

**Appendix 1: ECCO 76 reporting table      Glyphosate (Hb)**

**1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis**

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(i)	<p><b>Identity</b> manufacturing process/sources of glyphosate</p>	<p>There are 18 different sources of glyphosate. Two main pathways to manufacture glyphosate : the glycine process and the IDA process. Glyphosate is produced in 3 forms – the isopropyl salt, the sodium salt and the ammonium salt.</p> <p><b>IDA process</b> The Monsanto source was considered the definitive profile as it had the most comprehensive analytical suite, impurity profile and data package for the IDA process. For the IDA process, the other sources were compared to the Monsanto source.</p> <p><b>Glycine process</b> For the glycine process, all sources were compared to the Agrichem source as it was the first source listed in the summary table produced by the glycine route for which data were provided.</p>	<p>-      -</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(ii)	Sources that don't meet the FAO specification of 950g/kg	<p>The meeting noted that the FAO specification is being updated at present so they agreed to consider sources against the current FAO specification of 950g/kg glyphosate. The meeting considered that the following sources of glyphosate did not meet the current FAO specification and noted in some cases this may be because the company may not have presented their technical specification on a dry weight basis : Sinon, Industrias Afrasa *, Calliope* (IDA process) and Nufarm.</p> <p>* member of the Tulip Task Force – none of these companies analysed for N-nitrosoglyphosate.</p>	<p>IIA The following sources of glyphosate did not meet the current FAO specification : Sinon, Industrias Afrasa *, Calliope* (IDA process) and Nufarm.</p> <p>* member of the Tulip Task Force – none of these companies analysed for N-nitrosoglyphosate.</p>

No	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(iii)	Sources for which a decision on comparability of sources is not possible until further data submitted	<p>The meeting noted that for the following sources a decision on comparability of sources is not possible until further data are submitted : Feinchemie, Herbex, Sundat, Pinus, Alkaloida.</p> <p>Further data required are indicated below:</p> <p>Feinchemie – further validation data for the 5 batch analysis are required</p> <p>Herbex – clarification of method of manufacture is required and 5 batch analysis data are required.</p> <p>Sundat* – 5 batch analysis are required.</p> <p>Pinus* – there is a potential difference with MOD No 4, AGC Nos. 9 and 11. More accurate characterisation or measurement of impurities is required.</p> <p>Alkaloida – (a) glycine process : batch 3 doesn't meet Alkaloida's own specification, but it does meet the FAO specification, this requires clarification.</p> <p>(b) IDA process, on available data there is a potential difference with MOD No 12 and additional batch analysis data are required.</p> <p>* member of the Tulip Task Force – none of these companies analysed for N-nitrosoglyphosate, this analysis is required.</p>	<p>IIA A statement on the comparability of sources is not possible until further data are submitted as indicated below:</p> <p>Feinchemie – further validation data for the 5 batch analysis are required</p> <p>Herbex – 5 batch analysis are required.</p> <p>Sundat* – 5 batch analysis are required.</p> <p>Pinus* – more accurate characterisation or measurement of impurities MOD#4 = PMIDA and nitroglyphosate.</p> <p>Alkaloida – (a) glycine process : batch 3 doesn't meet Alkaloida's own specification, but it does meet the FAO specification, this requires clarification.</p> <p>(b) IDA process : additional validation data are required.</p> <p>* member of the Tulip Task Force – none of these companies analysed for N-nitrosoglyphosate, this analysis is required.</p>

No	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(iv)	Potential differences between sources, need advice as to the significance of the impurities listed in summary table attached.	<p><u>IDA process – compared to Monsanto source</u></p> <p><u>Agrichem* – analysis by LC/MS but did not use any standards. Therefore new data required. On the available data there is a potential difference with impurities MOD No. 12, AGC Nos. 9, 11 and 12.</u></p> <p><u>Aragonesas* - analysis by LC/MS but did not use any standards. Therefore new data required. On the available data this source is similar to the Agrichem source.</u></p> <p><u>Barclay – 3 batch analysis provided, needs more batch analysis and validation data. Similar to Monsanto source but there is a potential difference with 2 impurities AGC No 5 and 11 which are present at a low level in this source but not found in the Monsanto source.</u></p> <p><u>Portman –5 batch analysis data required. There is a potential difference with impurities AGC No 5 and POR No 8.</u></p> <p><u>Sanachem – water loss was very high, values given as for the IPA salt so clarification needed. The meeting were unsure if the data had been expressed as dry or wet weight. On the available data there is a potential difference with MOD No 12 and SAC No. 5. New 5 batch analysis data may be required.</u></p> <p><u>Glycine process – compared to Agrichem source</u></p> <p><u>Calliope* - analysis by LC/MS but did not use any standards. On the available data the main difference is the impurity MOD No. 12.</u></p>	<p>IIA Open point – ECCO 1.111 Mammalian Toxicology meeting to provide advice to the overview meeting about the impurities in the different sources of glyphosate – are they of toxicological significance?</p>
(v)	Sources with FAO compliance and acceptable 5 batch analysis data and which are considered chemically comparable	<p>* member of the Tulip Task Force – none of these companies analysed for N-nitrosoglyphosate.</p> <p>The meeting agreed that the following sources which showed compliance with the FAO specification and had acceptable 5 batch analysis data, could be considered comparable:</p> <p>Monsanto Chemimova Luxan IPC</p>	-

