Level 2

Glyphosate

Overall Conclusions

2 Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

2.1 Identity

Monsanto/Cheminova

All points (Annex II and III) have been addressed and the information supplied is acceptable except some CAS-Numbers, the degree of ethoxylation, and the alkylgroups of some components of the formulants are lacking.

Feinchemie Schwebda

All points (Annex II and III) have been addressed and the information supplied is acceptable.
The batch analysis shows one unknown impurity with a content lower than 1 g/kg. The batches will be checked for N-nitrosylglyphosate (NNG) and the lacking validation data for the methods to determine the impurities will be submitted in the near future. It is conspicuous that all batches sum up at the same level of 1000 g/kg.
Moreover the chemical names of the components with their CAS-Nrs. and/or EEC-Nrs. of the formulant are lacking.

Sinon

All points (Annex II and III) have been addressed except checking for N-nitrosylglyphosate and lacking of some validation data of the analytical methods for determining the impurities.
Moreover the chemical names of the components with their CAS-Nrs. and/or EEC-Nr. of one formulant are lacking, for the other formulant only the CAS-Nr. and EEC-Nr. are lacking.
The minimum purity of the active substance as manufactured (900 g/kg) does not comply with the FAO specification (950 g/kg).

Herbex

The applicant stated that only one organic impurity besides water and hydrochloric acid is present. No batch analysis and their analytical methodology has been submitted.
Moreover the CAS-Nrs./EEC-Nrs. and trade names of the formulants are lacking.

Tulip Task Force

For all members of the task force the same testing facility has determined the contents of impurities resulting from the Glycine or IDA manufacturing process. The batch analysis for Sundat is in progress. Concerning N-nitrosylglyphosate the batches were reanalysed. This work is in progress. The method validation data are incomplete. Data on accuracy/precision were not submitted.
Moreover for the ppp of Agrichem the chemical name of the fatty acid and the degree of ethoxylation of the formulant are lacking.
The minimum purity of the active substances as manufactured of Industrias Afrasa (940 g/kg) and of Calliope (900 g/kg, IDA process)

does not comply with the FAO specification (950 g/kg).
The high content of N-(phosphonomethyl)iminodiacetic acid (30 g/kg) in the active substance as manufactured of Pinus does not comply with the FAO specification (10 g/kg).

Luxan

All points (Annex II and III) have been addressed except checking for N-nitrosylglyphosate and lacking of validation data of the analytical methods for determining the impurities.

IPC

All points (Annex II and III) have been addressed and the information supplied is acceptable except the chemical names of the components with their CAS-Nrs. and/or EEC-Nrs. of the surfactant are lacking.

Nufarm

The applicant stated that the technical substance contains 19 impurities. The batch analysis is in progress. The analytical methods have not yet been submitted.
Moreover no data for Annex III are submitted.
The minimum purity of the active substance as manufactured (940 g/kg) does not comply with the FAO specification (950 g/kg).

Barclay

For the technical substance of Barclay all points (Annex II and III) have been addressed except for the determination of N-methylglyphosate only a statement was submitted.
Moreover the degree of ethoxylation for the component of the surfactant is lacking.

For the technical substance of Portman no batch analysis and methods were submitted. The applicant stated that the conditions for manufacturing the as are identical with those of Barclay. Therefore the impurity profile virtually corresponds.

Alkaloida

Glycine process:
All points (Annex II and III) have been addressed and the information supplied is acceptable.

IDA process:
All points (Annex II and III) have been addressed only the methods are not fully validated.

Moreover the degree of ethoxylation for the components of both surfactants in Glialka 36 and Glistar 68 are lacking.

Sanachem

The batch analysis shows one unknown impurity with a content lower than 1 g/kg. The batches are not checked for N-nitrosylglyphosate (NNG). Methods are fully validated but no data are submitted. Moreover the chemical name of the fatty acid, the degree of ethoxylation and CAS-Nrs./EEC-Nrs. are lacking.

2.2 Physical and chemical properties

Glyphosate acid is a colourless crystalline solid without odour. It melts at 189.5 °C. The free acid dissociates readily (pKa = 0.97) resulting in a high water solubility of 10 - 12 g/l (20 - 25 °C) wich is enhanced by isopropylamine, NaOH and NH_4OH. In the as water soluble concentrates formulated products the isopropylamine salt is chiefly used. Only one example exists using the sodium salt in a formulation as water soluble granules. The n-octanol/water partition coefficient is in the range of -2 to -3.4 at 20 to 25 °C indicating no potential for bioaccumulation. Its vapour pressure amounts to $1.3 \cdot 10^{-5}$ Pa at 25 °C. Henry's law constant is $2.1 \cdot 10^{-7}$ $Pa \cdot m^3 \cdot mol^{-1}$. Glyphosate is stable towards hydrolysis and photolysis. The dissociation constants pK_a (25 °C) are 2.92 and 5.92. Photochemical oxidative degradation occurs fast in 1.6 hours.
Its flammability and oxidizing properties are not critical. Since one trial shows a positive reaction to shock sensitivity it has to be considered as explosive.

MON 44068 is a water soluble granule, it poses no flammable or explosive hazard. Its pH at ca. 4 is slightly acidic. It is stable during accelerated ageing studies. Real shelf life studies will be shortly completed.
The technical properties show that the product is suitable for commercial use and it is compatible with many other herbicides.

MON 52276 is an aqueous soluble concentrate. It is not flammable or explosive. It is slightly acidic and moderately viscous. Stability testing shows that the product has a shelf-life in excess of two years and is not affected by short periods of low temperature exposure. The product can form a persistent foam in certain types of spray equipment, the use of a defoamer may be advisable in certain use conditions.
The test for dilution stability was carried out but the study was not provided.

Taifun forte is an aqueous soluble concentrate which is not explosive nor oxidising. Its pH is 4.8 being in the range that naturally occurs. Its stability allows storage under practical and commercial conditions. Its technical properties indicate that no particular problems are to be expected when it is used as recommended.

Agrichem Glyfosaat 2 (Glyphosate 360 g/l) is an aqeous soluble concentrate which is not explosive, neither oxidising nor flammable. Its pH is 4.9 being in the range that naturally occurs. Its stability allows storage under practical and commercial conditions. Its technical properties indicate that no particular problems are to

be expected when it is used as recommended. The Glyphosate formulation is compatible with Brabant Diuron Flowable which is recommended for use in combination with Glyphosate.

