agrar Submitted by : Monsanto Company Report no. : XX-98-196 Date : December, 1998	yes	no
10.5.1	Kleiner, R.	MON 52276: (Final report 98 10 48 065) Testing toxicity to beneficial arthorpods Predatory mite - *Typhlodromus pyri* (Scheuten) (extended laboratory test) following the IOBC Guideline (Oomen 1988). Generated by : BioChem Agrar Submitted by : Monsanto Company Report no. : XX-98-195 Date : December, 1998	yes	no

Appendix J

Volume 1, Level 1, Point 1.5.4-2 Approvals in the EU

Non confidential

Information on the approvals in the EU for Cheminovas glyphosate products.

1.5.4-1 Information on the approvals in the EU

The tables do not include Cheminova Agro approvals.

Current Cheminova Agro approvals are listed below:

Member State	Trade Name	Reg. No.	Formulation	Year Reg./Expiry date
Belgium	Glyfos	8387/B	SL 360 g/l	1992 - 2002
Denmark	Kvikdown 360	11-10	SL 360 g/l	1995 - 2000
	Glyfonova 360	11-7	SL 360 g/l	1994 - 2000
	Glyfonova 400	11-8	SL 400 g/l	1994 - 2000
	Kvikdown 2000	11-11	SL 360 g/l	1994 - 2000
Finland	CHE 3607	13/470/92	SL 360 g/l	1995 - 2003
	EK 290 SF	15/470/92	SL 400 g/l	1995 - 2003
	Hankkijan Glyfos	14/470/92	SL 360 g/l	1995 - 2003
France	Glyfos Total	9100155	SL 360 g/l	1992 - 2002
	Glyfos	9100154	SL 360 g/l	1992 - 2002
	Arbalette	9400217	SL 360 g/l	1994 - 2004
	Potomac	9300354	SL 360 g/l	1994 - 2004
	Glyfos Jardin	9400495	SL 360 g/l	1995 - 2005
Germany	Glyfos	04162-00	SL 360 g/l	1996 - 2006
Great Britain	Glyfos	07109	SL 360 g/l	1995 - 2003
	Glyfos 480	08014	SL 480 g/l	1996 - 2003
	Glyfos Proactive	07800	SL 360 g/l	
	MSS Glyfield	08009	SL 360 g/l	
Greece	Clear	7465/94	SL 360 g/l	1994 - 1998
Ireland	Glyfos	P00464	SL 360 g/l	1994 -a.R. 1)
	Scutchout	P00769	SL 360 g/l	1994 -a.R. 1)
	Glyfos 480	P00767	SL 480 g/l	1994 -a.R. 1)
	Scutchout 480	P00802	SL 480 g/l	1995 -a.R. 1)
	Glyfos 180	P00714	SL 180 g/l	1994 -a.R. 1)
	Scutchout 180	P00761	SL 180 g/l	1994 -a.R. 1)
Italy	Klaro	9011	SL 360 g/l	1996 -unli. 2)
	Glyfos	8429	SL 360 g/l	1994 -unli. 2)
Luxembourg	Glyfos	1249-91	SL 360 g/l	1993 - 1998
Netherlands	Glyfos	11227 N	SL 360 g/l	1993 - 1998
Portugal	Glifos	2814	SL 360 g/l	1997 - 1998
Spain	Glyfos	19100/98	SL 360 g/l	1994 - 1998
	Glyfos Ultra	19101/98	SL 360 g/l	1994 - 1998
	Arbonal	21541	SL 120 g/l	- 2007
Sweden	Kvick Down 360	4017	SL 360 g/l	1994 - 2002
	Kvick Down 400	406	SL 400 g/l	1994 - 1997

1) a.R. :annual Renewal
2) unli. :unlimited

PESTICIDES SAFETY DIRECTORATE
Mallard House, Kings Pool, 3 Peasholme Green, York YO1 7PX, UK
Switchboard: 01904 640500 GTN: 5138 5891
Direct Dial: 01904 455891 Fax: 01904 455722
International: (+44) 1904 455891 International Fax: (+44) 1904 455722
e-mail: s.c.dobson@psd.maff.gov.uk

Dr Lundehn,
Biologische Bundesanstalt für Land und
Forstwirtschaft
Messeweg 11-12
D-38104
Braunschweig
GERMANY

4 March 1999
Our reference: ASY 43

Dear Dr Lundehn,

EC REVIEW MONOGRAPHS FOR GLYPHOSATE AND GLYPHOSATE TRIMESIUM

RAPPORTEUR - GERMANY

ECCO 76 -PHYSICAL & CHEMICAL PROPERTIES MEETING

On behalf of the Pesticides Safety Directorate of the Ministry of Agriculture, Fisheries and Food, please find attached our comments on the monographs for glyphosate and glyphosate trimesium. We are submitting these comments for your information as rapporteur and for discussion at the ECCO 76 meeting in March 1999. With regard to both substances it is considered that the monograph is a very well presented comprehensive discussion of a complex submission. The following general comments are considered relevant to the submission:

- it is unclear from the monograph why the glyphosate trimesium has been presented separately form the other glyphosate salts. It is considered the active principle is glyphosate and therefore the trimesium should be considered as an additional source.

- however, in relation to the above, confirmation should be sought form the Mammalian Toxicology group on the effect of the different salts on the toxicological profile of glyphosate.

Our specific points are given in the attached appendices - **please note that a separate letter has also been sent which relates to the confidential section of the monograph**.

Yours sincerely,

S C DOBSON
cc: ECCO Team - PSD

6276/ECCO/PSD/99

GLYPHOSATE - VOLUME 3 [part 1 of 4] (ANNEX B)

B. 2 PHYSICAL AND CHEMICAL PROPERTIES

B. 2.1 Physical and Chemical properties of the active substance

B 2.1.1.1 (page 1) Melting point

There seems to be some inconsistency in the results as the highest purity material gives the lowest melting point.

For the isopropylamine salt it is suggested the lower value is used as that was generated with the slowest heating rate in the study.

B 2.1.3.1 (page 3) Vapour pressure

PSD agrees with the conclusions of the rapporteur with respect to the acceptability of results.

B 2.1.3.2 (page 5) Volatility, Henry's law constant
It is unclear whether the results listed in the table were submitted from the notifier(s) or were calculated by the rapporteur. However, PSD agrees with the comment.

B 2.1.4 (page 6) Appearance
Data are required on the pure glyphosate salt

B 2.1.6.1 (page 9) Solubility in water
PSD considers data are required for the pure glyphosate salts.

B 2.1.8 (page 12) Partition co-efficient
The choice of pH for the studies covered the environmentally significant range but would not have measured the log Kow of the free acid, rather a dissociated form.

B 2.1.9 (Pages 13, 14, 15) Stability in water
It would be useful to have a brief description of the principles of the EPA and BBA methods and comparison with the OECD/EC methods.

B 2.1.9.2 (page 17) Photochemical degradation
PSD agrees with the assessment of the rapporteur.

B 2.1.13 (page 26) Explosive properties (technical active substance)
The evaluation suggests that glyphosate acid should be classified as explosive but the end point sheets describe the active substance as 'not explosive'.

There appears to be some discrepancy in results for the isopropylamine salt as in some tests it is described as explosive but non-explosive in others.

B. 2.2 Physical , chemical and technical properties of the plant protection products (Annex IIIA)

Monsanto
Mon 44068
420 g/kg soluble granule sodium salt

B 2.2.8.4 (page 32) Dilution stability
It is unclear how the results reported were determined. A CIPAC method (MT 179) is now available for the determination of solution stability for SGs

B 2.2.8.5 (page 32) Wet sieve test
PSD considers a wet sieve test is appropriate to this preparation. Alternatively MT 179 for the determination of solution stability also includes a wet sieve test and this may be used.

B 2.2.8.6 (page 32) Particle size distribution
No data appear to have been submitted for this preparation, only a specification. The particle size distribution should be determined.

Monsanto
Mon 52276
360g/l soluble concentrate

B 2.2.8.2 (page 37) Persistent foaming
The relevance of the high levels of persistent foam should be discussed with the Operator Exposure experts.

PSD agrees with the Rapporteur assessment.

Feinchemie Schweba
Taifun forte
360g/l soluble concentrate

B 2.2.2.1 (page 40) Explosive properties
Have data been submitted to support the statement on release of hydrogen? If so is there a concern over the use of metal spray tank equipment.

PSD agrees with the overall Rapporteur assessment.

Sinon
360g/l soluble concentrate
(page 40)
PSD agrees with the Rapporteur assessment.

Herbex
360g/l soluble concentrate
(page 43)
PSD agrees with the Rapporteur assessment.

Agrichem Glyfosaat 2, Agrichem Glyphosaat 360
(page 43)
PSD agrees with the Rapporteur assessment.

Luxan
360g/l soluble concentrate
(page 46)
PSD agrees with the Rapporteur assessment.

IPC
360g/l soluble concentrate
B 2.2.8.4 (page 49) Dilution stability
PSD considers data on the dilution stability of the preparation are required.

Nufarm
(page 50)
PSD agrees with the Rapporteur assessment.

Alkaloida
680g/l soluble granules

B 2.2.2 (page 50) Explosive properties, Oxidising properties, Flammability, Auto-flammability
PSD agrees with the Rapporteur assessment.

B 2.2.7 (page 51) Storage stability
The data indicate agglomeration of the granules may occur. Did the extent of agglomeration depend on the relative humidity?
Did the notifier provide any information on the extent of the agglomeration on ambient storage?

B 2.2.7 (page 51) Shelf life
As above, dependent on the extent of the agglomeration the shelf life of the product could be compromised. This is supported by the results for flowability.

B 2.2.8.1 (page 51) Wettability
PSD agrees with the Rapporteur assessment.

B 2.2.8.4/ B 2.2.8.5 (page 52) Dilution stability, Wet sieve test
PSD agrees with the Rapporteur assessment.

Glialka 36
360g/l soluble concentrate
(page 53)
Data are required on the physical and chemical properties of the formulation.

Barclay Gallup 360
360g/l soluble concentrate

B 2.2.2.1 (page 53) Explosive properties
PSD agrees with the Rapporteur assessment.

B 2.2.7.2 (page 55) Storage stability
PSD agrees with the Rapporteur assessment.

B 2.2.7.3 (page 55) Shelf life
PSD agrees with the Rapporteur assessment.

B 2.2.8.4 (page 55) Dilution stability
PSD agrees with the Rapporteur assessment.

Sanachem
360g/l soluble concentrate

B 2.2.2.1 (page 57) Explosive properties
The results for the test for mechanical sensitivity appear anomalous given that the preparation is a soluble concentrate.

B 2.2.7.3 (page 58) Shelf life
PSD considers data on the shelf life of the preparation are required.

B. 3 DATA ON THE APPLICATION AND FURTHER INFORMATION

B 3.1 Resistance
(page 1)
The glyphosate monograph lists two cases, but at Section 2.3.1 in the Report states that no resistant weeds have been found. In contrast, the trimesium monograph states that this is not known. The mode of action of the two salts is the same so that it is very likely that the weeds are resistant to both. The two monographs and their different parts should agree.
It is likely that resistance risk is low, although there have been two further reports of possible cases in America and Asia. However, there should be a consideration of the risk of resistance developing and a consideration of whether the company should develop a resistance management strategy, particularly in perennial crops or where crop rotation is limited.

B 3.4.2.1 Controlled incineration
(page 3)
PSD considers the temperature of incineration should be included.

B. 3.5.1 Packaging (type, materials size etc.) compatibility on the perpetration with proposed packaging materials (Annex IIIA 4.1)

Monsanto
(page 5) Mon 44068 420 g/kg soluble granule sodium salt

It is unclear whether the packaging has been assessed by the rapporteur or notifier.

Feinchemie Schweba
(page 6) Taifun forte 360g/l soluble concentrate

PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

Sinon 360g/l soluble concentrate
(page 6)
PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

Herbex 360g/lsoluble concentrate
(page 6-7)
PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

Luxan 360g/l soluble concentrate
(page 9)
PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

IPC 360g/l soluble concentrate
(page 9)
PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

Nufarm
(page 10)
PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

Alkaloida 680g/l soluble granules
(page 11)
PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

Glialka 36 360g/l soluble concentrate
(page 11)
PSD considers data regarding the suitability of the packaging and compliance with standard tests are required.

B 3.5.2 Procedures for cleaning application equipment (Annex IIIA 4.2) (page 11)

It is unclear whether the recommendations in section 3.5.2 on page 11 apply to all preparations. However, no data have been presented on the effectiveness of cleaning procedures and as glyphosate is a broad spectrum weedkiller these data should be available.

B 3.5.3 Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment (Annex IIIA 4.3) (page 12)

Although this section indicates a period between last application and sowing or planting succeeding crops, and includes a cross reference to B 6.9, the issue of waiting periods to avoid phytotoxic effects on succeeding crops (Annex IIIA 3.8) is not dealt with explicitly in Section B 3. This is usually included as it relates to the activity of the active substance. No comments are included in this section of the monograph. Given the moderately long DT 90 values, of up to 280 days, given in Section 2.8.1 of the Report it is considered that this should have been included in the section. However, this should not be an issue for glyphosate as it is not usually biologically available once it contacts soil but some consideration should be given to this aspect of the evaluation.