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(vi)	changes to the contact details for the notifier Sundat	<p>The contact details for Dr T Searls in the Report, Level 1, page 3 (D) should be deleted. A new address for the notifier Sundat in Europe was provided, as follows :</p> <p>Sundat (Europe) Ltd                      Leeghwaterweg 5                      1951 NA Velsen-Noord                      The Netherlands</p>	- -
(vii)	changes to the contact details for the notifier Sanachem GmbH	<p>The notifier Sanachem GmbH has been taken over by Dow AgroScience GmbH. The contact details in the Report, Level 1, page 5, No. 12 should now read :</p> <p>Dow AgroScience GmbH                      Letcombe Regis                      Wantage                      Oxfordshire OX12 9JT                      UK</p> <p>Person to contact :                      Dr R.E. Briant                      Tel. No. + 44 (0) 171 730 0502                      Fax No. + 44 (0) 171 730 0702</p>	- -
(viii)	Physical and chemical properties for the active substance	<p>The meeting agreed that to be consistent with the discussion on 2,4-D the end point sheets should be completed for all 4 forms of glyphosate i.e. the isopropyl salt, the ammonium salt, the sodium salt and the trimesium salt.</p>	- -
(ix)	melting point	<p>Data were provided for all three salts. The meeting noted that less pure active substance usually has a lower melting point than the higher purity material. This did not appear to be the case but the RMS agreed to check.</p>	<p>IIA Open point – RMS to check                      2.1 the melting point for the active substance.</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(x)	appearance, odour, physical state	Data were provided for the technical material but data are required for the pure salts.	IIA 2.4 The appearance, odour and physical state of the pure salts are required.
(xi)	Spectra	Spectra are required for any impurities of significance.	IIA 2.5 Open point –The ECCO Mammalian Toxicology, Fate and Ecotoxicology meetings to advise if any impurities are of significance – spectra will be required for those of significance.
(xii)	Solubility in water	The sodium salt appeared to be of very low purity and the meeting agreed that the company should check whether this was pure active substance or technical.	IIA 2.6 The purity of the sodium salt used in the determination of solubility in water to be checked.
(xiii)	Solubility in organic solvents	No data were provided for the ammonium salt or sodium salt.	IIA 2.7 Data on solubility of the ammonium and sodium salts in organic solvents are required.

No	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xiv)	Stability in water	<p>The EPA and BBA methods were thought to be comparable with the OECD/EC methods but clarification was required from the ECCO Fate meeting.</p> <p>It was noted that when dissociation occurs, the ionic species must be reported.</p>	<p>IIA Open point – ECCO Fate meeting to confirm if the methods used in determining the stability in water are comparable</p> <p>The ionic species must be reported when dissociation occurs.</p>
(xv)	Flammability and autoflammability	<p>The purity of the material tested required clarification.</p>	<p>IIA The purity of the material used in the determination of flammability and autoflammability to be checked.</p>
(xvi)	Explosive properties	<p>The glyphosate acid and IPA salt were both classified as explosive in a GLP test, but the meeting were unsure as to the exact identity of the material tested. Although the data submitter do not believe glyphosate is explosive, they had not submitted any data to counteract the results of the test. Given the physical characteristics of glyphosate and that the test material was not fully characterised, further studies on the acid and IPA salt are required.</p>	<p>IIA A Differential Thermal Analysis (DTA) up to 1000 °C of glyphosate and its salts of all sources is required.</p>
(xvii)	Physical and chemical properties for the plant protection products	<p>Of the eight products containing glyphosate, the data package supporting two formulations MON 44068 SG and Tulip Task Force SL were examined by the meeting.</p>	<p>-</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xviii)	MON 44068 SG Wet sieve test	A wet sieve test is to be required at MS level	IIIA A wet sieve test for the product MON 44068 SG – 5 is required at MS level
(xix)	Granule size	A statement on granule size is required.	IIIA A statement on granule size 2.8. is required for the product MON 44068 SG. 6
(xx)	Shelf life	Two years shelf life data are required.	IIIA Two years shelf life data for 2.7. the product MON 44068 SG 3 are required.
(xxi)	Tulip Task Force SL	A full data package was submitted and no further physical and chemical properties data were required for the product Tulip Task Force SL. If the other ECCO meetings are content with this formulation then the data requirements for Monsanto will be required at MS level.	- -
(xxii)	Further information Resistance	A resistance management strategy was not considered necessary as resistance to glyphosate only appeared under extreme conditions (ref. Powles, 1998 in Weed Science 46, pp 604-607).	- -
(xxiii)	Controlled incineration	The temperature and residence time for controlled incineration are required.	IIIA The temperature and 4.6. residence time for 2 controlled incineration are required.
(xxiv)	Packaging	The meeting were content with the packaging.	- -
(xxv)	Efficiency of cleaning procedures	Information on the efficiency of cleaning procedures is required	IIIA Information on the 4.2 efficiency of cleaning procedures is required



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(xxvi)	Re-entry periods	Re-entry periods are required.	IIIA Re-entry periods are 4.3 required.
(xxvii)	Transport	The active substance may have explosive properties and the meeting noted this may have implications for the transportation of the material.	- -
(xxviii)	Methods of analysis Method for surface water	Methods using chloroform were no longer acceptable but there was a published method available for surface water.	- -

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21

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5

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(v)	Sources with FAO compliance and acceptable 5 batch analysis data and which are considered chemically comparable	<p>The meeting agreed that the following sources which showed compliance with the FAO specification and had acceptable 5 batch analysis data, could be considered comparable :</p> <p>Monsanto</p> <p>Chemimova</p> <p>Luxan</p> <p>IPC</p>	<p>-</p> <p>-</p>