Ipiglyce 36 SL (soluble concentrate) is neither explosive nor oxidising. Its pH is 4.75 being in the range that naturally occurs. Its stability at accelerated and low temperatures anticipates no problems for storage under practical and commercial conditions. Its technical properties indicate that no particular problems are to be expected when it is used as recommended.
No studies for surface tension and shelf lifes at ambient temperatures are submitted.

It is stated that Glistar 68 (water soluble granules has neither explosive, nor oxidising, nor flammable properties but no studies were submitted. Its pH of 4.0 ± 0.5 is slightly acidic. Its stability allows storage under practical and commercial conditions. However, the test for flowability indicates that problems of caking may occur at high temperatures. The dissolution of the granules in water was not confirmed e.g. by a wet sieving test. Hence problems during storage and application may occur.

Barclay Gallup is aqueous soluble concentrate whoch is neither oxidising, nor flammable. No study for explosivity was submitted. Its pH values of 4.3 to 6.3 are within the range that naturally occurs. It is possible to form a diluted spray without persistent foam. There are no studies about the physical and chemical stability at accelerated and low temperatures for the concentrate formulation. Hence storability under commercial conditions is not confirmed.

Glyphosan 360 SL (soluble concentrate) is neither explosive, nor oxidising, nor flammable. Its pH is 4.9 being in the range that naturally occurs. Its stability allows storage under practical and commercial conditions. Its technical properties indicate that no particular problems are to be expected when it is used as recommended.

The follwing applicants have not submitted any data for their products: Sinon, Herbex, Luxan, and Nufarm.

2.3 Details of uses and further information

2.3.1 Details of uses

Plant protection products containing glyphosate are commenly used for the control of annual and perennial grass and broad-leaved weeds in agriculture, horticulture, viticulture, forestry, orchards, plantation crops, amenities, home gardening and greenhouses. Furthermore it is used for weed control on aquatic areas, on industrial areas, on railroad tracks, along roads, and on non-cultivated areas.

Plant protection products containing glyphosate are non-selective

herbicides and could therefore be used in field crops only at predrilling, preemergence and postharvest. In row crops a protective plate or a under leave sprayer must be used for the application between the rows. In a crop stand weed control could be carried out in BBCH stage 89, when the crop is fully mature and the weeds are still green.

The application rate varies across the EC depending on type and time of application and also of the weed species which are present on the treated area. Because of the uptake through the leaves, the best efficacy is to achieve, if the application is done on well developed foliage and especially for perennial weeds, in a period with sugar translocation to roots or other underground parts (spring or autumn). Warm weather (15-22 °C) and high air humidity (75-80 %) are optimal conditions. No sufficient effect will be achieved, when weed growth is restricted by natural senescence or by drought, frost, high temperature or rainfall immediately after spraying.

In most European countries glyphosate is applied alone as well as in combination with many other herbicidal active ingredients with a conventional hydraulic sprayer, rotary atomiser, hand hold weedwiper, knappsack applicator, or a rope-wick applicator.

Besides weed control, plant protection products containing glyphosate are also used for the control of suckers, for the destruction of grassland before renewal and for harvest management in various crops.

Although glyphosate containing herbicides are used worldwide since many years, no glyphosate resistant weed biotypes occured until now.

Since several years genetically modified plants are available, which are tolerant against glyphosate. These plants over-produce the EPSP synthase and could tolerate higher glyphosate rates without visual phytotoxic symptoms. In such transgenic crops plant protection products containing glyphosate can be used for a selective weed control.

At the present time applications for the use of glyphosate on tolerant crops are pending in France (maize, oilseed rape, sugar beet and soybean) and fodder beet in Denmark. An application for cotton is expected in 1998.

After application of glyphosate containing herbicides, the soil should not be cultivated for a period of 7 days (perennial weeds) of 1 day (annual weeds).

Glyphosate containing herbicides should not be used for harvest management of weed control in standing crops for seed production. In perennial crops contact with green parts of the plants should be avoided.

Straw from cereals treated pre-harvest should not be used as a horticultural growth medium.

2.3.2 Further information

Information of handling, storage, transport or fire, destruction or decontamination, emergency measures for the active substance as manufactured, the water soluble granules, and the soluble concentrates have been supplied and are acceptable.
Although not all applicants have addressed all points of these chapters, virtually the submitted information are sufficient as examples for the active substance and the formulations.

2.4 Impact on human and animal health

2.4.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

Toxicokinetics and metabolism
Following oral administration, glyphosate is absorbed from the gastrointestinal tract rapidly but only to a limited extent of not more than 30 - 40%. Percutaneous absorption of glyphosate at least through the intact skin is confined to a small portion of less than 3%. Elimination via faeces and urine is rapid and nearly complete. Distribution into the organs and tissues is limited with generally low residues occurring. There is no evidence of accumulation in the animal body. After a period of 3 to 7 days following oral administration, total body burden accounted for less than 1% of the applied radioactivity with highest residues measured in bone, followed by kidney and liver. This pattern of absorption, distribution and elimination was not significantly changed neither by single high doses administered nor by repeated administration of low doses. Similarly, there was no consistent sex influence.
Metabolism of glyphosate, if occurring, is very limited. Most of the parent glyphosate is eliminated unchanged. To a little extent of less than 0.5%, aminomethylphosphonic acid (AMPA) which is known to be the major plant metabolite of glyphosate may be formed also in mammals. A comparison of the studies performed in rats, rabbits, goats and laying hen did not reveal significant species differences in the pattern of toxicokinetics and metabolism.

Acute toxicity
Glyphosate acid and its salts exhibited a low acute toxicity in laboratory animals by the oral and dermal route with LD50 values greater than 2000 mg/kg bw. General signs of oral intoxication were breathing difficulties, ataxia and convulsions. The acute inhalation toxicity was also low with an LC50 above the limit test dose of 5 mg/l air per 4 hours when the acid and the isopropylammonium salt (IPA) were tested. Toxic symptoms after inhalative exposure included irritation of the upper respiratory tract, hyperactivity, loss of hair, ruffled fur and slight decrease in body weight but were not consistently seen throughout all the studies.
Regarding primary irritation, glyphosate acid and the salts were

found to be non-irritant at least to intact skin. In contrast, undiluted glyphosate acid was found to be strongly irritant to rabbit eyes. There was markedly less eye irritation observed with the salts. On the basis of the eye irritation data, the following classification/labelling of glyphosate (acid) is proposed:

R 41 (Risk of serios damage to eyes).