B 4 METHODS OF ANALYSIS

B 4.1.1/B 4.1.2 Technical material and preparations

Alkaloida
It is unclear how the specificity of the complexometric titration can be established.

Sanachem
PSD considers the validation data must be submitted for the method of analysis.

B 4.2.1 Analytical methods (residue) for plants and plant products (page 5)

The residue method using post column derivatisation is extremely complex and time consuming. However due to the nature of glyphosate as an analyte it is considered acceptable.
PSD agrees with the overall assessment.

Environmental samples
(page 9)

B 4.2.2 Water (including drinking water) (Annex IIA 4.2.3; Annex IIIA 5.2.3)

No validation data are listed for surface water and it is considered these should be submitted.

PESTICIDES SAFETY DIRECTORATE
Mallard House, Kings Pool, 3 Peasholme Green, York YO1 7PX, UK
Switchboard: 01904 640500 GTN: 5138 5891
Direct Dial: 01904 455891 Fax: 01904 455722
International: (+44) 1904 455891 International Fax: (+44) 1904 455722
e-mail: s.c.dobson@psd.maff.gov.uk

Dr Lundehn,
Biologische Bundesanstalt für Land und
Forstwirtschaft
Messeweg 11-12
D-38104
Braunschweig
GERMANY

4 March 1999
Our reference: ASY 43

Dear Dr Lundehn,

EC REVIEW MONOGRAPH FOR GLYPHOSATE

RAPPORTEUR - GERMANY

ECCO 76 -PHYSICAL & CHEMICAL PROPERTIES MEETING

COMMENTS ON CONFIDENTIAL SECTION OF MONOGRAPH

On behalf of the Pesticides Safety Directorate of the Ministry of Agriculture, Fisheries and Food, please find attached in the appendix to this letter **our comments on the confidential section** of the monographs for glyphosate. Please note we have no comments on the glyphosate trimesium confidential section.

These comments relate to the confidential section of the monograph and also the overall assessment made by the rapporteur given in the Report in relation to this section of the monograph.

We are submitting these comments for your information as rapporteur and for discussion at the ECCO 76 meeting in March 1999.

Comments on the non-confidential part of the monograph have been sent in a separate letter.

Yours sincerely,

S C DOBSON

cc: ECCO Team - PSD

5277/ECCO/PSD/99

GLYPHOSATE - VOLUME 4

CONFIDENTIAL

Technical specification and determination of impurities (Confidential Information)

These comments relate to the confidential section of the monograph and also the overall assessment made by the rapporteur given in the Report in relation to this section of the monograph.

General comments

For a number of the technical specifications the maximum value for the components in the technical specification appear to be derived from the maximum values detected in the batch analyses. It is unlikely that the manufacturer would be able to meet these specifications on a routine basis.

In most of the specifications reference is only made to the determination of N-nitrosoglyphosate - should consideration be given to the determination of other nitrosamine compounds in the technical material?

In a number of specification, the determination of N-nitrosoglyphosate is dependent on determination by HPLC under basic conditions. Does the acidic nature of glyphosate interfere with the determination?

Monsanto
It is unclear how the technical specification for the Monsanto source is derived as the maximum values for the individual impurities are considerably higher than those found in the batch analyses. In addition, no determination of water is included in the batch analyses but a value of up to 200 g/kg is given in the technical specification. A potential range of 0 - 20% is very large - have the notifiers provided an explanation?

The recoveries reported are glyphosine are very variable - was an explanation provided by the notifier?

Feinchemie
PSD agrees with the rapporteur assessment.

Sinon
The methods of analysis for impurities did not include a determination of accuracy or linearity. These data are required to support the method of analysis.

Herbex
PSD agrees with the rapporteur assessment.

Tulip Task Force
The technical specification has been developed using LC-MS for which validation data are not yet available. It is also reported that no reference standards are available were available for most of the listed impurities. It is considered that LC-MS is not an appropriate method for this purpose in the absence of such standards. LC-MS is not usually used to identify unknowns. It is difficult to obtain meaningful full scan spectra at low levels using LC-MS techniques. It is important to use reference standards for quantification and for characterisation of retention time, and to consider matrix-matched calibration for quantification (to counter ionisation suppression and similar effects). Identification of unknown compounds can be particularly difficult using API techniques because of the lack of information in the spectra. Even where MS-MS is used with API, identification can be more equivocal than that for GC-MS.

Luxan
PSD agrees with rapporteur assessment.

IPC
The value for AMPA in the technical specification of 17 g/kg is very high as the mean value was 2.8g/kg in the batch analyses. Was an explanation provided?

Nufarm
PSD agrees with rapporteur assessment.

Barclay
PSD agrees with rapporteur assessment.

Alkaloida
For the monomethylester, methanol and triethylamine, the levels determined in the 5 batch analyses are higher than the maximum value specified. However, in the 10 batch analyses, the value drops - was an explanation provided?
It is unclear from the table what are the units for the formaldehyde content.

Annex III p	MON 44068 SG	MON 52276 SL	Taifun forte SL	Tulip task f. SL	IPC SL	Glistar 68 SG	Barclay SL	Sanachem SL
2.1	x	x	x	x	x	x	x	x
2.2.1	x	x	–	x	–			x
2.2.2	x	x		–	–		–	–
2.3	x	x	x	x				x
2.4.1	x	x	x	x	–	x	x	x
2.4.2	x	x	x	x	x	x	x	x
2.5.1	–	x	x	x	x	–	x	x
2.5.2	–	–	x	–	–	–	x	–
2.5.3	–	x	x	x	–	–	x	x
2.6.1	–	x	x	x	x	–	x	x
2.6.2	x	–	–	–	–	x		–
2.7.1	x	x	x	x	–			x
2.7.2	–	x	x	x	x	–	–	x
2.7.3		x	x	x		x		
2.8.1	x	–	–	–	–		–	–
2.8.2	x	x	x	x	x	x	x	x
2.8.3	–	–	–	–	–	–	–	–
2.8.4	x		x	x	x			x
2.8.5	–	–	–	–	–	–	–	–
2.8.6.1	x	–	–	–	–		–	–
2.8.6.2	x	–	–	–	–		–	–
2.8.6.3	x	–	–	–	–	–	–	–
2.8.7.1	–	–	–	–	–		–	–
2.8.7.2	–	–	–	–	–	–	–	–
2.8.8.1	x	–	–	–	–		–	–
2.8.8.2	–	–	–	–	–	–	–	–
2.8.8.3	–	–	–	–	–	–	–	–
2.9.1	x	–	–	x	–	–	–	–
2.9.2	x	x	–	x	–	–	–	–
2.10	–	–	–	–	–	–	–	–

x data submitted
– not applicable
blank no data submitted

No studies submitted for: Sinon SL, Herbex SL, Luxan SL, Nufarm SL, Glialka 36 SL

6310/ECCO/PSO/94

Glyphosate

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DOCUMENTS ON GLYPHOSATE DRAFT ASSESSMENT REPORT

Section: Environmental Fate and Behaviour (ECCO 80)

Comments

Date	Supplier	ECCO Ref No.
12 February 1999	Monsanto Life Sciences	6422/ECCO/PSD/99
22 April 1999	The Netherlands	6423/ECCO/PSD/99
23 April 1999	Finland	6424/ECCO/PSD/99

Other documents

NONE

Additional information considered at the meeting but not included in this report

Date	Supplier	Content	ECCO Ref No.
25 May 1999	ECCO 76	CGA 245 704/Thiram/ Ziram/Amitraz/Lindane/Glyphosate: Questions and Information	6439/ECCO/PSD/99

Monsanto Life Sciences
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium
Tel number: +32 2 776 41 99
Fax number: +32 2 776 48 69

Registration Department

Date : February 12, 1999

From : Hilde Van Parijs

FACSIMILE TRANSMISSION

To	Company name	Location	Fax number
	ECCO-TEAM PSD	York	+44 19 04 45 57 22
Dr. Bruno	ECCO-TEAM BBA	Braunsschweig	+49 5 31 2 99 30 03

This fax contains page(s) (including this one). Please call Sender +32 2 776 4199, if you do not receive all the pages.

P.S.D.
15 FEB 1999
I.D. No. 54854

URGENT MESSAGE:

Re: EC evaluation of Glyphosate (according to regulation EC Nr 3600/92 and concerning inclusion of the active substance Glyphosate in Annex I of Directive 91/414)

Dear Sirs,

Attached is a copy of the Monsanto/Cheminova comments on the second draft of the Monograph on Glyphosate.

We have sent as well full copies (relevant appendixes + separate confidential folder) of the comments
- 4 copies to BBA
- 1 copy to PSD

Yours sincerely,

Hilde Van Parijs
Registration Correspondent

6422/ECCO/PSD/99

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Monsanto Services International S.A./N.V.
Avenue de Tervuren 270-272
Tervurenlaan 270-272
Letter Box n°1
B - 1150 Brussels Belgium

☎ direct (+32) 2 776 4607
Fax direct (02) 776 4869
e-mail:USERID@Monsanto.com

Cheminoca Agro A/S
P.O. Box 9
DK-7620 Lemvig
Denmark

☎ (+45) 96 90 96 90
Fax (+45) 97 83 45 55
Telex 66514 CHEMV DK

ECCO-Team (BBA)
Biologische Bundesanstalt für Land- und Forstwirtschaft
Abteilung für Pflanzenschutzmittel und Anwendungstechnik
Messeweg 11/12
D-38104 Braunschweig

PSD ref.: PRD 3624
Our ref. : RPG/hvp

Brussels, February 11, 1999

URGENT

Dear Sirs,

Re: EC evaluation of Glyphosate (according to regulation EC Nr 3600/92 and concerning inclusion of the active substance Glyphosate in Annex I of Directive 91/414)

Please find enclosed our comments on the second draft of the Monograph on Glyphosate. The major point from our review are:

a) We do not believe that Glyphosate is explosive.
b) An anaerobic metabolism study is not needed as the use on rice is to bare soil, before planting the rice.
c) Beneficial insect laboratory studies are affected by the "sticky nature" of the dried deposit.
d) We have a disagreement on the impact of Glyphosate on aquatic organisms.

We have done the best we can, within the time allocation for review, and look forward to further discussion on the data.

Yours sincerely,

Richard Garnett

R.P. Garnett
Registration Manager, Glyphosate

cc: ECCO-Team (PSD) - York

attachments

GENERAL COMMENTS

We suggest that the evaluation should establish a principle for the acceptance of data. Some pivotal studies are utilised where a company's compositional data shows incomplete analysis, i.e. unidentified impurities. The dosing levels for glyphosate studies are so high that slight variations in manufacturers impurity patterns may contribute to the variation in toxicological results which can be seen in the monograph. We would recommend that to be used for any critical endpoint the study concerned should be classified as "Acceptable" and the test material adequately defined, in terms of purity, impurities and description.

There are two main manufacturing routes for glyphosate, one called the Glycine process and the other the IDA process. Although they both produce >95% pure material the impurity profiles are different, and because the toxicological studies have been carried out at extremely high dose levels the significance of the impurities increases.

In a similar manner glyphosate formulations are available with a wide spectrum of Risk and Safety phrases because the major source of toxicological impact comes from the additional components, not glyphosate itself. It follows that critical endpoints for glyphosate which are based on formulation studies, such as ecotoxicological studies, should be considered by the Member States when they assess specific formulations, provided, for the purpose of Annex I listing it can be demonstrated that at least one formulation is within the acceptable limits.

We have given as many comments as possible in the limited time available but may not have covered all the items. We will continue to work on the document.

We are discussing with the rapporteur the most appropriate means of supplying additional data that have become available since the submission was first made - See Appendix I.

Volume 1, Level 1, Statement of Subject Matter and Purpose of Monograph

1.3.7 Manufacturer or manufacturers of the active substance

We believe that a number of the "Manufacturers" quoted in the list are in fact traders and have no manufacturing facility of their own. If they are just traders should they be included in the process? As a minimum we would suggest they have to declare their sources and the process.

We would like to add the following source of Monsanto material to the list of manufactory plant:

MONSANTO SAO JOSE DOS CAMPOS PLANT
AV. CARLOS MARCONDES, 1200
12241-420 SAO JOSE DOS CAMPOS-SP
BRAZIL

TEL : +55 123 327100
FAX : +55 123 327199

1.3.10 Identity of isomers, impurities and additives

In conjunction with FAO we have submitted new specifications to comply with the new requirements for the establishment of FAO specifications. These will be considered at their meeting of 29th June 1999. As a result of the batch analyses carried out on material from our manufacturing plants, there are some slight amendments to our original submission. The new levels are disclosed in CONFIDENTIAL Appendix A.

1.3.11 Analytical profile of batches

As mentioned in 1.3.10 we have carried out recent analyses of our material and the results are attached in CONFIDENTIAL Appendix A - see section "impurity profiles Monsanto glyphosate".

1.5.4-1 Information on the approvals in the EU

Information on the approval in EU for Cheminova's glyphosate products is missing. This is now provided in Appendix J.

The tables for Austria and Belgium were missing from our copy but we assume this is just a copying error as they were included in the original draft.

We submitted the data below for Denmark on a previous occasion and the compounds noted below for France all have 10 year registrations. The product concentrations for Sweden and Greece should be amended as indicated.