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(vi)	changes to the contact details for the notifier Sundat	<p>The contact details for Dr T Searls in the Report, Level 1, page 3 (D) should be deleted. A new address for the notifier Sundat in Europe was provided, as follows :</p> <p>Sundat (Europe) Ltd                      Leeghwaterweg 5                      1951 NA Velsen-Noord                      The Netherlands</p>	- -
(vii)	changes to the contact details for the notifier Sanachem GmbH	<p>The notifier Sanachem GmbH has been taken over by Dow AgroScience GmbH. The contact details in the Report, Level 1, page 5, No. 12 should now read :</p> <p>Dow AgroScience GmbH                      Letcombe Regis                      Wantage                      Oxfordshire OX12 9JT                      UK</p> <p>Person to contact :                      Dr R.E. Briant                      Tel. No. + 44 (0) 171 730 0502                      Fax No. + 44 (0) 171 730 0702</p>	- -
(viii)	Physical and chemical properties for the active substance	<p>The meeting agreed that to be consistent with the discussion on 2,4-D the end point sheets should be completed for all 4 forms of glyphosate i.e. the isopropyl salt, the ammonium salt, the sodium salt and the trimesium salt.</p>	- -
(ix)	melting point	<p>Data were provided for all three salts. The meeting noted that less pure active substance usually has a lower melting point than the higher purity material. This did not appear to be the case but the RMS agreed to check.</p>	<p>IIA Open point – RMS to check                      2.1 the melting point for the active substance.</p>

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(xi)	Spectra	Spectra are required for any impurities of significance.	IIA 2.5 Open point –The ECCO Mammalian Toxicology, Fate and Ecotoxicology meetings to advise if any impurities are of significance – spectra will be required for those of significance.
(xii)	Solubility in water	The sodium salt appeared to be of very low purity and the meeting agreed that the company should check whether this was pure active substance or technical.	IIA 2.6 The purity of the sodium salt used in the determination of solubility in water to be checked.
(xiii)	Solubility in organic solvents	No data were provided for the ammonium salt or sodium salt.	IIA 2.7 Data on solubility of the ammonium and sodium salts in organic solvents are required.

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xiv)	Stability in water	The EPA and BBA methods were thought to be comparable with the OECD/EC methods but clarification was required from the ECCO Fate meeting.  It was noted that when dissociation occurs, the ionic species must be reported.	IIA 2.9 Open point – ECCO Fate meeting to confirm if the methods used in determining the stability in water are comparable  The ionic species must be reported when dissociation occurs.
(xv)	Flammability and autoflammability	The purity of the material tested required clarification.	IIA 2.11 The purity of the material used in the determination of flammability and autoflammability to be checked.
(xvi)	Explosive properties	The glyphosate acid and IPA salt were both classified as explosive in a GLP test, but the meeting were unsure as to the exact identity of the material tested. Although the data submitter do not believe glyphosate is explosive, they had not submitted any data to counteract the results of the test. Given the physical characteristics of glyphosate and that the test material was not fully characterised, further studies on the acid and IPA salt are required.	IIA 2.13 A Differential Thermal Analysis (DTA) up to 1000 °C of glyphosate and its salts of all sources is required.
(xvii)	Physical and chemical properties for the plant protection products	Of the eight products containing glyphosate, the data package supporting two formulations MON 44068 SG and Tulip Task Force SL were examined by the meeting.	-



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(xviii)	MON 44068 SG Wet sieve test	A wet sieve test is to be required at MS level	IIIA A wet sieve test for the product MON 44068 SG – 5 is required at MS level
(xix)	Granule size	A statement on granule size is required.	IIIA A statement on granule size 2.8. is required for the product MON 44068 SG. 6
(xx)	Shelf life	Two years shelf life data are required.	IIIA Two years shelf life data for 2.7. the product MON 44068 SG 3 are required.
(xxi)	Tulip Task Force SL	A full data package was submitted and no further physical and chemical properties data were required for the product Tulip Task Force SL. If the other ECCO meetings are content with this formulation then the data requirements for Monsanto will be required at MS level.	- -
(xxii)	Further information Resistance	A resistance management strategy was not considered necessary as resistance to glyphosate only appeared under extreme conditions (ref: Powles, 1998 in Weed Science 46, pp 604-607).	- -
(xxiii)	Controlled incineration	The temperature and residence time for controlled incineration are required.	IIIA The temperature and 4.6. residence time for 2 controlled incineration are required.
(xxiv)	Packaging	The meeting were content with the packaging.	- -
(xxv)	Efficiency of cleaning procedures	Information on the efficiency of cleaning procedures is required	IIIA Information on the 4.2 efficiency of cleaning procedures is required

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xxxvi)	Re-entry periods	Re-entry periods are required.	III A Re-entry periods are 4.3 required.
(xxvii)	Transport	The active substance may have explosive properties and the meeting noted this may have implications for the transportation of the material.	- -
(xxviii)	Methods of analysis Method for surface water	Methods using chloroform were no longer acceptable but there was a published method available for surface water.	- -