Classification and labelling of the salts is not considered necessary.
Sensitization was not observed neither with glyphosate acid nor with the salts.

Short-term toxicity

Subacute and subchronic oral toxicity studies also show a low toxicity of the compound. The lowest NOELs observed were in the range of 50 - 150 mg/kg bw/d with first effects occurring in the range of 250 - 300 mg/kg bw/d or above. Changes in clinical chemistry parameters and liver weight changes might indicate an impact on the liver at least in rats. Soft stools and diarrhea, together with occasionally reduced body weight gain and food consumption, suggest irritation of the gastrointestinal tract. In some oral rat studies and in one experiment with mice, effects on salivary glands were elucidated upon histopathological examination.
Repeated dermal exposure of rabbits and rats to glyphosate did not result in any systemic effects. Dermal irritation was only observed at doses as high as 5000 mg/kg bw/d in rabbits or 1000 mg/kg bw/d in rats.
Subacute inhalative toxicity of glyphosate active ingredient in rats is low. Up to the highest tested concentration of 3.8 mg/l air, neither local nor systemic toxicity was noted upon repeated exposure.

Mutagenicity

Glyphosate was examined for mutagenicity in a wide range of test systems covering all relevant endpoints in vitro as well as in vivo. Against the background of this large database, it can be concluded that the active ingredient does not exhibit a mutagenic risk to humans. It should be also taken into consideration that there is no evidence of cancerogenic effects in humans although glyphosate products have been in world-wide use for many years.

Long-term toxicity and cancerogenicity

In long-term studies in rats and mice, no evidence of cancerogenicity was obtained. The lowest NOELs of 10 mg/kg bw and 100 ppm (approximately 6 mg/kg bw/day, female animals), respectively, were established in chronic rat studies with first effects occurring in the range of 60 - 100 mg/kg bw/day. A further study did not reveal effects up to the highest dose of 31 mg/kg bw/day. Mice appeared less vulnerable.
Concerning the non-neoplastic effects upon long-term exposure, considerable differences among the different studies became apparent. In general, there were no adverse effects on survival and no clinical signs of toxicity in any of the chronic studies. Body weight gain was compromized in female Sprague-Dawley rats at the upper dietary level of 20000 ppm, equivalent to a mean daily intake of 1183 mg/kg bw. A lower body weight was also noted in male CD-1 mice receiving the extremely high dietary dose of 30000 ppm

(ca 4800 mg/kg bw/d) for two years. A higher activity of alkaline phosphatase and liver weight changes in rats as well as centrilobular hepatocyte hypertrophy in male mice were assumed to reflect a weak effect on the liver. In addition, effects on the eyes and on salivary glands were observed in rats but not consistently seen in all studies. A higher incidence of cataracts was noted in male Wistar rats at 10000 ppm and in male Sprague-Dawley rats at 20000 ppm. In Sprague-Dawley rats, non-neoplastic histological changes accompanied by a higher organ weight occurred in the parotid and mandibular salivary glands in both sexes at 100 mg/kg bw/d and above. Further investigation suggested a possible adrenergic mechanism behind. Local inflammation of gastric mucosa was noted in one study on Sprague-Dawley rats at the high and mid dose levels in both sexes. This finding was most likely due to mucosal irritation and might well correspond to epithelial hyperplasia in the urinary bladder as observed in a long-term mouse study at 5000 ppm and above.

Reproduction toxicity

A number of multigeneration studies in rats did not indicate a specific hazard of glyphosate for reproduction. Weak effects on the offspring as evidenced by a reduced pup weight were confined to dose levels as high as 30000 ppm. Compound-related effects in the parent animals were similar to those seen in the subchronic and long-term studies including salivary gland changes and occurred at comparable dose levels.

Glyphosate does not cause teratogenicity. Adverse effects on the number of viable fetuses and the fetal weight were noted in rats and rabbits at higher dose levels causing also maternal toxicity. A reduced ossification and a higher incidence of skeletal and/or visceral anomalies at these dosages were also indicative of fetotoxicity. The NOEL for developmental effects was 300 mg/kg bw/day in rats and 350 mg/kg bw/day in rabbits. In rabbits, maternal effects occurred at doses of 100 mg/kg bw/day and above which were lower than those found effective in developmental toxicity, subacute and subchronic studies in rats and might indicate a higher vulnerability of this species.

Other experimental data

Glyphosate has no specific potential for neurotoxicity.

Acute and subacute toxicity studies in goats and cattle confirmed the low toxicity of the compound. A specific hazard for farm animals is not expected.

The metabolite AMPA was investigated for acute and subchronic effects, mutagenicity and teratogenicity. These studies have shown that AMPA has a lower toxicity than the parent compound and is devoid of a mutagenic or teratogenic potential.

Medical data

Clinical examinations of employees involved in the manufacturing process gave no evidence of adverse health effects as result of potential exposure to the active ingredient. No data on exposition of general population and no appropriate epidemiological studies are

available. However, there is a number of cases of acute intoxication in humans following accidental and intentional ingestion of glyphosate products. Clinical reports suggest that toxicity of formulations was mediated through an impact on cardiovascular (circulatory) and respiratory functions. The toxic syndroms resulting from massive oral intake consists of gastrointestinal mucosal irritation, hypotension and pulmonary insufficiency. There is a strong evidence also supported by pharmacological studies that these effects were rather due to certain surfactants but not to the active ingredients itself.
Following inhalative exposure to formulations containing glyphosate, transient symptoms like headache were occasionally observed but there is no confirmed evidence of serious or long-lasting adverse health effects. Investigations with a Roundup formulation in human volunteers did not provide evidence of skin irritation, allergic or photoallergic contact dermatitis.

2.4.2 ADI

The acceptable daily intake should be based on the highest dose at which no adverse effect is observed in the most appropriate study in the most sensitive species. In the case of glyphosate, the different notifiers have proposed ADI values covering a wide range between 0.05 and 1.75 mg/kg bw.