Denmark			
Roundup 2000	48-9	SL 400 g/l	1991-1999
Marvel	48-10	SL 120 g/l	1991-1999
Roundup 480	48-15	SL 480 g/l	1991-1998
Roundup Spray	48-19	SL 7.2 g/l	1994-1999

France
Roundup Geoforce, Roundup Bioforce, Roundup360, Hockey Pro, Spasor A, Aristo TS, Durano TX, Honcho TS, Roundup Acti, Nomix Agri 2000, Roundup Alphee, and Ragtime -- all have 10 year registrations in France.

Sweden	
Roundup Bio	SL 360 g/l
Roundup Garden	SL 120 g/l
Roundup Spray	AL 7.2 g/l

Greece	
Roundup Armada	SL 90 g/l

1.5.4-2 Approvals in the EU

The "Details of Intended Uses", Table 1.5.3-1, should be amended with the following uses which are approved in the countries indicated (see also annotated table Appendix B):

Citrus Fruit	Application rate: 0.54-4.32 kg as/ha
Pome and Stone Fruit	Application rate for Southern Europe: 0.54-4.32 kg as/ha
Almonds	Add use in Greece as indicated in Appendix B
Rape Seed	Pre harvest: application rate 1.08-1.44 kg as/ha Harvest Management: application rate 1.08-1.44 kg as/ha Add Germany to countries
Linseed	Pre-harvest: add Germany to countries Harvest Management: application rate 0.36-1.08 kg as/ha Add Germany to countries
Winter wheat, durum wheat, barley, oats	Add use as indicated in Appendix B
Maize	Delete Greece
Sugar Beet	Delete Greece
Annual spring crops	Application: add inter-row equipment Application rate: 0.54-3.6 kg as/ha Max application per season: 3.6 kg as/ha
Stubbles	Spring use: add UK to countries, delete Greece
Stubbles of various crops	Add cotton to list of crops (Greece only)
Conifer sites	Application after finish of shoot elongation: • add SG to first line • second line: application rate 0.54-1.08 kg as/ha, UK only

Home & Garden	- First line (all EU countries): water l/ha 400-700 - Insert second line for watering can application in all EU countries: water l/ha 1600-5000, otherwise as for sprayer Add watering can in same way for SG formulation Ready to Use Italy: 0.72 kg/hl
Railway	Application rate: 0.54-4.32 kg as/ha
Drains	Amend drains to "Drains - only when dry" Add Greece below Italy
Other non-crop land	Southern Europe: application rate 0.54-4.32 kg as/ha
Flower, poplar, shrub, ornamentals	Add all EU countries
Glyphosate tolerant crops:	
Maize	Growth stage 1-10 leaves for N and S Europe
Soya bean	Max/season 2.16 kg as/ha (ie 2 x 1.08 kg as/ha)

This distinction is made very clearly in the plant metabolism summary Annex B, Section B.6.1.8, but is not translated into the MRL recommendation consistently. The need for AMPA MRLs should not be routinely assumed to be necessary for all glyphosate-tolerant plants.

Table 2.7.3-2 acknowledges that it is not feasible to enforce separate MRLs for the glyphosate ion derived from treatment with isopropylamine, sodium, or ammonium salts as compared to MRLs for glyphosate derived from treatment with trimethylsulfonium salt. Similarly, it is not reasonable establish separate MRLs for non-tolerant crops and glyphosate-tolerant crops. Practical reality argues that the higher value must prevail. Thus, for beets, the glyphosate MRL of 1 ppm should be proposed over that of 0.2 ppm. However, additional data to be submitted to the rapporteur would indicate to us that a more appropriate MRL would be 2 ppm (see Appendix F).

For the crop groups "Root and Tuber Vegetables" and "Bulb Vegetables" where the MRL is proposed to be 0.1* ppm, We do not understand why the Rapporteur proposes to establish MRLs at the same level separately for beet root and onions, while still maintaining all others at the same 0.1* ppm level.

The existing MRL on Lentils of 0.1* ppm seems to have been inadvertently eliminated in this proposal.

2.8.1 Fate and Behaviour in soil

An anaerobic metabolism study in soil should not be needed since the use in rice cultures is only preemergent or after harvest. At these times, water is not present at the time of treatment, so the soil is not anaerobic. Information on the breakdown of glyphosate under anaerobic conditions in water / sediment conditions have been provided in Brightwell (1978) and in Kesterson and Jackson (1990) to account for processes that might occur in soil which is flooded after application. The results show that conversion to AMPA and CO_2 occurs under both anaerobic and aerobic conditions, so there is no basis for concern that unusual conversions might occur in rice culture.

The table presented on pages 80 - 81 of Volume 3 (3 of 4), Annex B in Section B.7.2 seems to indicate that glyphosate was detected above 0.1 µg/L in 61, 138, 1217, and 1347 determinations in the years 1991 - 1994. Apparently the legend is in error, because this seems to be the number of investigations made, not the number of positive detections. The phrase "which was detected above 0.1 µg/L" should be deleted for better clarity.

Volume 3 (3 of 4), Annex B in Section B.7.3 indicates "The majority of glyphosate will be used at a rate of 4320 g as/ha (single treatment) and 2 x 4320 g as/ha (double treatment)". These rates are a maximum allowed treatment rate, and should not be characterised as typical application made by the majority of users. These are reasonable to consider for an upper bound estimate of PEC.

The comment "AMPA can accumulate in certain soils" is the Rapporteur's conclusion based on data taken from dissipation studies initiated with parent glyphosate. The rate of AMPA dissipation was inferred from data collected late in the study after glyphosate had mainly dissipated. At these late time points, AMPA was likely tightly bound to the soil, and not readily available for microbial breakdown. It is expected that freshly applied AMPA would degrade much more rapidly, comparable to glyphosate itself. While the studies indicate that AMPA may remain detectable in soil for periods of time longer than 1 year, We do not believe that there is evidence demonstrating accumulation. Such a conclusion can lead some readers to believe there is regulatory concern about AMPA in soils. Since AMPA is biologically inactive and does not leach, perhaps the monograph could emphasise that the situation as described does not indicate regulatory concern.

ctb

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Biologische Bundesanstalt für Land- und
Forstwirtschaft, Abteiling fur Pflanzen-
schutzmittel
und Anwendungstecknik Messeweg 11-12
D-38104 BRAUNSCHWEIG
GERMANY

college voor de toelating van bestrijdingsmiddelen

Briefnummer 99/1858 JJM/IVH
Behandeld door ir. J.J. Meeussen *doorkiesnummer* 471858
Uw kenmerk
Datum 22 april 1999

Betreft Comments on the draft-monograph of the active substance **glyfosate**
Ecco-meeting 80
Section: Fate and Behaviour

The Board for the Authorization of Pesticides (CTB) has received the draft monograph of the active substance glyfosate.

Please find hereafter the comments of the CTB with respect to the draft-monograph as prepared by Germany.

Level 3
An additional note: products with glyphosate for the use *in surface water* are currently not registered in the Netherlands (reference date 06-04-99).

Level 2
2.5. Fate and behaviour in the environment (listing of endpoints)

$DT_{50,FIELD}$ for AMPA in the US and Canada is > 1 year. Using these values for Europe would imply withdrawal of the registration, as AMPA is a major metabolite that does not fulfill the criterium of a $DT_{90,FIELD}$ not exceeding one year. It is interesting that in field studies with glyphosate-trimesium — also with AMPA as a major metabolite in laboratory studies — AMPA was almost not detectable.
For the reregistration of glyphosate in the Netherlands it has been concluded that there are not enough reliable data for an adequate assessment of the persistence of AMPA in the soil. Therefore both laboratory and field studies will probably have to be submitted in the near future to the Dutch registration authorities.

In a strict way, one could say in view of field studies in Canada — possibly comparable with some Scandinavian countries — that glyphosate does not always comply with the requirement that the $DT_{90,FIELD}$ should not exceed a period of one year. In those Canadian field studies the $DT_{90,FIELD}$ was max. 514 days for the PMG anion (PMG data can be used for the evaluation of various other glyphosate salts). However, this was exceptionally high.

Level 3 and 4
We agree with the RMS. The AMPA issue (see above) should be solved first.

6423/ECCO/PSD/99

Stadsbrink 5
6707 AA Wageningen
Postbus 217
6700 AE Wageningen
Telefoon: 0317-471810
Telefax: 0317-471899
Internetadres: http://www.ctb.agralin.org

ctb

college voor de toelating van bestrijdingsmiddelen

These comments also have been sent to the ECCO-team.

Yours sincerely,

Ir. A.W.H.M. Meijs
(Deputy secretary of the Board)

cc: ECCO-team (PSD)
Pesticide Safety Directorate
Room 208
Mallard House, Kings Pool
3 Peasholme Green
UK-York Y01 7PX

FINNISH ENVIRONMENT INSTITUTE
Chemicals Division

Helsinki 23 April 1999

Our ref. SY99P0037-042

Your ref.

Mr. J.–R. Lundehn
BBA
Messeweg 11/12
D-38104 Braunschweig

Subject COMMENTS ON GLYPHOSATE, GLYPHOSATE-TRIMESIUM (DRAFT MONOGRAPH AND PROPOSED DECISION, PREPARED BY GERMANY)
- ENVIRONMENTAL FATE

Dear Mr. Lundehn,

Please find below the Finnish comments on the section "Fate and Behaviour in the Environment" of the Draft Monograph of glyphosate and glyphosate-trimesium to be considered during the seventh round ECCO Peer Review Meeting, ECCO 80.

The first remark concerns the field dissipation studies. On page 36-37 (Annex B, Vol 3 (3 of 4) the DT_{50} values obtained in the field studies performed in USA ranged from 2 to 326 days. However, in Level 2 summary and in end point sheets, the range for field dissipation DT_{50} is given as 3 to 68 days.

The results from a leaching study (on page 74) give leachate rates of 0.05 to 6.56 % of the applied amount. However, in end point list the range of radioactivity leached is given as from 0.12 to 1.45 %.

The degradation of AMPA in soil is much slower than the degradation of glyfosate. Therefore we suggest that the possible accumulation of AMPA in soil could be modelled to be used in the risk assessment. In addition, although it seems that the leaching of AMPA to groundwater is not very likely, it could be useful to test this assumption by modelling with a high DT_{50} value and a small K_{OC}-value.

Otherwise the documentation supplied of the fate and behaviour of glyfosate is considered adequate and we agree with the few further studies demanded for glufosinate-trimesium.

6424/ECCO/PSD/99

Postal address: P.O. Box 140 FIN-00251 Helsinki
Visiting address: Kesäkatu 6 Helsinki
Telephone: international +358 0 403000
Telefax: international +358 0 40300591
Telex: 126086 vyh sf

The overall conclusion of postponement in inclusion to Annex I and the prohibition of the use in surface waters and rice cultivation is agreed.

Yours sincerely,

Division Manager — Esa Nikunen

Senior Advisor — Leona Mattsoff

CC. ECCO Team/ PSD
Plant Production Inspection Centre, Finland
National product Control Agency for Welfare and Health, Finland

Postal address: P.O. Box 140 FIN-00251 Helsinki
Visiting address: Kesäkatu 6 Helsinki
Telephone: international +358 0 403000
Telefax: international +358 0 40300591
Telex: 126086 vyh sf

DOCUMENTS ON GLYPHOSATE DRAFT ASSESSMENT REPORT

Section: Ecotoxicology (ECCO 84)

Comments

Date	Supplier	ECCO Ref No.
22.6.99	European Commission	6490/ECCO/PSD/99
28.6.99	Mr R A R Bruce	6522/ECCO/PSD/99
14.7.99	Monsanto	6553/ECCO/PSD/99
14.7.99	Finland	6554/ECCO/PSD/99
14.7.99	Monsanto	6556/ECCO/PSD/99
15.7.99	The Netherlands	6577/ECCO/PSD/99

Other documents

NONE

Additional information considered at the meeting but not included in this report

Date	Supplier	Content	ECCO Ref No.
14.7.99	Monsanto		6555/ECCO/PSD/99

10.06.

21878

AC/KG1,5

ECCO

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE

VI-B-II.1
Legislation relating to crop products and animal nutrition
G/pesticid/smeets/fax99/lundehn.doc
D/231430(99)

100637 / BII 1

FAX

10 25

Date:

From:	Mr. SCHARPE	**Telephone:**	(+32-2)295.96.12
	VI-B-II.1 L84 1/12		
		Fax:	(+32-2)296.59.63
To:	Mr. Lundehn ECCO – BBA	**Telephone:**	495312993450
		Fax:	495312993003
Number of pages:	1 + 4		

Subject: **Additional information on Glyfosate**

Message:

Dear Mr Lundehn,

I send you additional information on **glyfosate,** which I received from Dr. Pechlaner.
Could you please ensure that this information is being taken into consideration under the ongoing peer review.