## Appendix 1: ECCO 80 reporting table      Glyphosate (Hb)

### 2. Environmental Fate and Behaviour

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(i)	Route of degradation in soil	<p>The group agreed that the End point sheet for mineralisation and non-extractable residues should be amended to reflect the full range of data available. It was only necessary to give details of the soil properties where there was a clear correlation between soil biomass and mineralisation.</p> <p>The group noted that there was an apparent relationship between the degradation rate of glyphosate, correlated to the adsorption.</p>	<p>Open point: RMS to amend the End point sheet so that the range for mineralisation and bound residues is reported for all the available data.</p>
(ii)	Route of degradation in soil (anaerobic)	<p>The group noted that an anaerobic study had been presented, however it was considered unacceptable by the RMS as the study had been conducted at 30°C and not the required 20°C, and the conditions of the study had not been fully reported. As a reliable study was not available, and there were autumn uses and an application for use on rice, the group agreed that a reliable anaerobic study was required.</p> <p>Although there were insufficient information to obtain a DT<sub>50</sub> from the existing anaerobic study, the group considered that the study demonstrated that the degradation rate for aerobic and anaerobic conditions were comparable. The RMS should reassess the study.</p>	<p>2.1 Address the route of degradation in soil in anaerobic conditions. (IIA, 7.1.1.2.1)</p> <p>Open point: RMS to reassess the anaerobic study presented.</p>
(iii)	Route of degradation in soil (photolysis)	<p>From the available data, soil photolysis was not a major route of degradation. The group noted that the first results for soil photolysis in the End point sheet were not consistent with the results in the monograph and should be amended (illuminated 90 d; dark 96 d).</p>	<p>Open point: RMS to amend End point sheet to correct the results for soil photolysis.</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(iv)	Rate of degradation in soil	<p>The group considered that when reporting DT<sub>50</sub> values, the range and mean values should be reported.</p> <p>There was a comment regarding the footnotes to the table on page 26 of the monograph (section B-7, vol 3, 3 of 4). Regarding the reference to (***), it was not clear what was meant by first order dissipation equation and first order degradation equation. Therefore the RMS should provide an explanation to the reference from the footnote and check the DT values.</p> <p>The group considered that although it was not possible to state a DT<sub>50</sub> value for anaerobic conditions, it was possible to compare the results from the aerobic study with the anaerobic study. Therefore the anaerobic results in the End point sheets should be amended to state 'comparable to aerobic'.</p>	<p>Open point: RMS to amend End point sheet to reflect the range and mean DT<sub>50</sub> values.</p> <p>RMS to provide an explanation to the reference from the footnote to the table on p 26 (sec B-7, vol 3, 3 of 4) and check the DT calculations.</p> <p>RMS to amend the anaerobic results in the End point sheets to state 'comparable to aerobic'.</p>
(v)	Rate of degradation in soil (metabolites)	<p>From the available data, AMPA appeared to be persistent, with high DT<sub>50</sub> values. The group considered that there were no reliable data on the degradation rate of AMPA. As there was a potential for accumulation of AMPA, the group agreed that this was an area which needed further addressing. In addition, the potential for the accumulation of glyphosate should also be considered.</p>	<p>2.2 Accumulation potential (persistence) of AMPA and glyphosate must be addressed further. (IIA, 7.1.1.2.2)</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(vi)	Adsorption/ desorption in soil	<p>The <math>K_{oc}</math> values for glyphosate and AMPA were relatively high, and there was a large range (384 to 60000 for glyphosate). It was considered that as the <math>K_{oc}</math> values were high, it would be useful in addition to state the <math>K_d</math> values in the End points. The RMS should reassess the data and consider the importance and relevance of the aged column leaching study reported on p 76 of the monograph (section B-7, vol 3, 3 of 4).</p>	<p>Open point: RMS to reassess the importance of the aged column leaching study. <math>K_d</math> values must be calculated and reported in the End point sheets for glyphosate and AMPA; the range and median to be included.</p>
(vii)	PEC <sub>s</sub>	<p>As soil PEC values had been calculated assuming 20% plant cover, they must be recalculated using the default 50% plant cover as agreed. The DT<sub>50soil</sub> of 150 days was considered to represent the realistic worst case scenario.</p>	<p>Open point: RMS to recalculate PEC<sub>s</sub> assuming 50% plant cover and amend End point sheet.</p>
(viii)	Route and rate of degradation in water	<p>Regarding degradation in water/sediment systems, the results for mineralisation and non-extractable residues from the two available studies should be reported separately in the End point sheets.</p>	<p>Open point: RMS to report results for mineralisation and non-extractable residues from the 2 water/sediment studies separately in the End point sheet.</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(ix)	Route and rate of degradation in water (metabolites)	<p>The group noted the unusual finding that AMPA was apparently only found in the water phase from the water/sediment study. The group considered that it was possible that AMPA did move to the sediment, however, extraction techniques were unable to extract AMPA from the sediment. It was also noted that if AMPA was persistent, there would be high amounts of AMPA detected in the study. The fact that AMPA was found in low amounts suggested that it was fast degraded. Therefore the group concluded that these apparent discrepancies should be addressed.</p>	<p>2.3 Address the apparent discrepancies with the water/sediment studies as there appears to be no movement of AMPA to sediment. (IIA, 7.2.1.3.2)</p>
(x)	PEC <sub>sw</sub>	<p>The group agreed that the End point sheet should reflect the worst case scenarios for the proposed uses of glyphosate. They considered that PEC<sub>sw</sub> should be calculated for overspray (rice use) and 1 metre spray drift for other uses.</p>	<p>Open point: RMS to calculate PEC<sub>sw</sub> overspray for rice and 1 m spray drift for other uses, and amend End point sheet accordingly.</p>
(xi)	PEC <sub>sed</sub>	<p>For long term single applications, the highest concentration was reported to be 55% on day 56. The meeting considered that it was more appropriate to state concentrations rather than percentages when reporting PEC values. Therefore the table should be amended.</p>	<p>Open point: RMS to amend the End point sheet so that results for PEC<sub>sed</sub> are expressed as concentrations and not %.</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xii)	PEC <sub>gw</sub>	<p>The group considered that it was more appropriate for the method of calculation for PEC<sub>gw</sub> to state PEC<sub>gw</sub> was 'negligible' or '&lt; LOD', rather than 'zero', as was currently reported.</p> <p>As glyphosate was unlikely to leach to ground water, the following phrase, as agreed by the meeting, should be included in the End point sheet: 'On the basis of current knowledge it is considered unlikely that glyphosate will leach to ground water. Therefore contamination of ground water in excess of 0.1µg/l is not expected'.</p> <p>The meeting noted that glyphosate and AMPA may bi-pass other environmental compartments, in addition to soil.</p>	<p>Open point: RMS to amend PEC<sub>gw</sub> to state 'negligible' or '&lt; LOD', rather than 'zero' in the End point sheets.</p> <p>The standardised phrase should be included in the End point sheet to indicate that leaching to ground water was unlikely.</p>
(xiii)	PEC <sub>gw</sub> (metabolites)	<p>The RMS stated that there were new data available on leaching to ground water which had not been available in time to be considered at the meeting. Given the apparent variability of the degradation rate and mobility of AMPA, the meeting agreed that this must be further addressed.</p>	<p>2.4 Address the possibility of ground water contamination, given the apparent variability in degradation rate and mobility of AMPA. (IIIA, 9.2.1)</p>
(xiv)	Fate and behaviour in air	<p>An amendment to the End point sheet was required, where 'direct photolysis in air' should read 'direct photolysis in water'.</p> <p>The group noted that there were no data to address photolysis in air, however, an Atkinson calculation was available.</p>	<p>Open point: RMS to amend End point sheet to state 'direct photolysis in water' and not 'air'.</p>