Usually, a chronic study is considered most appropriate to derive the ADI. Since the rat proved the most sensitive species upon long-term exposure, it is suggested to establish the ADI for glyphosate on the basis of the chronic toxicity data obtained in rats. Four studies are available. Taking the results together, one can assume the NOEL for chronic effects of glyphosate in the rat between 10 and 100 mg/kg bw/d. In the study by Suresh (1996), an increase in alkaline phosphatase activity was apparent at the mid dose level of 1000 ppm in female rats. Hence, it appears reasonably to establish the LOEL for glyphosate-related long-term effects in rats at this dose corresponding to an approximate daily intake of 60 mg/kg bw. Accordingly, the next lower dose applied can be assumed to represent a reliable NOEL from which the ADI value should be derived. This was the dose of 31 mg/kg bw/d at which no treatment-related effects were observed in another chronic rat study (Lankas, 1981).

For calculation of the ADI, the usual assessment factor of 100 is considered appropriate since there was no evidence of cancerogenicity, mutagenicity, teratogenicity or any other specific hazard of glyphosate. Thus,

an ADI of 0.3 mg/kg bw

is proposed. It should be emphasized that this proposal is not based on one single study but on the overall assessment of all available long-term studies in rats.

2.4.3 AOEL

The acceptable operator exposure level should be established on the basis of the highest dose at which no adverse effect is observed in relevant studies in the most sensitive species. However, in contrast to the setting of an ADI, the AOEL is usually based on mid-term studies (i.e. subacute/subchronic and reproduction or developmental toxicity studies) since these studies in most cases can be considered a more appropriate model for the actual operator exposure to be expected.
The different notifiers proposed oral AOELs for glyphosate varying between 0.4 mg/kg bw/d and 10.0 mg/kg bw/d. However, the low oral absorption of glyphosate has not been taken into consideration by any of the notifiers.

The rabbit is considered the most sensitive species in studies of short or midterm duration. The critical endpoint is maternal toxicity observed in teratogenicity studies in this species. It is proposed to derive the AOEL from the highest dose providing no evidence of maternal toxicity. Thus, the NOEL of 75 mg/kg bw/d as established in a rabbit developmental toxicity study (Tasker, 1980), should be used to calculate the oral AOEL. The lowest dose at which toxic effects were noted in female rabbits was 100 mg/kg bw/d (Suresh, 1993). Taking into account the toxicological profile of glyphosate, an assessment factor of 100 is considered adequate. For calculation of a systemic AOEL, the low oral absorption rate of about 30% has to be taken into account. This would result in a numeric value of 0.225 mg/kg bw/d but for practical reasons, an approximate value should be established. Thus, an

AOEL of 0.2 mg/kg bw/d (systemic)

is proposed.

2.4.4 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it

According to the toxicological properties of glyphosate, harmful effects on the health of operators, bystanders, workers or consumers are not to be expected when the products are used in accordance with good plant protection practice.
The potential exposure for operators was estimated for the intended uses. Very different basic data were used by the notifiers in model calculations (German model and/or UK model) and/or in field tests. The Rapporteurs calculation using the German model and data for worst case conditions results in estimated exposures of 38 - 212% of the proposed systemic AOEL if no PPE are worn. By wearing of gloves during mixing/loading, the proposed systemic AOEL was never exceeded indicating a sufficient margin of safety for the operator.
Therefore, in view of the indended uses and application techniques, it is not likely that the potential exposure of bystanders will exceed the AOEL.

The active substance intake by consumers was estimated according to the BBA guideline. The theoretical maximum daily intake (TMDI) accounted for only a part of the ADI which represents a large margin of safety for consumers.

In view of the recommended uses and application techniques, harmful effects on the health of domestic or wild animals are not to be expected.

Experimental as well as medical data suggest that by products in some formulations may cause toxic effects upon oral or inhalative exposure which are not seen with the active substance.
With regard to genotoxicity of certain formulations, cytotoxicity and a potential for damage to the DNA have been observed in some tests systems. These findings will be especially adressed in an addendum to this monograph.
Thuse, possible effects of by-products or impurities should be carefully considered when a product containing glyphosate is to be registered.

2.5 Methods of analysis

2.5.1 Analytical methods for analysis of the active substance as manufactured

For the determination of glyphosate in the active substance as manufactured the generally used method is the AOAC-CIPAC method. The principle is HPLC using an anion exchange column, UV detection at 195 nm and evaluation by external standardization. Mobile phase is a buffered solution (pH = 1.9 - 2) of KH_2PO_4 in water/methanol.
Beyond an HPLC method using an amino phase (NH_2) column, UV detection at 210 nm and evaluation by external standardization and acetonitrile/water/phosphoric acid as mobile phase is used.
A third HPLC method quantifying glyphosate as a copper II complex using a Hypersyl-MOS column and UV detection at 230 nm with copper acetate in ammonium carbonate solution as mobile phase was used.
Another method is complexometric titration with copper volumetric solution for the determination of glyphosate and the impurity glyphosine together. By titrating with bismuth volumetric solution the glyphosine content can be measured. The difference gives the glyphosate content.

2.5.2 Analytical methods for formulation analysis

For the determination of glyphosate in SL and SG formulations the generally used method is the AOAC-CIPAC method. The principle is HPLC using an anion exchange column, UV detection at 195 nm and evaluation by external standardization. Mobile phase is a buffered solution (pH = 1.9 - 2) of KH_2PO_4 in water/methanol.
Beyond an HPLC method using an amino phase (NH_2) column, UV detection at 210 nm and evaluation by external standardization and acetonitrile/water/phosphoric acid as mobile phase is used.

Another method is complexometric titration with copper volumetric solution for the determination of glyphosate and the impurity glyphosine together. By titrating with bismuth volumetric solution the glyphosine content can be measured. The difference gives the glyphosate content.

2.5.3 Methods for residue analysis

Adequate analytical methodologies are available for the determination of residues of glyphosate and its metabolite AMPA for a wide range of plants and plant products, food of animal origin including milk and eggs, soil, water and air.

It is possible to analyse glyphosate and AMPA residues with HPLC-methods using fluorescence detection after post-column derivatisation with o-phthaldialdehyde (OPA) or after pre-column derivatisation with 9-fluorenylmethylchloroformate (FMOCCl). Residues can also be determined with gas chromatography methods using a mass spectrometric or electron capture detection after derivatisation with trifluoroacetic anhydride and trifluoroethanol or heptafluorobutanol. Additionally, a GC-method with flame photometric detection after derivatisation with trifluoroacetic anhydride and diazomethane can be applied for the determination of glyphosate residues.