Yours sincerely,

A. Scharpé
Head of Sector

Copy: M. Seiwald

6490/ECCO/PSD/99

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 E
Telephone: direct line (+32-2)295.96.12, exchange 299.11.11.
Telex: COMEU B 21877. Telegraphic address: COMEUR Bru

262

Dr. Roland Pechlaner
o.Univ.-Prof. für Limnologie i.R.
Riedgasse 30
A-6020 Innsbruck
Tel. (0512) 28 31 20

Innsbruck, 25. Mai 1999

Herrn
Dr. Hubert SEIWALD
Europäische Komm.
B-1000 Brüssel
FAX 00322-295-9225
Für Sie und Dr. FISCHLER
zur Kenntnis u. Weitergabe
Herzliche Grüße!
R. Pechlaner
3.6.99

An die
Teilnehmer der
92. Jahresversammlung der
Deutschen Zoologischen Gesellschaft
in Innsbruck (Leopold-Franzens-Universität, 24.-27.V.1999)

Verteilt am 25.V.99

Betreff: *Roundup® (Wirkstoff: Glyphosate) des Monsanto-Konzerns;*
Folgewirkungen für Gewässer und Böden
Information, Protest, Anfrage, Bitte um Mitarbeit

Information: „Roundup ist ein nichtselektives Blattherbizid mit systemischer Wirkung. Es wird über die grünen Teile der Pflanze aufgenommen und mit Hilfe des Saftstromes in der ganzen Pflanze einschließlich der unterirdischen Speicherorgane verteilt, sodaß auch die ausdauernden, unterirdischen Pflanzenteile (Rhizome) mehrjähriger Unkraut- und Ungrasarten vernichtet werden" (AGROLINZ MELAMIN GmbH., Pflanzenschutz-Katalog 1997, p. 249)

Produzenten und Handel bewerben dieses Produkt als „erster umweltfreundlicher Total-Unkrautvernichter", „biologisch vollständig abbaubar", „hinterläßt keine wirksamen Rückstände im Boden", „schont nützliche Insekten und Regenwürmer", „ungefährlich für Mensch und Tier" ... .

All dies sind behördlich zugelassene Verharmlosungen! Im weltweiten Verkauf brachte Glyphosate 1981 mehr als 410,000.000 US Dollars, und im Vorwort der Glyphosate-Monographie von GROSSBARD und ATKINSON wird angekündigt: „... by 1986 it will be the first 'one-thousand million dollar herbicide molecule'."

Viel Jubel und viel Geschäft, aber ein fundiertes „risk-assessment" bzw. eine Quantifizierung des Bruttosozialschadens fehlt bis heute!!

Glyphosate wirkt auf den aromatischen biosynthetischen Aminosäurestoffwechsel, indem es die 5-Enolpyruvyl-Shikimat-3-Phosphat-Synthese (EPSPS) hemmt. Die Feststellung von COLE (1985, p. 48) „the most significant property of glyphosate with respect to mode of action is its negligible animal toxicity; thus, inhibition of the shikimic acid pathway, which occurs only in plants and microorganisms, may explain the favourable difference in toxicity" darf für Zoologen bzw. für ökosystemar denkende Bodenbiologen und Limnologen keine Entwarnung bleiben.

Ein Wirkstoff, der generell für Pflanzen, Bakterien und Pilze tödlich ist,

- muß indirekt Bodentiere, deren Gedeihen von Mikroorganismen abhängt, schädigen,

- birgt durch oberflächlichen „runoff" Risken für Oberflächengewässer (LIESS et al. 1999, SCHULZ 1997), zumal dieses Spritzmittel (als Isopropylaminsalz des Glyphosate) durch Adsorption an Tonminerale an der Bodenoberfläche akkumuliert),
- bedroht Biofilm und Folgekonsumenten im Grundwasser und in grundwassergespeisten Oberflächengewässern, wo immer Glyphosate bei Unkrautbekämpfung auf Eisenbahn-Gleiskörpern die „Bodenschranke" umgeht (WEIGL 1994, PFEFFER 1997);
- aus den „raindrop-Düsen" der Giftzüge von Bahngesellschaften droht durch Pestizid-Infiltration in den Grundwasser-Tauchbereich der Gleisschotter aber auch Schaden für tiefwurzelnde Begleitvegetation, da COUPLAND (1985, p. 28) von Experimenten berichtet, in denen Nutzpflanzen „were treated via the roots in hydroponic solution This was considered to be the most efficient means of loading the plant with ^{14}C-glyphosate."

Protest: Mein (unser) Protest muß sich darauf beziehen, daß Erzeuger, Prüfbehörden und beratende Gremien das oben erwähnte Schadensrisiko

- weder vor der staatlichen Zulassung bzw. vor der Anwendungsempfehlung zu quantifizieren und durch spezifische Anwendungshinweise einzuschränken versuchten,
- noch in der derzeit laufenden Prüfung für EU-weite Freigabe die produktimmanenten Folgen für das ökologische Wirkungsgefüge der gefährdeten Systeme kompetent ansprechen.

Zum Beweis meiner Gründe für die obige belastende Aussage halte ich fest: Die EU-Wirkstoffprüfung für Glyphosate hat Deutschland übernommen. Benannte Behörde („Rapporteur") ist die Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) in D-38104 Braunschweig, Messeweg 11/12. Diese Behörde hat im Herbst 1998 den zur Begutachtung gelangten Entwurf für eine Glyphosat-Monographie geliefert. Er wurde und wird in mehreren Ecoteam-Meetings bereichsweise diskutiert, damit im Herbst 1999 die revidierte Monographie der EU-Kommission als Basis für die Glyphosat-Zulassung übermittelt werden kann. Aber: Das einschlägige Standardwerk von GROSSBARD & ATKINSON (1985) war bei meiner Diskussion der Problematik am Institut für Ökotoxikologie der BBA in Berlin-Kleinmachnow im Februar 1999 den versammelten Sachbearbeitern gar nicht bekannt, weshalb auch viele Fragen, die die dort (und bei ALTMANN 1993) publizierten Beiträge aufwerfen, nicht in den Glyphosat-Monographie-Entwurf aus 1998 eingeflossen sein können. Ähnlich die Situation im Umweltbundesamt in Wien, das sich erst auf meine Anregung hin im Mai 1999 GROSSBARD & ATKINSON (1985), WEIGL (1994) und PFEFFER (1997) zu beschaffen versucht. Andererseits ist die Einbeziehung von einschlägiger Fachkenntnis aus dem Universitätsbereich in das behördliche Prüfverfahren dadurch erschwert, daß eine EU-Verordnung keinen Einblick in den Monographie-Entwurf - der für bestmögliche Beratung der Behörde wichtig wäre - für „außerbehördliche Personen" zuläßt.

Es gilt somit, sowohl gegen die geringe Alertheit der Prüfbehörden als auch gegen die (tatsächliche oder behauptete) Abschirmung der zur Prüfung berufenen Instanzen gegenüber universitärem know-how bezüglich adäquater, ökologisch fundierter Risiko-Abschätzung anzukämpfen.

Anfrage: Ist der Shikimat-Zyklus wirklich nur bei grünen Pflanzen, Bakterien und Pilzen vertreten? Sollte er z.B. auch bei Protozoen vorkommen, wären mögliche Folgen der

Aufnahme Glyphosate-behandelter Pflanzen durch Wiederkäuer zu untersuchen, was bisher nicht geschehen ist (C.C.TERBE in Diskussion am 19.IV.1999 in Innsbruck).

Meine Bitte: Nehmen Sie Einfluß auf nationale Behörden, auf EU-Beamte und/oder EU-Parlamentarier,

- daß die Prüfung der ökologischen Folgen der Glyphosat-Anwendung eiligst nachgeholt und in die Zulassungsprozedur einbezogen wird,
- und daß in der Zwischenzeit das aus publizierter Information ableitbare Schadenspotential von Roundup und anderen Produkten mit diesem (und ähnlichen) Wirkstoffen zu wirksamen Beschränkungen bzw. gezielten Risiko-Aufklärungen und eventuellem Einsatzverbot umgesetzt wird.

R. Pechlaner

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Dr. Roland Pechlaner
Riedgasse 30
6020 Innsbruck

Innsbruck, den 5.V.1999

Erschienen in TT v. 22./23./24.V.99
(Pfingsten)

An die
Tiroler Tageszeitung
hier

Betrifft: *Leserbrief zu Artikel von W. SCHATZ in der TT vom 23.IV.1999*
Titel-Vorschlag: „Teufelssaft" bleibt Teufelssaft

Meine Stellungnahme zum TT-Artikel „Schadet ‚Teufelssaft' Wildsee?" (23.4.1999) muß und kann kurz sein. Die Angelegenheit wurde am 27. April in der ÖBB-Generaldirektion ausführlich diskutiert und dürfte mehr an Ausweg-Suche in Gang gesetzt haben, als verbal zugesichert wurde.

Den TT-Lesern sei heute dazu gesagt: Der wissenschaftliche Beweis für den ursächlichen Zusammenhang zwischen dem Wasserpflanzensterben im Wildsee und den Schadstoffen aus der Unkrautbekämpfung durch die ÖBB wird sich auf verschiedenen Ebenen führen lassen. Diesbezügliche Untersuchungen laufen, benötigen aber viel Zeit. Jederzeit beweisbar sind aber folgende Richtigstellungen zu den Äußerungen des ÖBB-Sprechers Arno Guggenbichler: Roundup wirkt keineswegs nur auf die Blattoberflächen, sondern dringt auch über Wurzeln ein (soferne es an solche herankommt). Der ÖBB-Giftzug sprüht bisher einen Cocktail aus Roundup (Wirkstoff Glyphosate), Goal (Oxyfluorofen) und einem Netzmittel. Glyphosat wirkt generell auf Pflanzen, Bakterien und Pilze tödlich, schädigt indirekt aber auch jene Tierarten, deren Gedeihen von Mikroorganismen (z.B. als Nahrung oder als Enzym-Lieferanten in der Darmflora) abhängt. Oxyfluorofen greift „nur" in die Photosynthese grüner Pflanzen ein, ist aber noch in der Konzentration von 1,4 Mikrogramm pro Liter für die Wasserlinse tödlich.

Ob der Wirkstoff Glyphosate in der EU zugelassen wird, ist derzeit erst in Diskussion. Die ÖBB hat versprochen, am Seefelder Plateau bis auf weiteres kein Gift auszubringen, injiziert ihren Mix - trotz der ökotoxikologischen Gegenargumente - jedoch weiterhin über ihr weitläufiges Gleiskörpernetz in das Grundwasser und die von diesem beeinflußten Oberflächengewässer.

Die ÖBB kennt durch mich seit Jänner 1999 eine für Fischzüchter publizierte Alternativmethode - Hydratkalk-Gaben in kluger Dosierung - und dürfte diesen Ausweg (obwohl noch nicht ausdrücklich zugesagt) nun doch näher (und schneller) untersuchen

Univ.-Prof. Dr. Roland Pechlaner
(Innsbruck)

2666

BIOLOGISCHE BUNDESANSTALT FÜR LAND- UND FORSTWIRTSCHAFT

Abteilung für Pflanzenschutzmittel und Anwendungstechnik

Biologische Bundesanstalt · Messeweg 11/12 · D-38104 Braunschweig

Federal Biological Research Centre
for Agriculture and Forestry (BBA)
Department for Plant Protection Products
and Application Techniques

Pesticides Safety Directorate, Ecco Team
Mallard House, Kings Pool
3 Peasholme Green

UK-YORK Y01 2PX

P.S.D.
28 JUN 1999
I.D. No. 56877

Telefon 05 31/2 99-5
Telefax 05 31/2 99-30 02 oder -30 03
E-mail: ap@bba.de

Ihr Zeichen/Ihre Nachricht vom	Mein Zeichen/Meine Nachricht vom	Durchwahl	Datum
	AP-WAM 004362-00/00 HB/Sc	2 99 - 34 55	June 25, 1999

EU-evaluation of glyphosate

Please find enclosed a comment of Mr. R. A. R. Bruce on glyphosate.

As glyphosate is currently discussed in the ECCO-Peer Review it seems appropriate to consider this comment during the remaining ECCO-meetings.

H. Kohsiek

Enclosure

6522/ECCO/PSD/99

Submission to the European Review of Glyphosate Products
from Richard A.R. Bruce. Tel ø1983 760827
Hill Place Cottage
Thorley
Yarmouth
Isle of Wight
PO41 OSS
4th May 1999

Dr Lundehn, the rapporteur (Germany)
Biologische Bundesanstalt fur Land und Forstwirtschaft
Abteilung fur Pflanzenschutzmittel und Anwendungstechnik
Messweg 11/12
D-38104 Braunschweig
Germany

Dear Dr Lundehn.

Please forgive me for writing in English but despite the fact that my late father married an Austrian girl and was fluent in the German language I fear that I now find difficulty even with my own language.

The UK Pesticide Safety Directorate has informed me that the EU review of glyphosate is currently derway and although they tell me that my observations in respect to the cholinesterase depressing action of glyphosate are to be reported to the review body by their representatives they suggest that I should contact you with any additional comments I wish to make. This is the reason for this letter.

I have been contacted by many people who have experienced adverse health effects when using glyphosate based products. The symptoms range widely from sore throats and headaches to dizziness and even permanent disability which at first I thought was very strange given the claims made by those who would promote its use as a "harmless" herbicide often given away free to gardeners with watering cans. However, as is all too common with pesticides, it appears that the entire world has been given false information as regards the action and safety of this group of chemicals.