No	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xv)	Definition of the residue	The End point sheet must be amended so that the residue definition refers to both soil and water.	Open point: RMS to include soil and water in the section covering definition of the residue in the End point sheet.
(xvi)	Monitoring data	Regarding ground water monitoring data and number of determinations, the group agreed that the RMS should check the UK results.	Open point: RMS to check the ground water monitoring data results (UK).



## Appendix 1: ECCO 84 reporting table      Glyphosate (Hb)

### 3. Ecotoxicology

No.	Subject	Discussion ECCO-Peer Review Meeting			Recommendations ECCO-Peer Review Meeting (Annex point)																												
(i)	Intended uses	<p><b>Discussion ECCO-Peer Review Meeting</b></p> <p>Rice cultivation: It was not clear whether water would be present at the time of application since glyphosate was usually applied pre-sowing and post-harvest. Dry paddy fields presented a very different risk. Due to the lack of information on how glyphosate would be used in such a specialised situation, it was agreed that this use should be dealt with at MS level.</p> <p>Use in or near water: The group noted the potential risk but in line with decisions taken at Working Group level regarding this type of use agreed that this should be dealt with at MS level.</p>																															
(ii)	General risk assessment	<p>The rapporteur provided details of the PECs used to calculate the TERs as follows:</p> <table border="1" data-bbox="598 548 869 1608"> <thead> <tr> <th>Distance (m)</th> <th>Drift (%)</th> <th>PECi Glyphosate (µg/l)</th> <th>PECi Glyphosate SL, 360 g a.s/l (µg/l)</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>100</td> <td>1440</td> <td>4000</td> </tr> <tr> <td>1</td> <td>4</td> <td>57</td> <td>160</td> </tr> <tr> <td>5</td> <td>0.6</td> <td>8.6</td> <td>24</td> </tr> <tr> <td>10</td> <td>0.4</td> <td>5.8</td> <td>16</td> </tr> <tr> <td>15</td> <td>0.2</td> <td>2.9</td> <td>8</td> </tr> <tr> <td>20</td> <td>0.1</td> <td>1.4</td> <td>4</td> </tr> </tbody> </table>	Distance (m)	Drift (%)	PECi Glyphosate (µg/l)	PECi Glyphosate SL, 360 g a.s/l (µg/l)	0	100	1440	4000	1	4	57	160	5	0.6	8.6	24	10	0.4	5.8	16	15	0.2	2.9	8	20	0.1	1.4	4			
Distance (m)	Drift (%)	PECi Glyphosate (µg/l)	PECi Glyphosate SL, 360 g a.s/l (µg/l)																														
0	100	1440	4000																														
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15	0.2	2.9	8																														
20	0.1	1.4	4																														
(iii)	Birds	<p>The acute and short-term risk was considered to be acceptable with TER (a) &gt;21 (grazing bird) and &gt;20 (insectivorous bird) and TER (st) &gt;12 (grazing bird) and &gt;37 (insectivorous bird).</p> <p>TER (lt) was below the Annex VI trigger of 5 but it cannot be assumed that birds will feed exclusively on contaminated food over several weeks. In addition residue decline on vegetation and insects had not been taken into account. The group noted that glyphosate could also be used on genetically modified crops to control non-tolerant weeds. Crop plants would therefore be present after treatment and the meeting questioned the relevance of the refinement step used. A risk to breeding birds was identified from the consumption of treated GM crops which needs to be addressed.</p> <p>The risk to breeding birds from use on 'conventional' crops was considered acceptable.</p>			<p>3.1 Address the risk to breeding birds from the consumption of treated crops. (III.A, 10.1)</p>																												