According to the residue definition (see 2.6) analytical methods for metabolites other than AMPA are not necessary. AMPA is a relevant metabolite only in soil and water. It is not included in the definition of residues relevant to MRL for non-glyphosate-tolerant crops, consequently methods for the determination of AMPA residues in food of plant and animal origin are not necessary. With regard to an application to glyphosate-tolerant crops both glyphosate and AMPA must be determined.

For assessment of the analytical methodology the following MRL or limits are relevant at the time of evaluation:

crops:	0.1	or >0.1 mg/kg (MRL)
meat, eggs:	0.1	mg/kg (MRL)
kidney:	2	mg/kg (MRL, kidney of swine: 0.5 mg/kg)
fat:	0.1	mg/kg (MRL)
milk:	0.1	mg/kg (MRL)
soil:	0.05	mg/kg (general upper limit)
water:	0.1	µg/l (EU drinking water limit)
air:	60	µg/m³ (calculation based on an AOEL-value of 0.2 mg/kg bw)

With the submitted methods the following limits of determination can be reached according to the notifiers:

crops:	0.02-0.06 mg/kg
meat:	0.02 mg/kg;
eggs:	0.01 mg/kg
kidney:	0.05 mg/kg
fat:	0.03 mg/kg
milk:	0.01 mg/kg;

soil: 0.02 mg/kg;
water: 0.05-0.1 µg/l
air: 7.2 µg/m³

2.6 Definition of the residues

2.6.1 Definition of the residues relevant to MRLs

Plant metabolism studies on both non-tolerant and tolerant crop plants demonstrate that there are two significant components of the residue of the parent glyphosate acid:
the corresponding N-(phosphonomethyl)glycine anion (PMG) and
the metabolite aminomethyl phosphonic acid (AMPA).

Glyphosate non-tolerant plants:
Metabolism data except of the results on soyabeans and early residue trials have demonstrated that the residues of AMPA are not significant. According to previous findings AMPA is an animal and soil metabolite and in addition an acute oral toxicity study has demonstrated an LD_{50} >5000 mg/kg, and a mutagenicity study has shown that AMPA is not mutagenic. Furthermore, there were problems in the analysis of PMG and AMPA which most of the analytical laboratories were not able to solve. For that, to avoid artefacts and mistakes in monitoring programs for supervision of MRLs it was proposed that AMPA should not be included in the MRL expressions.
Consequently, the following residue definition should be kept:
"glyphosate".

Animal products:
Radiolabelled studies in lactating goats and laying hens following oral administrations of glyphosate and AMPA, the primary metabolite of glyphosate, showed that metabolites resulting from the degradation of these compounds in edible tissues, milk and eggs were either insignificant or entirely absent.
Therefore, the residue definiton for animal products shall be
"glyphosate".

Glyphosate tolerant plants:
In contrast to the findings and conclusions following the use of glyphosate in non-tolerant crop plants containing the GOX enzyme in particular, the results from **glyphosate tolerant plant** metabolism exminations reveal another situation to be evaluated. The metabolite AMPA is present in such plants at higher levels as found in non-tolerant plants.
Dependent on the use pattern of glyphosate in the future and the residue situation in plant products it may be indicated to consider MRL proposals for residues of the plant metabolite AMPA in plants and in animal products of concern.
Then the residue definition should be **"AMPA"** besides the residue definition **"glyphosate"**.

2.6.2 Definition of the residues relevant to the environment

It is proposed to define the residue to include glyphosate and aminomethylphosphonic acid (AMPA).

2.7 Residues

2.7.1 Residues relevant to consumer safety

The registered, authorized, or intended uses of glyphosate containing products on various crops intended for human or livestock consumption are covered by residue data allowing to propose maximum residue limits (MRLs) for related commodities.
In-crop or pre-harvest applications yielding detectable glyphosate or AMPA residues require establishment of MRLs for glyphosate or AMPA other than MRLs based on the limit of determination e.g. small grain cereals and maize, pulses (beans and peas), oil seed crops, and potatoes.
Crop desiccation treatments shortly before harvest lead to the highest residue levels in cereal grain or oilseeds.

In-crop treatments of glyphosate tolerant plants at higher total rates as compared to genetically unchanged crop plants lead to different residue situations. The main residue in those crops is AMPA besides minor unchanged glyphosate. The absolute residue levels of both analytes, in general, are lower than in common crop species.

A special example of a pre-harvest application is the treatment of the ground beneath olive trees when there are groundlying fruits present. These olives are harvested from groundplaced nets and are normally used for the production of olive oil. Within DAT 0 - 14 significant residue levels of glyphosate are found in raw olives. However, oil of these fruits does not contain detectable glyphosate residues.

Another application of residue relevance is the ground treatment in forestry when there are wild growing mushrooms in the area. For this case one can expect significant residue levels in the mushrooms.

In-crop selective equipment (e.g. wet rope) or interrow applications of glyphosate also result in detectable residues in crops. For example, maize that received selective equipment applications. The residues in maize grain are low compared to levels in small grain cereal after "over-the-top" pre-harvest treatments.
Also, tea leaves that received post-directed applications contained residual glyphosate.

Although pre-harvest or selective equipment applications of glyphosate result in detectable residues, the major method of glyphosate application is a pre-emergence treatment that does not result in detectable residues.

Results of process fraction studies on citrus fruits, olives, lin-

seed, oilseed rape, soya bean, potatoes, tea, major cereal crops (barley, oat, wheat, maize), sugar beet and sugar cane including glyphosate tolerant crops treated with glyphosate containing products, in general, reveal no concentration of those residues in commodities to be used for consumption.

Considered in total, the results obtained show that the residual glyphosate present in raw agricultural commodities is primarily a surface residue. Industrial processing of raw agricultural commodities containing residual glyphosate results in concentration of the residues in only those processed commodities derived from surface tissues (i.e., bran, shorts, hulls, peel). The latter products can be used as feedingstuffs.

Livestock feeding studies show that glyphosate residues are less than 0.05 mg/kg in all tissues from animals that consume feed containing maximum expected residual glyphosate. Thus, the results of the processed commodities studies coupled with those of the livestock feeding studies show that dietary exposure to glyphosate will not increase as a result of industrial processing of raw agricultural commodities containing residual glyphosate.