In 1996 the British government sent a paper to all General Medical Practitioners entitled Pesticide Poisoning , the 2nd Edition.[1] This paper was edited by Dr Alex Proudfoot who was reported to be a member of the UK Advisory Committee on Pesticides. Under the heading GLYPHOSATE he wrote that "Glyphosate is an organophosphate which has ***no antcholinesterase*** activity. It inhibits an enzyme which is essential for the synthesis of aromatic amino acids in plants, but ***is not present in man***.....It is believed that this surfactant (polyoxyethyleneamine) was responsible for some of the features observed in cases of severe poisoning due to glyphosate containing products.....The new surfactants are expected to be less toxic than polyoxyethyleneamine ***but there is inadequate human experience to verify this***."
The emphasis is mine. You will no doubt observe several areas of concern in that statement.
Firstly it is an admission that formulations of glyphosate have been released into the environment and then found to be unsafe. ***There is even evidence that it <u>has</u> anticholinesterase action***.
Secondly there is the suggestion that it is ***merely believed and <u>not proven</u>*** that the surfactant was responsible for ***some*** of the adverse health effects experienced.
Thirdly that the surfactant was changed on the basis of that belief ***with no certainty of safety***.
In fact reports of adverse human reactions are awaited in order to prove that there is no risk..

Sadly the manufacturers do not recognise adverse effects from their chemicals unless they are confirmed by the UK Health and Safety Executive. This body has been shown to use every means possible to avoid recognising poisoning by pesticides – even when there is medical evidence supporting the diagnosis. The result is that few, if any, adverse reactions will be reported to the manufacturer and those vital early signs of danger will have been missed. This is an unsatisfactory and a dangerous situation, not just for the victims directly involved but for the entire population of the world since if the manufacturers have their way our crops will depend on the widespread use of the chemical.

Very slowly it is becoming apparent that the authorities are beginning to see that the safety data supplied to them by the manufacturers has not been accurate and in fact some reports suggest that data has been deliberately fabricated to give the impression that the product presents no risk.

This may explain the report issued in September 1997 that the New York Attorney General's office had taken the company (Monsanto) to task, **forcing them to withdraw adverts claiming that Roundup is biodegradable and environmentally friendly**.[2] Perhaps the fact that Roundup is not biodegradable explains the report by Greenpeace that residues have been found in lettuce plants grown over a year after the land was treated with the chemical. Farmers have reported to me that crops following those treated with glyphosate have suffered damage from the residues. Despite this the claim remains that no product is released into the environment unless it undergoes rigorous testing proving that it present no risk

In private correspondence it has been reported to me that one of the UK Government's Senior Medical Advisors, Dr Timothy Mars who adjudicates on pesticide incidents causing ill health as part of his work with the Pesticides Incidents Appraisal Panel, has actually confirmed that **glyphosate *is* a low level cholinesterase depressant** . Strange then that all glyphosate products escape the current review of anti-cholinesterase chemicals undertaken by the UK Ministry of Agriculture Fisheries and Food.
Repeated requests for an urgent review of data for glyphosate formulations because of the special place in the food chain as systemic herbicides which will soon be unavoidable have been ignored.

Evidence supporting the anti-cholinesterase properties of glyphosate recently came to me from the United States of America when I was informed that a Roundup formulation was used as an insecticide indoors. I must say that I did not believe the story at first but I am assured that evidence exists which proves that Roundup severely depressed the cholinesterase levels in the exposed victim. In my efforts to confirm or disprove this report I tested a formulation sold in supermarkets in a ready to use form and to my surprise I discovered that insects died almost instantly. The experiment was repeated with the same worrying result. I notified the Government and the Pesticide Safety Directorate with no response. Concerned about the possible effects on wildlife in general and birds in particular in respect of destruction of their food supply I informed the Royal Society for the Protection of Birds and again there was no response.
In order to ensure that this information was put on record I photographed the demise of insects treated with the ready to use Roundup herbicide using the clock which appears as broadcast with the television programmes here in the UK as background. Copies of those photos were then sent to the BSE Inquiry and after some persuasion they eventually acknowledged receipt.

BSE, as I am sure you are aware, began in the late 1980s in the UK. There has been much support for the theory that the disease was caused by organophosphates and Roundup is included in that chemical group. It may be significant to note that two approvals for Roundup were granted in the UK in the years preceding the BSE outbreak.
In 1981 the ADAS advisory service of the UK Ministry of Agriculture Fisheries and Food was recommending that arable farmers could use pre-harvest applications of Glyphosate on cereal crops [3] such as wheat, barley and oats as a means to control persistent grass weeds. The only concern shown was for use on malting barley for which permission had to be obtained from the potential purchaser of the grain. By 1985, presumably because no obvious adverse reactions had been recorded, that same advisory group was advocating the use of glyphosate on grassland [4] and significantly they declared that it would be good practice to graze the grass or preserve it as hay or silage **after** treatment.
This practice can only have added to the already high burden suffered by the cattle from OP insecticides in grain and straw, Lindane in grass, OPs in warble treatments and wormers, and fly control chemicals.

It would appear that these experiments paved the way for the use of Roundup on all crops before harvest as we now see in genetically modified crops which are resistant to glyphosate. There are reports that BSE cases are now being hidden as a means to support the now discredited meat and bone meal theory. If so it is extremely foolish and irresponsible, especially if the BSE cattle indicate a risk from glyphosate.

eturning briefly to the reports of adverse effects on human health the earliest indications of problems ime when I heard that men who handled thousands of bales of freshly harvested straw regularly every ear began to experience rashes on their arms. They wondered why this should be and discovered that it nly happened with bales from fields sprayed before harvest with glyphosate.

ther reports suggested that individuals already poisoned by organophosphates had collapsed when alking through the stubble of crops treated pre-harvest with glyphosate

nother man is reported to have operated the line-making machine used on sports fields. He was disabled ermanently by his work which involved the mixing of the whitening substance with a glyphosate ormulation. The mixture was then used to make permanent lines through which the grass could not grow. o his horror he discovered that phosphine was released during the application process.
he UK Government paper Notes on the Diagnosis of Prescribed Diseases [5] lists the dangerous effects aused by phosphine but it also notes that **"Phosphine is usually liberated accidentally when acid and ietal or alkali react to produce hydrogen. The action of hydrogen on phosphorus liberates hosphine"**
erhaps this is the reason why Agricultural formulations of Roundup carry the following warning
O NOT MIX, STORE OR APPLY ROUNDUP IN GALVANISED OR UNLINED MILD STEEL
O AINERS OR SPRAY TANKS.
O NOT leave spray mixtures in tank for long periods and make sure tanks are WELL VENTILATED

t is perfectly clear then that Roundup presents a serious risk to users in certain circumstances.

Now I will return to other and perhaps more serious aspects where the data seems less than accurate. This concerns cancer. In recent years glyphosate was regarded as a potential treatment for cancer. Nothing appears to have come of that research so far but the very existence of such plans proves beyond loubt that the chemical can influence human cells and is not simply restricted to plant amino acids. My wife and I know to our cost that chemicals which can cause cancer are often used to treat cancer. Currently she is undergoing chemotherapy using drugs which are derivatives of Mustard Gas in order to prevent a recurrence of a rapidly invasive malignant breast tumour of environmental origin. Lindane is he suspected causative agent but it is known that Mustard Gas is in itself carcinogenic and yet derivatives of such chemicals can control cancers by damaging cell growth in tumours.

In t' 'ournal of Pesticide Reform/Fall 1998-Vol.18,No.3. Herbicide Factsheet[6]on Glyphosate (Roundup) they report that "Given the marketing of glyphosate herbicides as benign, ***it is striking that laboratory studies have found adverse effects in all standard categories of toxicological testing.*** These include medium-term toxicity (salivary gland lesions), long-term toxicity (inflamed stomach linings), genetic damage (in human blood cells), effects on reproduction (reduced sperm counts in rats; increased frequency of abnormal sperm in rabbits), and carcinogenicity (increased frequency of liver tumors in male rats and thyroid cancer in female rats).
Glyphosate has been called "extremely persistent" by the U.S. Environmental Protection Agency, and half lives of over 100 days have been measured in field tests in Iowa and New York. Glyphosate has been found in streams following agricultural, urban, and forestry applications.
Commercial glyphosate herbicides are more acutely toxic than glyphosate. The amount of Roundup (containing glyphosate and the surfactant POEA) required to kill rats is about 1/3 the amount of glyphosate alone. Roundup is also more acutely toxic than POEA.
Glyphosate-**containing products are more toxic via inhalation than orally**. Inhalation of Roundup by rats caused "signs of toxicity in all test groups," even at the lowest concentration tested. These signs included gasping, congested eyes, reduced activity, and body weight loss. Lungs were red or blood-congested. The dose required to cause lung damage and mortality following pulmonary administration of two Roundup products and POEA (when forced into the trachea, the tube carrying air into the lungs) was only 1/10 the dose causing damage orally.

The report states that **adverse effects have been identified in each standard category of testing** (subchronic, chronic, carcinogenicity, mutagenicity, and reproduction). The publicly available studies of glyphosate's ability to cause cancer were all conducted by or for its manufacturer. In 1991, EPA alleged that Craven Laboratories, a company that performed studies for 262 pesticide companies including Monsanto, had falsified tests. "Tricks" employed by Craven Labs included "falsifying laboratory notebook entries' and "manually manipulating scientific equipment to produce false reports. " Roundup residue studies on plums, potatoes, grapes, and sugar beets were among the tests in question. The following year, the owner of Craven Labs and three employees were indicted on 20 felony counts. The owner was sentenced to five years in prison and fined $50,000: Craven Labs was fined 15.5 million dollars, and ordered to pay 3.7 million dollars in restitution. Although the tests of glyphosate identified as fraudulent have been replaced, this fraud casts shadows on the entire pesticide registration process.
In 1996, Monsanto Co. negotiated an agreement with the New York attorney general that required Monsanto to stop making certain health and environmental claims in ads for glyphosate products and pay the attorney general $50,000 in costs. Claims that glyphosate products are "safer than table salt, "safe for people, pets, and the environment, and degrade "soon after application" were challenged by the attorney-general because they are in violation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the national pesticide law. According to the attorney general, Monsanto had engaged in "false and misleading" advertising. **EPA made a similar determination about Roundup ads in 1998, finding that they contained "false and misleading" claims** and were in violation of FIFRA. However, EPA took no action and did not even notify Monsanto Co, about the determination because two years had elapsed between the time that the ads were submitted to EPA and the time that EPA made the determination.

At this point I would like to relate a sad story about a friend of mine. He was working in his garden when the spray boom covered him in Roundup. He had breathing problems and a rash but the operator of the machine declared there was no risk and thought it was a joke. His doctor told him not to be concerned as the symptoms would pass without further trouble. Just two and a half years later my friend died with cancer of the pancreas and his specialist dated the start of the cancer to a time shortly after the incident. I understand that cancer of the oesophagus has also been linked to the use of Roundup and I know of at least three cases of such incurable cancers in keen gardener friends who have used Roundup regularly.

I hope the information in this letter helps in your review and that there will soon be restrictions on the use of this chemical. As a former farm manager I was happy to see the introduction of the chemical as it replaced gramoxone which we all knew to be deadly in effect on humans with no antidote available. However we knew where we were with the chemical and no-one took risks with it for fear of death. Glyphosate formulations imply that no harm can be done and because this is not true the risk is greater. The danger is further enhanced with the introduction of Genetically Modified crops designed to withstand repeated applications of this chemical. Such actions will have devastating effects on the environment and upon the health of those using the chemical, living near areas sprayed with the chemical, and those eating the food which will inevitably contain residues of this systemic organophosphate herbicide / insecticide.

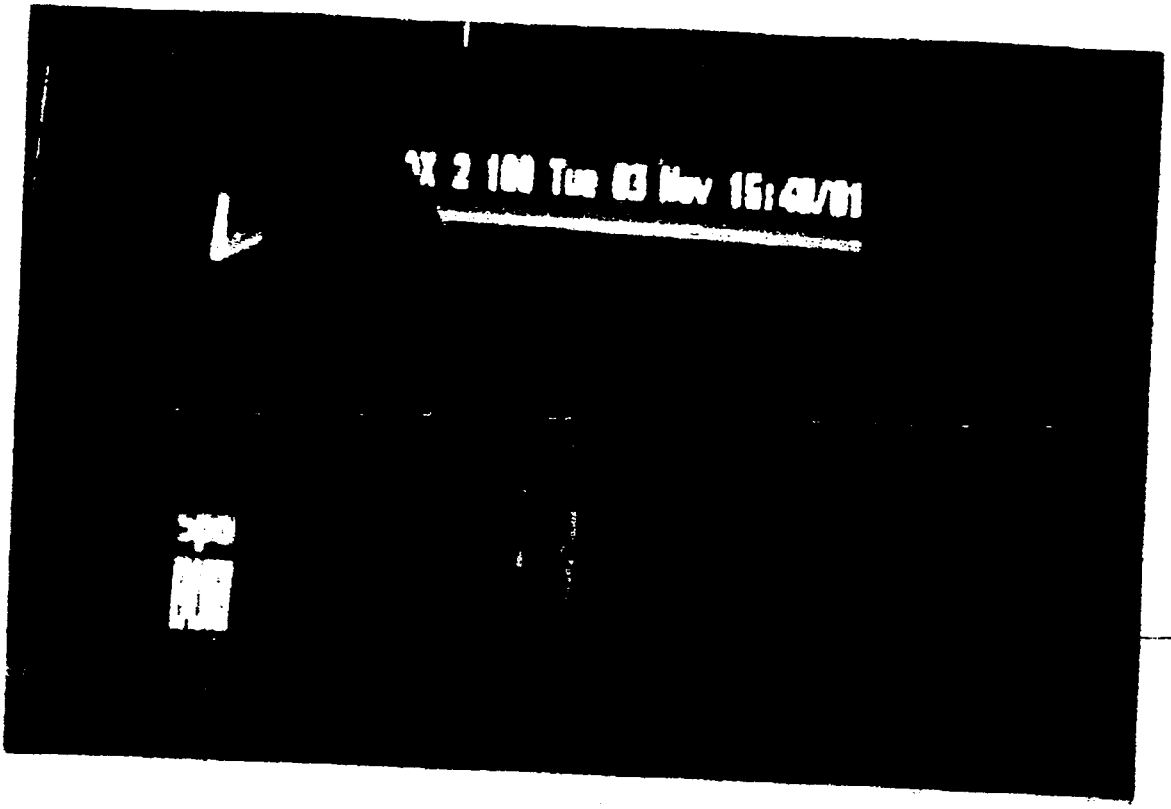
The dangers are obvious and I urge you to demand independent research and immediate restrictions on both its use and the importation into the EU of foods produced with the aid of the systemic poison.