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(iv)	Mammals	The acute and long-term risk to mammals was considered to be acceptable.	
(v)	Metabolites	No data were provided on the toxicity of the metabolite AMPA to birds and mammals. The group noted that the metabolite occurred in the mammalian toxicology package and agreed that the risk had been addressed.	
(vi)	Aquatic risk assessment	The group noted that the risk assessment had been based both on data submitted by the main data submitter and on validated data published in the IPCS report 159 for glyphosate. Rapporteur MS to add details on <i>Lemna</i> to the end point sheet. The meeting agreed that the risk assessment should concentrate on the active substance and one formulation, the IPA salt would be covered by the active substance.	Open point: rapporteur MS to add details on <i>Lemna</i> to the end point sheet.
(vii)	Toxicity to aquatic life	The toxicity data showed that the metabolite AMPA and the IPA salt were less toxic to aquatic life than the active substance and the formulations. The plant protection products pose a higher acute risk to aquatic life than just the active substance and hence formulation data should be provided at re-registration.	
(viii)	Algae	<i>Sketonema costatum</i> was shown to be most sensitive to the active substance with a chronic EC <sub>50</sub> of 0.6 mg/l. Although a marine algae it had been used as the basis for the TER. The group agreed that this was acceptable because marine and freshwater algae were usually of equal sensitivity. The main data submitter has argued that the EC <sub>50</sub> of 0.6 mg/l is an outlier as <i>S. costatum</i> is one to several orders of magnitude more sensitive than all the other algal species tested. This argument was not supported because the sensitivity of the other species considered by the group was in the same range. It was noted that the risk assessment had been based on the formulation and not the active substance. Risk mitigation measures (buffer zone of 5m) will be required at MS level.	
(ix)	Higher aquatic plants	The group noted that <i>Lemna</i> appeared to be less sensitive to glyphosate. Due to the mode of action of glyphosate, via leaves rather than roots, the group questioned whether the standard <i>Lemna</i> study was in fact appropriate. It was concluded that further data were required to address the risk from spray drift to <i>Lemna</i> at different concentrations using the plant protection product.	3.2 Address the risk from overspray to <i>Lemna</i> at different concentrations using the plant protection product. (IIA, 8.2.8)
(x)	Sediment dwelling organisms	No table had been provided in the end point sheet. Although 44% of the active substance partitions to sediment its low chronic toxicity to <i>Daphnia</i> mean that no further data are required.	
(xi)	Metabolites	The metabolite AMPA is of low toxicity to fish, <i>Daphnia</i> and algae. Rapporteur MS to add the metabolite TERs to the end point sheet.	Open point: rapporteur MS to add aquatic life TERs for the metabolite AMPA to the end point sheet.

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xii)	Non-target arthropods	<p>A high risk has been identified for a range of species from the use of the plant protection product. Studies with <i>Aphidius rhopalosiphi</i> and <i>Typhlodromus pyri</i> caused 100% mortality, and data on 2 crop relevant species <i>Chrysoperla carnea</i> and <i>Aleochara bilineata</i> indicated a medium risk but this was not at the maximum application rate. The main data submitter recently submitted new data which the rapporteur has not yet evaluated. A brief assessment indicated mortality at 25% and 88% for <i>A. rhopalosiphi</i> and <i>T. pyri</i> respectively. Therefore there is currently no change in the risk assessment for non-target arthropods.</p> <p>Due to the risk to non-target arthropods, further data are required to refine the initial assessment. These data will be dependent upon the use (e.g. GM vs non-GM) as well as the mode of application (e.g. spray vs weed wipe). However, the main data submitter should address the risk to non-target arthropods from the proposed GAP.</p>	3.3 Address the risk to 2 sensitive crop specific species and foliar dwelling predators and spiders using appropriate application rates (IIA, 8.2.3)
(xiii)	Earthworms	<p>No acute toxic effects are expected since the TERs are all above the Annex VI trigger of 10. The active substance and metabolite AMPA are both persistent in soil (glyphosate = DT<sub>50</sub> up to 208d with 3 applications, and metabolite = DT<sub>50</sub> 958d and DT<sub>50</sub> 100d). Therefore, further information is therefore required regarding long-term toxicity of the active substance and metabolite to earthworms.</p>	3.4 Address the long-term toxicity of the active substance and metabolite AMPA to earthworms. (IIA, 8.4.2)
(xiv)	Soil Macro-organisms	<p>The group was unable to draw a conclusion from the risk assessment for soil macro-organisms which is dependent on the earthworm data requirement at 3.4. However there was concern over potential exposure to the metabolite AMPA, which is highly persistent in soil (DT<sub>50</sub> 958d), and further data are required on the effects of the metabolite on leaf litter decomposition.</p>	3.5 Address the effects of metabolite AMPA on leaf litter decomposition. (IIIA, 10.6.2)
(xv)	Non-target flora and fauna	<p>Data are available. Glyphosate represents a high risk to non-target plants off-crop. This issue should be dealt with at MS level.</p>	
(xvi)	Endocrine disruption	<p>Various literature references suggest that glyphosate is an endocrine disruptor. The group recognised that there was no guidance available regarding how such information should be used so it was agreed that the rapporteur should consult the Chairperson of the mammalian toxicology meeting at the BBA to see if this is a concern.</p>	<p>Open point: rapporteur MS to clarify whether there is a concern regarding possible endocrine disruption.</p> <p>If there is a concern this may lead to a request for further data.</p>

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xvii)	Data protection	The rapporteur MS did not provide a list containing only those studies for which the main data submitter has claimed data protection. This information will be provided before the Overview meeting.	Open point: -Rapporteur to provide list of studies for which the main data submitter has claimed data protection.