TMDI estimates using MRL-level residues for all crops for which glyphosate MRLs are established or proposed are well below the ADI of 0.3 mg/kg bw. The two models used for calculation based on the WHO global diet and the German diet (BBA model) provide similar results: The TMDI is approximately 16 % or 23 % of the ADI, respectively indicating an acceptable safety margin for the consumers.

2.7.2 Residues relevant to worker safety

Glyphosate based preparations are used when it is not necessary to enter crops shortly after spraying. On the basis of the estimated operator exposures calculated by the Rapporteur for all the recommended uses, the proposed systemic AOEL was mostly not exceeded even without using PPE. Only in some cases, wearing of gloves during mixing/loading is needed to keep below the proposed AOEL. Therefore, health problems for workers are not anticipated.

2.7.3 Compliance with existing MRLs and/or proposed MRLs

Community Maximum Residue Limits have been set in the MRL Directive 93/58/EEC only for glyphosate acid (PMG). Additionally, in Germany a number of MRLs has been set. All data are presented in table 2.7.3-1 together with the corresponding MRL proposals for comparison.

The MRL proposal for citrus fruit is based on results obtained from trials conducted in US leading to a higher value of 0.5 mg/kg as the existing EU-MRL. This proposal includes a possible direct contamination of low hanging fruit during spraying.
The same effect was considered for the MRL proposal for grapes.

Some new MRLs for glyphosate could be derived from new submitted data. The open position for olives (table and oil consumption not divided by the EU), peas and beans (pulses) can be closed. From the submitted information it is not clear which PHI is valid for the treatment of olive orchards. Consequently, the residue data of groundlying olives (used for oil production) sampled at DAT 0 (worst case) was used for MRL calculation leading to the high proposal of 20 mg/kg. As soon as the corresponding PHI information is available the MRL proposal based on the residue data from samples collected at DAT 7 and 14 alone can be reworked.
A new proposal for tea leaves is made. The presented residue data do not confirm the existing EU-MRL (import tolerance).

Residue data of crops from glyphosate tolerant oilseed rape, soya bean and cotton plants, maize, and sugar beets have been submitted recently. MRLs for glyphosate separately are not proposed since the residue levels in crops are found to be significantly lower than in common plants and therefore, are covered by the MRL proposals for those commodities.
However, for these commodities new MRLs for AMPA are proposed separately except of oilseed rape since no residue data from southern Europe are available.

For products of animal origin a general MRL at the limit of determination is proposed because the assessment of the residues expected in each of those commodities used as feedstuff results in a "low residue situation". The assessment is based on the use of STMR values of all included residue data of possible fodder plants.

Table 2.7.3-1: Existing MRLs for Glyphosate in EU Member States and MRL proposals from evaluation

COMMODITY	EU MRL Glyphosate [mg/kg]	MRL proposal Glyphosate [mg/kg]	MRL proposal AMPA [mg/kg]
CITRUS FRUIT	0.1*	0.5	
TREE NUTS	0.1*	0.1*	
POME FRUIT	0.1*	0.1*	
STONE FRUIT	0.1*	0.1*	
BERRIES AND SMALL FRUIT			
Table grapes	0.1*	1	
Wine grapes	0.1*	1	
Strawberries (other than wild)	0.1*		
Cane fruit (other than wild)	0.1*		
Other berries and small fruit (other than wild)	0.1*	open	
Wild berries an wild fruit	0.1*		
MISCELLANEOUS FRUIT			
Olives (table consumption)	open	0.1*	

Olives (oil consumption)	open	20	
Others	0.1*	0.1*	
ROOT AND TUBER VEGETABLES	0.1*		
Beetroot		0.1*	
Others		0.1*	
BULB VEGETABLES	0.1*		
Onions		0.1*	
Others		0.1*	
FRUITING VEGETABLES		0.1*	
Solanacea	0.1*		
Cucurbits - edible peel	0.1*		
Cucurbits - inedible peel	0.1*		
Sweet corn	0.1*		
BRASSICA VEGETABLES		0.1*	
Cauliflower	0.1*		
Head cabbage	0.1*		
Leafy Brassicas	0.1*		
Kohlrabi	0.1*		
LEAF VEGETABLES AND FRESH HERBS		0.1*	
Salads	0.1*		
Lettuce and similar	0.1*		
Water cress	0.1*		
Spinach and similar	0.1*		
Chicory	0.1*		
Herbs	0.1*		
LEGUME VEGETABLES (fresh)	0.1*	0.1*	
STEM VEGETABLES	0.1*		
Asparagus		open	
Others		0.1*	
FUNGI			
Mushrooms (other than wild)	0.1*	0.1*	
Wild mushrooms	50	50	
PULSES			
Beans	open	1	
Lentils	0.1*		
Peas	open	5	
Others	0.1*	0.1*	
OIL SEEDS			
Linseed	10	10	
Rape seed	10	10	
Rape seed (glyphosate tolerant)		10	0.5[2]
Soya bean	20	20	
Soya bean (glyphosate tolerant)		20	5
Cotton seed (glyphosate tolerant)		5	0.2
Mustard seed	open	10	

Others	0.1*	0.1*	
POTATOES	0.1*	0.5	
TEA	0.1*	1	
HOPS	0.1*	0.1*	
CEREALS			
Wheat	5	5	
Rye	5	10	
Barley	20	20	
Oat	20	20	
Triticale	5	5	
Bran (raw)	20[1]		
Cereal products (except raw bran)	5[1]		
Maize		1	
Maize (glyphosate tolerant)		1	1
Others	0.1*	0.1*	
OTHER FOOD OF PLANT ORIGIN	0.1*	0.1*	
Sugar beets	0.2[1]	0.2	
Sugar beets (glyphosate tolerant)		1	0.1
FOODSTUFFS OF ANIMAL ORIGIN		0.1*	
Milks	0.1*		
Milk products	0.1*		
Eggs	0.1*		
Eggs (without shell)	0.1*		
Egg yolk	0.1*		
Meat	0.1*		
Meat products	0.1*		
Kidney of pig	0.5		
Kidney of cattle	2		
Kidney of goat	2		
Kidney of sheep	2		
Fat	0.1*		
Others	0.1*		
FODDER PLANTS			
Sugar and fodder beet root	0.2[1]		
Sugar and fodder beet leaves	2[1]		
Other feed of plant origin	0.1*[1]		

[1]) MRL set in DE only
[2]) provisional MRL for N-EU

2.8 Fate and behaviour in the environment

2.8.1 Fate and behaviour in soil

Glyphosate is considered to be mainly degraded biologically by micro-organisms. In laboratory studies under aerobic conditions DT50 values ranged between 2 - 25 days (20 and 25°C, respectively) and corresponding DT90 values between 17 - 280 days, respectively. The mineralisation rates ranged between 6 and 55% after 28 days at 30°C. In further laboratory studies mineralisation was observed to 86% in 14 days, 80% in 100 days and 42% of applied glyphosate in 364 days. The formation of non-extractable residues took place to 8 and 20% in these studies. The main metabolite of glyphosate, aminomethylphosphonic acid (AMPA), was detected in amounts of 26 to 29% in 14 days.