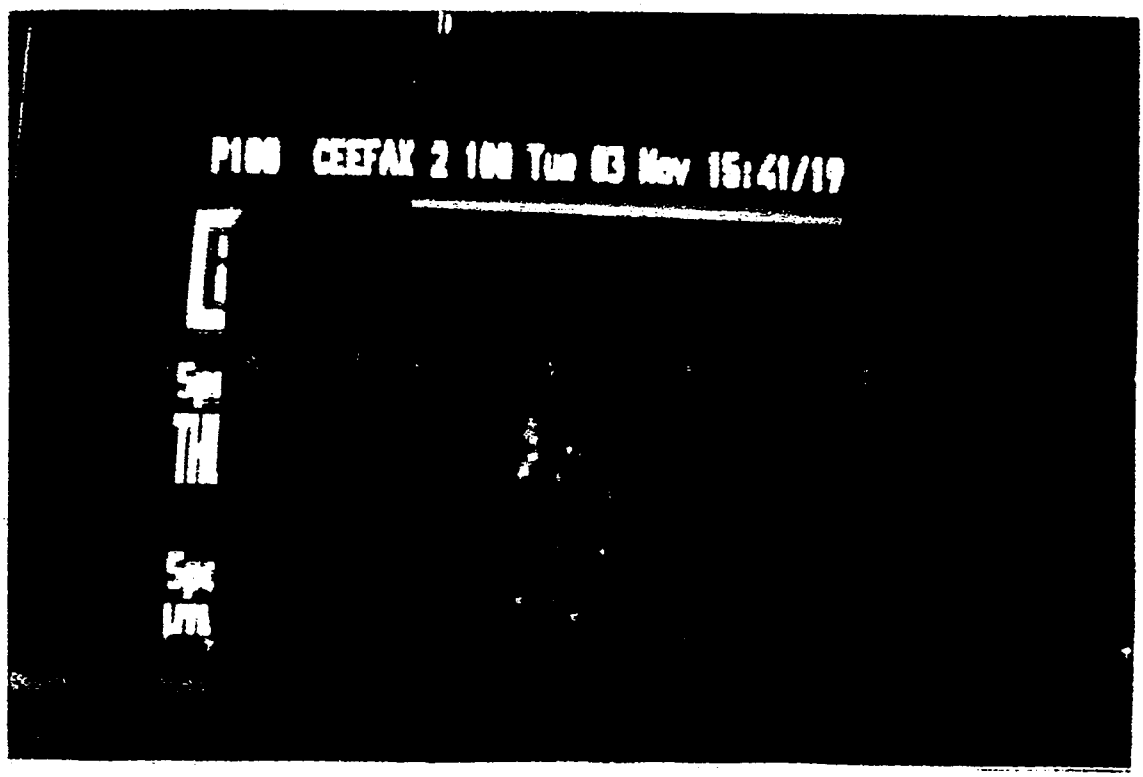
References

1. Pesticide poisoning, 2nd Edition, Notes for the Guidance of medical practitioners by Dr Alex Proudfoot 1996 (p 20)
2. Reported on page 23 of the Guardian Weekly September 28 1997 by George Monbiot
3. Pre-Harvest Glyphosate ADAS 1981.
4. Glyphosate on Grassland. ADAS "Progress" 1985
5. Notes on the Diagnosis of Prescribed Diseases 1992 from the UK department of Social Security (p72)
6. Journal of Pesticide Reform/Fall 1998 - Vol.18, No. 3, Herbicide Factsheet on Glyphosate (Roundup)

Yours sincerely, Richard R. Bruce.

Roundup Ready sprayed onto 4 flies at 15:40/01
on 3rd November 1998. All were DEAD at 15:41/19





Please forgive the quality. I had forgotten how to use the camera - I am O.P. poisoned myself. N.B The times shown do not allow for re-writing the backing label & resetting the camera

R.B. 4/5/99.

Monsanto Services International S.A./N.V.
Avenue de Tervuren 270-272
Tervurenlaan 270-272
Letter Box n°1
B - 1150 Brussels Belgium

☎ direct (+32) 2 776 4607
Fax direct (02) 776 4869
e-mail:USERID@Monsanto.com

Cheminoca Agro A/S
P.O. Box 9
DK-7620 Lemvig
Denmark

☎ (+45) 96 90 96 90
Fax (+45) 97 83 45 55
Telex 66514 CHEMV DK

ECCO-Team (PSD)
Pesticides Safety Directorate
Room 208, Mallard House,
Kings Pool, 3 Peasholme Green
UK - York Y01 7PX
United Kingdom

PSD ref.: PRD 3624
Our ref. : RPG/hvp

Brussels, February 11, 1999

URGENT

Re: EC evaluation of Glyphosate (according to regulation EC Nr 3600/92 and concerning inclusion of the active substance Glyphosate in Annex I of Directive 91/414)

Please find enclosed our comments on the second draft of the Monograph on Glyphosate. The major point from our review are:

a) We do not believe that Glyphosate is explosive.
b) An anaerobic metabolism study is not needed as the use on rice is to bare soil, before planting the rice.
c) Beneficial insect laboratory studies are affected by the "sticky nature" of the dried deposit.
d) We have a disagreement on the impact of Glyphosate on aquatic organisms.

We have done the best we can, within the time allocation for review, and look forward to further discussion on the data.

Yours sincerely,

R.P. Garnett
Registration Manager, Glyphosate

cc: ECCO-Team (BBA) - Braunschweig

- attachments

6553/ECCO/PSD/99

GENERAL COMMENTS

We suggest that the evaluation should establish a principle for the acceptance of data. Some pivotal studies are utilised where a company's compositional data shows incomplete analysis, i.e. unidentified impurities. The dosing levels for glyphosate studies are so high that slight variations in manufacturers impurity patterns may contribute to the variation in toxicological results which can be seen in the monograph. We would recommend that to be used for any critical endpoint the study concerned should be classified as "Acceptable" and the test material adequately defined, in terms of purity, impurities and description.

There are two main manufacturing routes for glyphosate, one called the Glycine process and the other the IDA process. Although they both produce >95% pure material the impurity profiles are different, and because the toxicological studies have been carried out at extremely high dose levels the significance of the impurities increases.

In a similar manner glyphosate formulations are available with a wide spectrum of Risk and Safety phrases because the major source of toxicological impact comes from the additional components, not glyphosate itself. It follows that critical endpoints for glyphosate which are based on formulation studies, such as ecotoxicological studies, should be considered by the Member States when they assess specific formulations, provided, for the purpose of Annex I listing it can be demonstrated that at least one formulation is within the acceptable limits.

We have given as many comments as possible in the limited time available but may not have covered all the items. We will continue to work on the document.

We are discussing with the rapporteur the most appropriate means of supplying additional data that have become available since the submission was first made - See Appendix I.

2.9.2 Effects on aquatic organisms

The review of aquatic effects of glyphosate concludes that, because of high toxicity to non-target aquatic organisms, aquatic uses and applications in rice cultures are not accepted. The decision is based on a 7-day EC_{50} of 0.64 mg/L for the marine algae species *Skeletonema costatum* exposed to glyphosate acid and a use rate of 4.32 kg as/ha.

The rapporteur has apparently used maximum use rate of 4.32 kg as/ha, however this is an Italian use only for dry drains. The true aquatic weed control rates is 3.6 kg as/ha per season. The Italian label specifically excludes the application of 4.32 kg as/ha directly over water.

A large data base exists for algae toxicity of glyphosate acid, glyphosate salts and various formulated products. Analysis of available data shows that *Skeletonema costatum* clearly represents an outlier, as it is one to several orders of magnitude more sensitive than all the other algae species tested. Monsanto believes that use of the most sensitive algae species combined with a highly conservative exposure estimate has identified a risk that will not be realised under field conditions. When more realistic field scenarios are taken into consideration (see Appendix D to this document), the use of glyphosate over water will be found to pose negligible risk for *Skeletonema* and other algae species. This assessment is confirmed by several field studies and observations made during the long history of over-water use of glyphosate in many parts of the world.

Furthermore, aquatic testing of several formulations has demonstrated that some products have better characteristics than others relative to non-target organism toxicity. MON 52276 and MON 44068 are glyphosate formulations submitted by Monsanto which has an extremely low toxicity to aquatic life, making these excellent candidates for aquatic weed control programs. Based on these formulation differences, Member States should be given the option of approving specific formulations and salts for over-water use.

A more detailed assessment of glyphosate effects on aquatic organisms is presented in Appendix D.

2.9.3.2 Effects on other arthropods

According to studies submitted in the original data package, glyphosate was considered to pose "high risk" to the standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* and "medium risk" to *Chrysoperla carnea* and lycosid spiders.

Since the original submission, follow-up studies have been produced as the science behind beneficial arthropod risk assessment evolved. Testing carried out on various Monsanto formulations has demonstrated that effects are product-specific and that formulation components other than the active ingredient may play a role in toxicity. This suggests that risk assessment should therefore be carried out separately for each product, rather than "globally" for glyphosate in general. As a direct consequence, Monsanto believes that, if data and reasoning are submitted which demonstrate that one or several individual Plant Protection Products do not cause unreasonable risk to beneficial arthropods, then Annex 1 listing should be allowed, with the provision that each formulation be assessed in regard to uses, rates, and occurrence of beneficial arthropods in the individual Member States.

In Appendix E to this document, the data package relevant to beneficial arthropod toxicity of the formulation MON 52276 is presented and discussed (formatted as an Annex III, Tier II chapter). Follow-up (extended laboratory) studies for *Aphidius rhopalosiphi* and *Typhlodromus pyri* are included. The data suggests that, for both traditional and Roundup-Ready crop uses of MON 52276, only low risk will exist for beneficial arthropod species exposed in the environment off-field and on-field habitats.

Based on these favourable formulation-specific results, Monsanto recommends allowing Annex 1 listing for glyphosate.

2.9.2 Effects on aquatic organisms

Glyphosate has been successfully used in many parts of the world as an important tool for rehabilitation/restoration of aquatic ecosystems damaged by exotic or invasive weeds. Glyphosate is effective at control of emergent and floating weeds, but cannot be used to control submerged vegetation because of low activity after it enters the water column. A number of field studies have been conducted to investigate the non-target effects of glyphosate associated with aquatic weed control programs and a summary of published scientific reports is included in this section. These studies demonstrate that unwanted vegetation can be successfully controlled without long-term effects on non-target organisms. Short-term reductions in plant biomass and associated animal populations can be expected due to habitat change.

The standard approach to assess risk of a herbicide active substance in accordance with ECCO Aquatic Risk Assessment Guidance Document (1998) is to use data from a green alga and another algal species (either a blue-green alga or a freshwater diatom). The studies for two standard green algal species (*Selenastrum capricornutum* and *Scenedesmus subspicatus*) and a freshwater diatom (*Navicula pelliculosa*) are included in the glyphosate monograph. EC_{50} values for all of these species are listed in the dossier as $\geq$ 42 mg/L. In addition, a 7-day regulatory study with *Anabaena flos-aquae* has also been conducted. The EC_{50} value for this study is 15 mg/L. When TER's are calculated using the EC_{50} values from these standard test species and the maximum initial PEC for overwater application (1.44 mg/L), TER values are 10 or greater which indicates acceptable risk for aquatic uses. The actual maximum use rate for aquatic uses is 3.6 kg as/ha rather then 4.32 kg as/ha, therefore, the maximum initial PEC for overwater application would be 1.2 mg/L.

In addition to the standard freshwater species, We submitted two studies on a marine diatom which reported EC_{50} values that were more sensitive than the standard test organisms. The most sensitive EC_{50} value for these two studies (7-day EC50 = 0.64 mg/L) was used to calculate the acute TER for aquatic use. Based on the marine diatom data, it is concluded that glyphosate poses significant risk to aquatic organisms and that the aquatic use of this product should not be approved. We believe that use of the most sensitive algal species and the highly conservative exposure estimate has identified a risk that will not be realized under field conditions. Specifically, we would suggest that the worst case exposure values be modified to allow for interception of the product before it enters the aquatic environment, and to consider using a lower safety factor considering the large number of algal data available for glyphosate and its formulations. We believe that with these considerations as discussed below, the use of glyphosate over water will be found to pose negligible risk for *Skeletonema* and for other algal species.