**Appendix 1: ECCO 78 reporting table      Glyphosate (Hb)**

**4. Mammalian toxicology**

No	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(i)	Sources of glyphosate	Consistent with previous situations involving multiple sources of active substance, the meeting considered the toxicology package for the source with the most comprehensive dossier, in this case Monsanto.	
(ii)	ADME	After a single intra-venous application, 72% of the radioactivity was recovered in the first 4 hours, indicating that elimination is more rapid than oral absorption. Given the complexities of the data it was difficult to give a numerical value for rate and extent of excretion.	
(iii)	Toxicologically significant compounds	In response to a question from ECCO 76 (physical/chemical properties) regarding the toxicological significance of the different impurity profiles between sources, the meeting had considered toxicological studies for the Monsanto source only. Therefore, it was concluded that where the impurity profile of a source differed to that of the Monsanto source (i.e. different impurities, or higher concentrations) then further information would be required to address the significance of these differences.	4.1 Toxicity of impurities in other sources to be addressed at Member State level (IIA 5.8)
(iv)	Short term toxicity: target/critical effects	Histological effects were observed in salivary glands in the 6 and 12 month dog study, however, since these lesions were without functional consequence or long term effects they were not considered to be adverse.	
(v)	Short term toxicity: Lowest relevant oral NOAEL/NOEL	The meeting agreed an NOAEL of 300mg/kg bw/day based on the 90 day rat and 6 and 12 month dog studies.	

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(vi)	Short term toxicity: Lowest relevant inhalation NOAEL/NOEL	It was noted that a study had been submitted, however, it was considered that this was supporting information only as it was not necessary for the risk assessment.	
(vii)	Reproductive toxicity: Lowest relevant developmental NOAEL / NOEL	The meeting agreed an NOAEL of 150 mg/kg bw/day from the rabbit developmental study based on the incidence of heart malformations, although it was acknowledged that the incidence of these effects was within the range of the historical control data. Other effects were observed to be occurring at levels which were both foetotoxic and maternally toxic.	
(viii)	ADI	The meeting agreed with the Rapporteur's proposal for an ADI of 0.3mg/Kg bw/day based on the NOAEL in the long term rat studies and applying a safety factor of 100.	
(ix)	AOEL	The meeting agreed with the Rapporteur's proposal for an AOEL of 0.2 mg/kg bw/day based on the NOEL for maternal toxicity in the rabbit developmental study, applying a correction factor of 30% for absorption and a safety factor of 100.	
(x)	Dermal absorption	It was noted that the dermal absorption in the in vivo monkey study was 2.2%, however, given that the recovery was 75 – 80% it was considered appropriate to round up to 3% to account for the remaining unrecovered 20%.	
(xi)	Data protection	Rapporteur to provide list of studies for which data protection has been claimed.	ope Rapporteur to provide list of npo studies for which data int protection has been claimed.

**Appendix 1: ECCO 82 reporting table      Glyphosate (Hb)**

**5. Residues**

No	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(i)	Metabolism - plants	The meeting noted that glyphosate takes 7-10 days to take effect yet PHIs lower than 7 days were stated in the intended uses.	- -
(ii)	Metabolism – plants and animals	It was noted that during monitoring analysis, it would not be known whether crops were genetically altered. Therefore, although AMPA is not of toxicological significance, AMPA should be included in the residue definition to monitor for compliance with GAP. Thus the meeting agreed to set a residue definition for monitoring and risk assessment purposes of glyphosate plus AMPA expressed as glyphosate equivalents.	- -
(iii)	Methods of analysis	The meeting asked the RMS to check whether there were validated methods for AMPA.	Open point: RMS to check whether there were validated methods for AMPA.
(iv)	Metabolism – tolerant sugar beet	It was noted that a metabolism study for tolerant sugar beet had not been submitted. The metabolism of glyphosate in genetically modified sugar beet must be addressed.	5.1 The metabolism of glyphosate in genetically modified sugar beet must be addressed. (IIA 6.1)
(v)	Metabolism – plants	It was noted that the metabolic pathway and residue definition may change as a result of future development of glyphosate tolerant crops.	- -

No.	Subject	Discussion ECCO Peer Review Meeting	Recommendations ECCO Peer Review Meeting (Annex point)
(vi)	Metabolism – animals	Based on the metabolism data submitted, the meeting agreed to set a residue definition of 'glyphosate plus AMPA expressed as glyphosate equivalents' for monitoring and risk assessment purposes for animal products.	- -
(vii)	MRLs – citrus	Only US residues data were submitted, yet there was no request for import tolerance. It was noted that only the lower branches of the citrus trees were sampled. Based on the data submitted, residues are expected to be low. However, 4 further trials are required on small citrus fruit with continuous harvesting and random sampling. Clarification of the GAP for citrus is required, as the number of applications and PHI in the residues trials differ from the intended uses.	5.2 4 residues trials are required on small citrus fruit with continuous harvesting and random sampling. (IIA 6.3)
			5.3 Clarification of the GAP for citrus is required. (IIIA 3.3)
(viii)	MRLs – stone fruits	Sufficient data on the intended use of glyphosate representing the stone fruit crop group were not submitted. 4 further trials on cherries are required.	5.4 4 residues trials on cherries are required. (IIA 6.3)
(ix)	MRLs – pome fruits	Clarification of the GAP for apple and pear in the southern region is required as the PHI in the residues trials differs from that stated in the intended uses.	5.5 Clarification of the GAP for apple and pear in the southern region is required. (IIIA 3.3)
(x)	MRLs – cultivated berries and small fruits	Clarification of the GAP is required for cultivated berries and small fruits.	5.6 Clarification of the GAP is required for cultivated berries and small fruits. (IIIA 3.3)