Several other minor metabolites were also detected. These minor metabolites included N-methylaminomethylphosphonic acid, N,N-dimethylaminomethylphosphonic acid, hydroxymethylphosphonic acid and two unidentified metabolites. None of these minor metabolites were present to an extent of greater than 3 % of the applied glyphosate and no metabolic products containing an intact N-phosphonomethylglycine moiety were detected. No N-nitrosoamines were detected in soil treated with glyphosate alone or together with sodium nitrite at normal application rates.

An anaerobic study (route and rate) for the special use in rice cultures is missing. An additional laboratory study of aerobic degradation at 10°C is not required because a field dissipation study under cold climatic conditions was provided.

The soil photolysis of glyphosate is a very minor pathway for the degradation of glyphosate in soil.

Field studies in areas representative for Middle-Europe (Germany, Switzerland) and - regarding climate and soil characteristics - comparable with those in Southern (USA/Tennessee, California, Georgia) and Northern Europe (Canada) provided DT50 values between 3 and 68 days and DT90 values between 38 and 208 days.

The variation in the degradation rate of glyphosate between different soils is large which probably depends on the naturally occurring microbial population producing the types of enzymes necessary for catalysing the degradation of glyphosate. The degradation rate is influenced by the addition of ions such as phosphate, Fe^{3+} or Al^{3+}.

In field dissipation studies the relevant metabolite AMPA was degraded with DT50 values of more than 100 days. AMPA can accumulate in certain soils.

For different soil and sediment types Koc values of glyphosate were determined between 884 and 51000. For the metabolite AMPA Koc values ranged between 1160 and 25000. Due to its high adsorption no relevant amounts of the active substance or the main metabolite AMPA are expected to enter groundwater.

2.8.2 Fate and behaviour in water

Under abiotic conditions glyphosate was stable to hydrolytic and photolytic degradation. Glyphosate is not readily biodegradable.

In water/sediment studies rapid dissipation of glyphosate in the sediment occured. Already after one day glyphosate amounted to 47 - 64% in the water pahse and to 31 - 44% in the sediment.After 100 days only 3% of the active substance was detected in water but 29 - 44% in the sediment.

Degradation of glyphosate in water/sediment systems occured with DT50 values of 27,31,124 and 146 days (whole systems) and of 1 4 days (water phase) under aerobic conditions. In the water phases glyphosate was fast degraded within 30 days to less than about 10% whereas in the sediments glyphosate was detected in maximum amounts of 50-60 % after 7 and 14 days, respectively, and degraded after about 100 days to 30-50 %.

If found the relevant metabolite AMPA occured only in the water phases with maximum amounts of about 16 % after 14 days and was degraded in 100 days to 0.5 %.

The metabolite (hydroxymethyl)-phosphonic acid occured in the water phases with maximum amounts of about 10 % after 61 days.

In the sediment no metabolites were detected.

Mineralisation occured to 6 - 26% after about 100 days andd up to 35% after365 days.

The formation of non-extractable residues took place to 14 - 35% after about 100 days.

2.8.3 Fate and behaviour in air

Glyphosate can be classified as not volatile substance based on its Henry's law constant and on volatilization experiments from soil and plants with no significant rates. Due to no significant UV-absorption, direct photolysis in air will not occur. Once in the atmosphere rapid photochemical oxidative degradation of glyphosate will occur.

2.9 Effects on non-target-species

2.9.1 Effects on terrestrial vertebrates

The toxicity of glyphosate to mammals and birds is low.

Acute toxicity to mammals:	LD50 >2000 mg/kg bw
Acute toxicity to birds:	LD50 >2000 mg/kg bw
Dietary toxicity to birds:	LC50 >4640 ppm
Reproduction toxicity to birds:	NOEC 200 ppm

Wild mammals and birds are exposed to glyphosate mainly by feeding on contaminated plants and invertebrates. Considering an application rate of 4.3 kg as/ha the acute and short-term TER-values meet the relevant trigger of 10 thus indicationg acceptable risk. The long-term TER for mammals meets the trigger of 5 whereas the long-term TER for birds is somewhat below 5. However, it is not quite realistic to assume that birds feed exclusively on treated vegetation or contaminated insects over weeks. Furthermore residue decline in insects has not been taken into account in the TER-calculation. Therefore the long-term risk also for birds is regarded to be acceptable.

2.9.2 Effects on aquatic organisms

Data from toxicity tests with fish, daphnia and algae were available for the active ingredient, the glyphosate-acid (technical), the metabolite AMPA and formulated products. The most sensitive organisms were algae in the test with glyphosate (technical). However, tests with two formulated products show a higher toxicity than the a.s. whereas other products are of comparable toxicity or much less toxic. Member states should consider whether additional studies with the most sensitive algae species on those formulated products are necessary which are more toxic than the a.s.

As overspray clearly represents misuse of a plant protection product, the initial step of the risk assessment is based on drift values for a distance of 1 m. The calculated TERs are equal or higher than the the relevant trigger indicating an acceptable risk for aquatic organisms. However, member states must ensure that farmers keep this distance.

Regarding aquatic uses of Glyphosate-Isopropylaminsalt the calculated TERs are lower than the relevant trigger indicating an unacceptable risk for aquatic organisms.

Due to the high toxicity to non-target aquatic organisms aquatic uses and applications in rice cultures should lead to unacceptable effects to aquatic organisms.

Glyphosate must be labelled with R 50 and R 53.