The PEC used in the TER calculation appears to be 0.834 mg/l, the time-weighted mean at 7 days. The actual maximum use rate for aquatic uses is 3.6 kg as/ha rather than the 4.32 kg as/ha as used by the rapporteur. Therefore, the 7-day time weighted value is approximately 0.7 mg as/L when applied to open water. Under conditions of use, this exposure level will be lower because of interception on target vegetation. This is a safe assumption for glyphosate because, as mentioned earlier, it is only effective on emergent or floating vegetation and is not effective on submerged vegetation. If it is assumed that 50% of the glyphosate is intercepted by vegetation, then the PEC will be reduced by half. Consequently, a worst case exposure for glyphosate in a 30 cm water column after 7 days would be 0.35 mg as/L.

The TER for algae based on the marine diatom was 0.7 (0.64/0.834 mg/L) for the use rate of 4.32 kg as/ha. The TER using the interception model and 3.6 kg as/ha would be 1.8. The NOECs for the two *Skeletonema* studies ranged from 0.3 to 0.6 mg a.s./L. Therefore, the 7-day time-weighted PEC falls in the range that is not expected to produce any effect on *Skeletonema*. Use of an additional safety factor is likely not necessary based on the relatively large data base available for glyphosate (see table below). As seen in the table the *Skeletonema* values are the lowest of 16 different tests on 12 different species/strains. Therefore, the likelihood of a new species being more sensitive than the *Skeletonema* data is low.

Species	Duration	EC_{50} (mg/L)	NOEC (mg/L)	Reference
Anabaena flos-aquae	7	15	9.7	Malcolm Pirnie 1987a
Anabaena variabilis	n.r.	2		Hutber et al. 1979
Aphanocapsa strain 6308	n.r.	2		Hutber et al. 1979
Aphanocapsa strain 6714	n.r.	100		Hutber et al. 1979
Navicula pelliculosa	7 days	42	34	Malcolm Pirnie Inc. 1987c
Nostoc sp.	n.r.	2		Hutber et al. 1979
Selenastrum capricornutum	4	21.8		Bozeman 1989
Selenastrum capricornutum	7	14	11	Malcolm Pirnie 1987b
Skeletonema costatum	4 days	1.3	0.6	EG & G Bionomics 1978a
Skeletonema costatum	7 days	0.64	0.28	Malcolm Pirnie Inc. 1987b
Scenedesmus acutus	4 days	10.2	2	Sáenz et al. 1997
Scenedesmus quadricauda	4 days	7.2	0.77	Sáenz et al. 1997
Chlorococcum hypnosporum	4 days	68		Maule and Wright 1984
Chlorella pyrenoidosa	4 days	590		Maule and Wright 1984
Chlorella pyrenoidosa	4 days	380		Anton et al.. 1993
Chlorella pyrenoidosa	4 days	1082		Anton et al.. 1993

n.r.: not reported

Several field studies have been conducted on the effects of aquatic weed control applications on aquatic organisms (Solberg and Higgins, 1993; Findlay and Jones, 1996; Simenstad *et al.*, 1996; Linz *et al.*, 1997). Field investigations for the IPA salt of glyphosate (Rodeo formulation) used for control of smooth cordgrass in estuaries showed no indications of either short- or long-term effects on benthic microflora (algae) or invertebrates (Simenstad *et al.*, 1996). No effects on density, abundance or survival of aquatic invertebrates have been reported from the direct effects of glyphosate in field studies (Haag 1986, Henry *et al.*1991, Gardner and Grue 1996). Solberg and Higgins (1993) observed fewer aquatic invertebrates in Rodeo treated wetlands, but observed more aquatic invertebrates in the cattail re-growth of Rodeo treated wetlands relative to controls. The authors suggested that the initial decrease in habitat was most likely responsible for the changes observed. Glyphosate herbicides were viewed as an important and effective tool in long term management of aquatic habitats infested with exotic or invasive species.

MON 52276 and MON 44068 are glyphosate formulation submitted by Monsanto which have extremely low toxicity to aquatic animals (all freshwater fish and invertebrate LC50s are above 100 mg/L). In addition, MON 52276 and MON 44068 can be classified as practically non-toxic to algae (Canton, 1991). The extremely low toxicity of these formulations to aquatic organisms makes it an excellent candidate for aquatic weed control programs.

These data demonstrate that glyphosate formulations can be successfully used to manage aquatic weed problems with minimal risk to non-target organisms and that to eliminate the aquatic use of glyphosate formulations with good aquatic toxicity profiles would remove a very effective product for control of exotic or invasive aquatic plants. Because some formulations have better characteristics than other relative to non-target organism toxicity, Member States should be given the option of approving specific formulations and salts for overwater use.

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Appendix E

Volume 1, Level 2, Point 2.9.3.2 Effects on other arthorpods
Non confidential
Data package relevant to beneficial arthorpods toxicity of the formulation MON 52276 (Annex II Tier III format)

FINNISH ENVIRONMENT INSTITUTE
Chemicals Division

Helsinki 7 May 1999

Our ref. SY99P0037-042

Your ref.

Mr. J.–R. Lundehn
BBA
Messeweg 11/12
D-38104 Braunschweig

Subject COMMENTS ON GLYPHOSATE, GLYPHOSATE-TRIMESIUM (DRAFT MONOGRAPH AND PROPOSED DECISION, PREPARED BY GERMANY) - ECOTOXICOLOGY

Dear Mr. Lundehn,

Please find below the Finnish comments on the section "Ecotoxicology" of the Draft Monograph of glyphosate and glyphosate-trimesium to be considered during the seventh round ECCO Peer Review Meeting, ECCO 84.

The monograph was well prepared and transparent. We agree with the suggestion that the inclusion of active ingredient to Annex I should be postponed until the risk for beneficial athropods is further assessed and also with the proposal that the later inclusion includes a condition that no application takes place in surface water or rice cultivation.

One small remark is made on the classification and labelling. There is some discrepancy in the given risk phrases. In volume 1, risk phrases R 50/53 are suggested for glyphosate acid. However, in the end point sheet R52/53 phrases are given with regard to ecotoxicological data.

Based on the submitted data glyphosate appears not to be extremely harmful to the environment. We would, however, like to remind that glyphosate is included in the OSPAR (OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic) list of candidate substances disrupting the endocrine and reproductive system. According to literature survey made by WWF for OSPAR, glyphosate has been reported to affect the sperm quality.

Since current studies required according to directive 914/14/EEC are not suitable for assessing endocrine disrupting effects, we suggest that risk mitigation should be based on the precautionary principle. The use of glyphosate containing products is enormous

Postal address: P.O. Box 140 FIN-00251 Helsinki
Visiting address: Kesäkatu 6 Helsinki
Telephone: international +358 0 403000
Telefax: international +358 0 40300591
Telex: 126086 vyh sf

round the world and therefore we suggest that it should be seriously discussed if there is a possibility to reduce the intended uses of glyphosate or to minimize the application rates.

Yours sincerely,

Division Manager — Esa Nikunen

Senior Advisor — Leona Mattsoff

CC. ECCO Team/PSD
Plant Production Inspection Centre, Finland
National product Control Agency for Welfare and Health, Finland

Postal address:
P.O. Box 140
FIN-00251 Helsinki

Visiting address:
Kesäkatu 6
Helsinki

Telephone:
international
+358 0 403000

Telefax:
international
+358 0 40300591

Telex:
126086 vyh sf

MONSANTO
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Mr. D. J. Flynn,
ECCO-Team (PSD),
Pesticides Safety Directorate,
Mallard House,
Kings Pool,
3 Peasholme Green,
York,
YO1 7PX
United Kingdom

22 June 1999

Dear Mr. Flynn,

EC EVALUATION OF GLYPHOSATE
Glyphosate ECCO round: Ecotoxicology

We enclose additional information prior to the Ecotoxicology Peer Review meeting (20-23 July). This information has also been sent to Dr. H. Bruno at the BBA, Braunschweig.

Your sincerely,

Richard Garnett
Registration Manager - Glyphosate

6555/ECCO/PSD/99

GLYPHOSATE TOXICITY TO THE AQUATIC ENVIRONMENT: RESPONSE TO ISSUES RAISED IN THE DRAFT MONOGRAPH

CLASSIFICATION AND LABELLING - hazard of glyphosate acid

1. Issue: The draft EU monograph (12-98) proposes to classify glyphosate acid as R50/R53.

Based on a large database available for glyphosate, Monsanto considers that this classification is very severe and does not reflect the real hazard of this active substance. Indeed, the data indicate a generally low toxicity to aquatic organisms and a rapid dissipation in the aquatic environment.

2. R50: The R50 label was proposed based on a 7d EC_{50} value of 0.64 mg/L for the marine green algae *Skeletonema costatum*. There are several reasons for considering this end point as unrepresentative for classification purposes:

- In the labelling and classification annex of EU directive 67/54, the data specified for algae is 72h EC_{50}. The 72 h EC_{50} extrapolated from the S*keletonema* study is in the range of 1 - 2 mg/L. *Skeletonema* is not a typical species to use for classification in the EU.
- The data submitted to the rapporteur in April 1995 showed that typical freshwater green algae species, such as *Selenastrum*, had 7d and 72h EC_{50} values for glyphosate acid > 10 mg/L. Additional data from the literature submitted in February 1999 showed that the weight of data is >10 mg/L although some values are in the range 1-10 mg/L. Most of the values below 10 mg/L are derived from a study in the literature for which the duration of the study is not reported. A summary of the data is attached (Table 1).
- a Canadian study tested periphyton from six natural ponds in solutions of filtered water from the same ponds, to which were added a range of concentrations of glyphosate (0.89 to 1800 mg/L). Calculated EC_{50} values, based on inhibition of photosynthesis, were >10 mg/L for all the ponds (range 35 - 69 mg/L). (**new data,** Goldsborough, L.G., Brown, D.J., (1988), Bull. Environ. Contam. Toxicol., 41: 253-260))

Conclusion: glyphosate has a favorable general aquatic toxicity profile. For most algae species tested the EC_{50} values are above 10 mg/L. S*keletonema costatum* clearly represents an outlier and, therefore, is not a good representation of the environmental hazard posed by glyphosate.

3. R53: The R53 label was proposed based on a series of inherent (not "ready") biodegradability studies (OECD 302B) and BOD/COD analyses which showed that, **when biodegradation is measured as decrease of total organic carbon**, glyphosate is practically not degradable. When the entire available database on environmental fate of glyphosate is considered, the above results can be put into a more realistic

perspective. The degradation products of glyphosate enter the one carbon pool and are utilised as a carbon source.

- A ready biodegradability study was conducted for the Northern Ireland Environment and Heritage Service on the formulated product, MON 52276, using an OECD 306 assay (marine ready biodegradability). Under the strict conditions of this test (the inoculum is sea water alone) where **biodegradation is measured as oxygen consumption**, MON 52276 was found to degrade as completely as the positive control, sodium benzoate in the 28d test period. **(new data)**
- The apparently contradictory results suggest that, in the above test systems, glyphosate may be degrading to metabolites, although not mineralizing, in the 28d test duration of the biodegradability studies. Consequently, the decrease in total organic carbon does not indicate the actual degradation of glyphosate.
- Many studies on the fate of glyphosate in water have shown that:
  - biological degradation is the principle mechanism for degradation in water and water/sediment systems
  - it disappears rapidly from the water phase and is transferred to sediment phase for further degradation. The DT_{50} for water is consistently well below 28 days.
  - in both phases, glyphosate degrades to a major metabolite of low toxicity:

Glyphosate ⟶ aminomethyl phosphonic acid (AMPA) ⟶ CO_2, NO_3, PO_4, H_2O

  - AMPA has a half life in water of 2-5 days, and also partitions to the sediment, where it is held in the humic and fulvic fractions (**new data - Monsanto report**). AMPA has been recognised in the draft monograph as being of no toxicological or ecotoxicological concern.

We propose that this evidence meets the requirement in 67/548 that substances may be considered readily degradable "*if other convincing evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level of >70% within a 28 day period.*"

4. SUMMARY

- typical EC_{50} values for algae are >10. The *Skeletonema* result is an outlier, and calculated at 72 hrs is >1.0.
- the apparent poor degradation of glyphosate in inherent degradability studies is a function of the methods of measurement, whereas, in fact, glyphosate is readily degraded.
- glyphosate has no potential for bioaccumulation ($\log P_{ow} < 0$).

General conclusion:

- **glyphosate and its major metabolite have been shown to pose no long-term hazard to the aquatic environment.**
- **we propose that glyphosate is rapidly degraded, with most algal EC_{50} >10, so the classification should be R52/R53 and should not include the symbol 'N'.**

HAZARD OF THE FORMULATION

Data already submitted to the rapporteur shows that MON 52276 (360 g/L glyphosate) and MON 44068 (420 g/kg glyphosate) are of low toxicity to algae (LC_{50}>100 mg/L).