No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xi)	MRLs – wild raspberries	The meeting agreed that the GAP for the forestry use of glyphosate on wild raspberries must be amended so that glyphosate cannot be applied during the fruiting of berries. The GAP in Austria (critical GAP) must be clarified.	5.7 GAP for the forestry use of glyphosate on wild raspberries must be amended so that glyphosate cannot be applied during the fruiting of berries.
			5.8 The GAP in Austria (critical GAP) must be clarified. (IIIA 3.3)
(xii)	MRLs – grapes	The residues data submitted for grapes does not support critical GAP for the southern region. However, given the amount of data from the northern region which does cover GAP, and that glyphosate is not subject to photolytic degradation, no further data are required. The meeting agreed to propose an MRL of 0.5 mg/kg excluding the data from the ground lying grapes.	- -
(xiii)	MRLs – miscellaneous fruit	If an import tolerance has been requested then further data will be required on miscellaneous fruit.	5.9 Further data will be required on miscellaneous fruit if an import tolerance has been requested. (IIA 6.3)
(xiv)	MRLs – olives	The meeting noted that the difference between harvesting and processing olives for table use and oil use affects residue levels. Although it was noted that for enforcement purposes, crops are not usually split, the meeting proposed MRLs of 0.1 mg/kg for table olives and 20 mg/kg for olives processed into oil.	- -

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xv)	MRLs – asparagus	Clarification of the GAP is required. If the time of application is stated as pre-emergence or post-harvest then further data are not required and an MRL of 0.1 mg/kg can be proposed. However, if time of application is specified as close to harvest, then further data are required.	5.10 Clarification of the GAP for non-tolerant asparagus is required. If the time of application is stated as pre-emergence or post-harvest then further data are not required and an MRL of 0.1 mg/kg can be proposed. However, if time of application is specified as close to harvest, then further data are required. (IIA 6.3, IIIA 3.3)
(xvi)	MRLs – wild mushrooms	Clarification of the GAP for the use of glyphosate to clear ground for harvesting wild mushrooms is required.	5.11 Clarification of the GAP for the use of glyphosate to clear ground for harvesting wild mushrooms is required. (IIIA 3.3)

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xvii)	MRLs – wheat and rye	Residue levels occurring above the proposed MRL of 5 mg/kg were discussed by the meeting. The RMS must assess the outliers and recalculate the proposed MRL.	<p>Open point:                      RMS must assess the outliers and recalculate the proposed MRL for wheat. (Submitted by the RMS after the meeting and referred to the Overview meeting for consideration (ECCO 6589/PSD/99).)</p> <p>Open point:                      RMS must assess the outliers and recalculate the proposed MRL for rye. (Submitted by the RMS after the meeting and referred to the Overview meeting for consideration (ECCO 6590/PSD/99).)</p>

No	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xviii)	MRLs – tea	Residue levels occurring above the proposed MRL of 1 mg/kg were discussed by the meeting. The meeting concluded that the outliers must be assessed and the MRL recalculated by the RMS. The meeting also sought clarification of which country had requested the import tolerance.	<p>Open point:</p> <p>The RMS must assess the outliers and recalculate the proposed MRL for tea. (Submitted by the RMS after the meeting and referred to the Overview meeting for consideration (ECCO 6591/PSD/99))</p>
(xx)	MRLs – tolerant cotton	In the residues data submitted, the rate of application was too high and the PHI too short for the intended use pattern. Clarification of the GAP is required.	<p>Open point:</p> <p>Clarification of which country had requested the import tolerance is required.</p>
(xxi)	MRLs – tolerant maize	In the residues data submitted, the rate of application was too high and the PHI too short for the intended use pattern. Clarification of the GAP is required to allow an import tolerance to be considered for US uses.	<p>5.13 Clarification of the GAP is required to allow an import tolerance to be considered for US tolerant maize uses. (IIIA 3.3)</p>
(xxii)	MRLs – tolerant soya beans	An import tolerance of 20 mg/kg for the US and an MRL of 5 mg/kg were proposed.	-
(xxiii)	MRLs – sorghum	An import tolerance of 20mg/kg was proposed based on the US data submitted.	-

No.	Subject	Discussion ECCO-Peer Review Meeting	Recommendations ECCO-Peer Review Meeting (Annex point)
(xxiv)	Processing factors –tolerant cotton	The meeting agreed that despite only one study being submitted, no further data on cotton were required as there is no consumption of cotton products.	- -
(xxv)	Dietary intakes	Revised TMDI calculations were submitted by the RMS after the meeting and are referred to the Overview meeting for consideration.	- Open point: Revised TMDI calculations were submitted by the RMS after the meeting and are referred to the Overview meeting for consideration. (ECCO 6592/PSD/99) (ECCO 6593/PSD/99)
(xxvi)	End points	RMS to update the end points to fully reflect the outcome of the meeting.	Open point: RMS to update the end points to fully reflect the outcome of the meeting.