	Growth rate 72h LC_{50} *Selenastrum capricornatum*	
glyphosate acid	54	mg/L
MON 52276	392.9	mg/L
MON 44068	936	mg/L
	1118	mg/L

The results clearly show that the relative toxicity of the formulated products is several times less than for the glyphosate acid. The reason for this has not been resolved. However, it is believed that.....FRANCESCA ~ add your notes from Chris here!

We support the conclusion of the rapporteur that there should be no classification of the formulations, or the salts which they contain.

The draft Monograph recognises that some formulations show greater toxicity than glyphosate acid, so it is clear that the formulation must be taken into account when assessing hazard.

Conclusion:

- **The labels for MON 52276 and MON 44068 should have no risk phrases or hazard symbols.**
- **Other formulations may require risk phrases concerning the hazard to aquatic life, and may require the 'N' symbol.**

FRANCESCA can you find the paragraph in 67/548 which indicates that the data on the formulation takes precedence over the data for the substance.

OVER-WATER USE

1. Issue: The draft EU monograph (12-98) proposes that glyphosate should not be recommended for over water uses for aquatic weed control.

The first draft monograph proposed to accept over water uses, but this was changed in the second draft. We understand that this is primarily because of the unacceptable TER arising from glyphosate acid on *Skeletonema* which was discussed under "Classification and Labelling". Argumentation has been made to show that this TER does not reflect the real hazard to the environment of glyphosate acid, and that the data for MON 52276 and MON 44068 show that they are considerably less toxic to algae than the active substance.

2. Background: aquatic weed control

The need for managing vegetation in bodies of water has increased over the past 20 years, primarily due to human disturbances of this sensitive ecosystem:

- eutrophication, and other pollutants
- the introduction of alien species (*Heracleum, Impatiens, Azolla, Hydrocotyle etc.)*,
- water abstraction, and the over-widening of river channels for flood relief
- engineering schemes which disturb soil and water, and may import new soil.
- greater use of waterways for leisure and recreation

Combinations of these factors lead to reduced biodiversity and excessive growth of remaining, often invasive, species.

Mechanical methods are the most common methods of weed control, but environmental (*eg* shading or manipulation of flow) and biological methods (*eg* bottom feeding fish or grazing birds) are available as well as herbicides. Typically managers use a combination of techniques to meet their specified results: "integrated control" or "vegetation management". All methods have a significant environmental impact to be balanced against the benefits. Mechanical methods disturb the water and sediment, and adjacent areas. Vegetation dumped at water margins is slow to rot, particularly if it contains significant quantities of algae, and can encourage the spread of invasive perennial species into agricultural fields. Mechanical weed control leads directly to the removal and death of aquatic invertebrates, as demonstrated, for example, in Ireland:

method	**growth removed**	**loss of invertebrates**	**recovery time**
mechanical cutter	cut back to 25cm	62%	9 months
weed bucket	cut back to sediment	84%	12 months

3. Over water uses of glyphosate are approved in 9 EU states:

North Europe: France, Ireland, UK	max. dose 2.16 as kg/ha
Belgium	max. dose 2.88 as kg/ha
South Europe: Greece, Italy, Portugal, Spain	max. dose 3.60 as kg/ha

One application per season is recommended at a maximum dose below that used in the TER calculations (4.32 as kg/ha). Glyphosate is herbicidally active on emergent and floating species only, and exposure of water to applications is reduced by interception on the target plants. Furthermore, application is typically by localised (bands, patches or spot treatments) and it is normal to leave untreated vegetation at the water's edge. A statutory condition of use in the UK and Ireland is that the maximum concentration in water after use 0.2 mg/l. At this concentration there is no herbicidal effect when the water is used to irrigate crops. It is also well below the lowest EC_{50} for aquatic life.

Aquatic weed control is one of the most regulated uses of pesticides. For example, in the United Kingdom users must be specifically trained and certificated to use aquatic herbicides, and must follow detailed guidelines. They must request permission for each usage of a herbicide from the Environment Agency.

4. Monitoring the impact of glyphosate uses in the field

Many studies have monitored the impact of glyphosate used for the control of aquatic weeds. These and commercial experience suggest there is little negative impact on aquatic life. Glyphosate is used to improve aquatic habitats, for example :

- reduction of *Spartina* cover in coastal nature reserves to improve habitat for feeding and roosting ducks and waders (UK). (published, **new data**)
- clearance of dense *Sparganium* to allow access for fishing, which increased the river flow, re-exposing gravel which allowed salmon to breed for the first time in several years (Ireland). (published, **new data**)
- creating "two stage" channels in mechanically over-widened rivers by removing vegetation in a central channel. The river flow flushes out silt from the channel, leaving vegetated margins, without disturbance from mechanical methods (UK).
- management of ponds for intensive carp rearing (Poland). (published, **new data**)
- component of management programmes for invasive weeds, particularly *Reynoutria, Impatiens, Heracleum* (several member states).

5. Conclusions

- **glyphosate is a valuable tool to manage aquatic habitats. It can be used where mechanical weed control is difficult, less effective, or potentially damaging.**
- **rapid dissipation and use as a spot or band treatment mean that instantaneous PECs are localised and short term**
- **effects on algae are formulation dependent:**
  - **for MON 52276 and MON 44068 TER > 10**
  - **for ipa salt TER > 10**
  - **for glyphosate acid TER >10 most species, >1 others**
  - **field experience and data suggests no significant impact on aquatic life**
- **Conclusion:** ***over water uses poses no unacceptable risk***

USE OF GLYPHOSATE IN RICE

1. Issue

The draft EU Monograph requests an anaerobic study of the fate of glyphosate for the special use in rice. We understand that the calculation of PECs in rice will be discussed at ECCO.

2. Clarification of usage

- The list of intended uses in the monograph states: multiple uses per season, maximum dose per season 4.32 kg/ha..
- Use in rice is recommended only in Italy and at rates below that assumed in the monograph. Any risk assessment should be based on doses of glyphosate applied prior to flooding the rice, pre plant of the crop. **Pre-plant use is 1.08 kg as/ha** to control weeds which have emerged after cultivation. These are mainly annual grasses.
- Post harvest treatments are not appropriate for this assessment. Post-harvest use is at up to 2.16 kg as/ha.
- There are two alternative cropping systems, each estimated by Monsanto to take about half the area of rice:

a) cultivate >> glyphosate >> flood after 7 days >> broadcast drill into water >> remain flooded for 4 weeks >> dry 2-3 weeks for weed control >> flood again

time from treatment to flooding: 7 days

b) cultivate >> glyphosate >> drill after 7 days >> flood 6-7 weeks later

time from treatment to flooding: 7-8 weeks

Thus, the fate of glyphosate in flooded conditions is relevant largely to system a).

3. Additional studies:

- an anaerobic degradation study is being initiated in response to the request in the monograph.
- PEC's have been calculated assuming that there is total release of glyphosate from the treated area after flooding and 25% release. This is a severe worst case, since much glyphosate will be adsorbed to soil or sediment particles and will not be freely available in water (data on adsorption has already been submitted to the rapporteur). Adsorption also prevents leaching through the saturated soil.
- TER's based on these PEC's are greater than 10, with the exception of that for *Skeletonema costatum.* The relevance of which was discussed under "Classification and Labelling".

4. Conclusion

The additional data will be provided to the rapporteur to address the issues raised in the monograph.

Francesca Tencalla, Ph. D.
Ecotoxicology Specialist, Europe/Africa

Monsanto Europe S.A.
Parc Scientifique Fleming, Rue Laid Burniat 5,
B - 1348 Louvain-La-Neuve, Belgium
Tel direct: +32 10 49 44 12, Fax: +32 10 49 44 44
e-mail: francesca.tencalla@.monsanto.com

Mr. D. Flynn
ECCO-Team (PSD)
Pesticide Safety Directorate
Room 208
Mallard House, King's Pool
3, Peasholme Green
York Y01 2PX
UK

Louvain-La-Neuve, July 12 1999

Re: Glyphosate toxicity to non-target arthropods

Dear Mr. Flynn, → Mr Radford – for action please. DF 13/7.

As agreed with Dr. Bruno during a meeting at the BBA on 19 February 1999 to discuss effects of glyphosate on non-target arthropods, please find attached for consideration during the upcoming ecotoxicology ECCO session:

- a revised and final summary of all studies carried out on non-target arthropods with our formulation MON 52276, along with the corresponding risk assessment,

- a copy of two promised new studies (Tier 1 assay with *Chrysoperla carnea* and advanced Tier 2 assay with *Typhlodromus pyri*).

This information is also being sent to the BBA.

With best regards,

Francesca Tencalla

Attached: - 1x MON 52276 Annex III, Tier II, Section 6, Chapter 10.5.3: "Effects on beneficial arthropods other than bees"
- 1x Monsanto study no. US-99-092: "An extended laboratory test to determine the effects of MON 52276 on the predatory mite, *Typhlodromus pyri*"
- 1x protocol and summary of intermediate results for Mambo-Tox study no. MON-99-3: "A laboratory evaluation of the effects of MON 52276 on the green lacewing, *Chrysoperla carnea*"

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ctb

P.S.D.
15 JUL 1999
D. No. 57125

Biologische Bundesanstalt fur Land- und Forstwirdschaft, Abteiling fur Pflanzen-schutzmittel und Anwendungstecknik
Messeweg 11-12
D-38104 BRAUNSCHWEIG

Briefnummer 99/2871 JJM/LVI
Behandeld door ir. J.J. Meeussen *doorkiesnummer* 471858
Uw kenmerk
Datum 6 juli 1999

Betreft Comments on the draft-monograph of the active substance **glyfosate**
Ecco-meeting 84
Section: Ecotoxicology

The Board for the Authorization of Pesticides (CTB) has received the draft monograph of the active substance glyfosate.

Please find hereafter the comments of the CTB with respect to the draft-monograph as prepared by Germany.

Level 2.

- Par. 2.9.2: aquatic organisms: it must be stressed that the formulations are in several cases much more toxic than the active substance. In the next table the available data in The Netherlands for algae (the most sensitive organism) are given.

a.s./Form	Organism	Toxicity (mg/L)
glyfosaat	*Selenastrum capricornutum*	96-uurs E_bC50 26.3 mg/l (nominal)
	Selenastrum capricornutum	96-uurs E_bC50 7.8 mg/l (nominal)
	Selenastrum capricornutum	72-uurs NOE_bC 10 mg/l (nominal)
	Selenastrum capricornutum	72-uurs NOE_rC 32 mg/l (nominal)
	Selenastrum capricornutum	72-uurs E_bC50 48 mg/l (nominal)
	Selenastrum capricornutum	72-uurs E_rC50 54 mg/l (nominal)
	Selenastrum costatum	96-uurs E_bC50 1.3 mg/l (nominal)
MON44068	*Selenastrum capricornutum*	72-uurs E_bC50 149 mg a.s./L (nominal)
MON44068	*Selenastrum capricornutum*	72-uurs E_rC50 >420 mg a.s. /l (nominal)
MON44068	*Selenastrum capricornutum*	72-uurs NOEC 134 mg a.s./L (nominal)
MON2139	*Selenastrum capricornutum*	72-uurs E_bC50 0.77 mg a.s./L (nominal).
MON2139	*Selenastrum capricornutum*	72-uurs E_rC50 2.88 mg a.s./L (nominal).
MON2139	*Selenastrum capricornutum*	72-uurs NOEC 0.26 mg a.s./L (nominal)
Roundup	*Chlorella pyrenoidosa*	72-uurs E_bC50 >87.3 mg a.s./L (nominal)
Roundup	*Chlorella pyrenoidosa*	72-uurs NOE_bC < 17.0 mg a.s./L (nominal)
MON52276	*Selenastrum capricornutum*	72-uurs E_bC50 54.0 mg a.s./L (nominal)
MON52276	*Selenastrum capricornutum*	72-uurs E_rC50 86.1 mg a.s./L (nominal)
MON52276	*Selenastrum capricornutum*	72-uurs NOEC 27.3 mg a.s./L (nominal)
MON14478	*Selenastrum capricornutum*	72-uurs E_bC50 0.014 mg a.s./L (nominal)
MON14478	*Selenastrum capricornutum*	72-uurs E_rC50 0.040 mg a.s./L (nominal)
MON14478	*Selenastrum capricornutum*	72-uurs NOEC 4.8 µg a.s./L (nominal)
AMPA	*Scenedesmus subspicatus*	96-uurs NOEC 79.7 mg/l (nominaal)

6577/ECCO/PSD/99

Bij beantwoording gaarne het onderwerp, het briefnummer en de datum van deze brief vermelden.

Stadsbrink 5
6707 AA Wageningen

Postbus 217
6700 AE Wageningen

Telefoon: 0317-471810
Telefax: 0317-471899

Internetadres: http://www.ctb.agralin.org

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Level 3.
NL supports the view of the RMS to postpone the decision for inclusion of glyphosate in Annex I.

Level 4.
NL agrees with the RMS-proposal.

These comments also have been sent to the ECCO-team.

Yours ~~sincerely~~,

Dr J.S.M. Boleij
(secretary of the Board)

cc: ECCO-team (PSD)
Pesticide Safety Directorate
Room 208
Mallard House, Kings Pool
3 Peasholme Green
UK-York Y01 7PX