2.9.3 Effects on bees and other arthropod species

2.9.3.1 Effects on bees

Based on toxicity data for the active substance glyphosate the risk for honey bees is classified "low risk" according to the EPPO/CoE Risk Assessment Scheme.

2.9.3.2 Effects on other arthropod species

Predatory mites
According to EPPO/CoE Risk Assessment Scheme the study submitted for formulated glyphosate (360 g as/l) indicates "high risk" to Typhlodromus pyri (Acari: Phytoseiidae).

Parasitoids
According to EPPO/CoE Risk Assessment Scheme the study submitted for formulated glyphosate (360 g as/l) indicates "high risk" to Aphidius rhopalosiphi (Hymenoptera: Braconidae).

Plant dwelling predators
According to EPPO/CoE Risk Assessment Scheme the study submitted for formulated glyphosate (360 g as/l) indicates "medium risk" to Chrysoperla carnea (Neuroptera: Chrysopidae) with regards to an exposure up to 0.7 kg ai/ha.

Ground dwelling predators
According to EPPO/CoE Risk Assessment Scheme the studies submitted for formulated glyphosate (360 g as/l) indicate "low risk" to carabid beetles and rove beetles if sprayed directly whereas "medium risk" must be assumed for lycosid spiders.

Summary
According to the studies submitted using standard species A. rhopalosiphi and T. pyri in the laboratory "high risk" for terrestrial non-target arthropods must be assumed, in general. For more robust species, however, such as ground dwelling predators, "low risk" to "medium risk" may be anticipated according to the EPPO/CoE Risk Assessment Scheme. For C. carnea, representing the group of plant dwelling predators, risk is classified "medium risk" for an exposure up to 0.7 kg ai/ha.

Since Annex VI trigger-values are exceeded further studies are required to prove acceptability of effects.

2.9.4 Effects on earthworms and other soil macro-organisms

Based on toxicity data and intended application rates the risk for earthworms and other soil non-target macro-organisms is considered acceptable. Sublethal effects on some single species, e.g. isopods, might occur.

2.9.5 Effects on soil micro-organisms

The test results presented show that when applying glyphosate containing products according to the mentioned amounts no negative effects on microbial activities are to be expected. Many published papers on glyphosate confirm that when applying according to the recommended pattern of use the microflora will not be affected.

2.9.6 Effects on other non-target organisms (flora and fauna)

According to the data submitted glyphosate will be of low risk for most species of the soil fauna. With single species sublethal effects like reduced growth might occur.

Data submitted for terrestrial non-target higher plants reveal that there will be a risk when glyphosate is applied postemergent to foliage. No or low risk has to be assumed when glyphosate is applied preemergent. Around nature reserves a buffer zone of 5-10 m is recommended.

2.9.7 Effects on biological methods of sewage treatment (Annex IIA 8.7)

Not relevant.

2.10 Classification and labelling

Glyphosate
Classification and labelling of glyphosate on the basis of the available toxicology information according to Directive 67/548/EEC, 18th adaption (Directive 93/21/EEC):

GLYPHOSATE ACID

Hazard symbol:		Xi
Indication of danger:		Irritant
Risk phrases:	R 41:	Risk of serious damage to eyes.
	R 50/53:	Very toxic to aquatic organisms, may cause long-term adverse aquatic environment.

GLYPHOSATE, ISOPROPYLAMINE SALT

Hazard symbol:	none
Indication of danger:	none
Risk phrases:	none

GLYPHOSATE, SODIUM SALT

Hazard symbol:	none
Indication of danger:	none

Risk phrases: none

GLYPHOSATE, AMMONIUM SALT

Hazard symbol: none
Indication of danger: none
Risk phrases: none

Classification and labelling of the **preparations** on the basis of the available toxicology information according to Directive 78/631/EEC in combination with Directive 67/548/EEC 18th adaption (Directive 93/21/EEC):

Monsanto: "MON 52276"

Hazard symbol: none
Indication of danger: none

Risk phrases: none
Safety phrases:

S 2:	Keep out of reach of children.
S 13:	Keep away from food, drink and animal feedingstuffs.
S 37:	Wear suitable gloves.

Monsanto: "MON 44068"

Hazard symbol: none
Indication of danger: none
Risk phrases: none
Safety phrases:

S 2:	Keep out of reach of children.
S 13:	Keep away from food, drink and animal feedingstuffs.
S 37:	Wear suitable gloves.

Agrichem [Task Force]: "Agrichem Glyphosate 360"

Hazard symbol: Xi
Indication of danger: Irritant

Risk phrases:

R 41:	Risk of serious damage to eyes.

Safety phrases:

S 2:	Keep out of reach of children.
S 13:	Keep away from food, drink and animal feedingstuffs.
S 20/21:	When using do not eat, drink or smoke.
S 23:	Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer.
S 26:	In case of contact with the eyes, rinse

immediately with plenty of water and seek medical advice.
S 37/39: Wear suitable gloves and eye/face protection.
S 46: If swallowed, seek medical advice immediately and show this container or label.

For **"Agrichem Glyphosate 360"**,
a sensitization study was not submitted.
If **"Herbolex-Glyphosate"** is identical to
"Agrichem Glyphosate 360",
according to the sensitizing properties seen in the respective study,
the risk phrase
R 43: May cause sensitization by skin contact
is additionally needed for proper classification of the formulation.

Alkaloida: "Glialka 36"

On the basis of the notifier's data, classification and labelling is not required.

Alkaloida: "Glistar"

On the basis of the notifier's data, classification and labelling is not required.

Barclay: "Barclay Gallup"

Hazard symbol: Xi
Indication of danger: Irritant
Risk phrases:
R 38: Irritating to skin.
R 41: Risk of serious damage to eyes.

Safety phrases:
S 2: Keep out of reach of children.
S 13: Keep away from food, drink and animal feedingstuffs.
S 20/21: When using do not eat, drink or smoke.
S 23: Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer.
S 24: Avoid contact with skin.
S 26: In case of contact with the eyes, rinse immediately with plenty of water and seek medical advice.
S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S49: Keep only in the original container.

Feinchemie: Taifun forte

Hazard symbol: Xi
Indication of danger: Irritant
Risk phrases:

R 38: Irritating to skin.
R 41: Risk of serious damage to eyes.

Safety phrases:

S 2: Keep out of reach of children.
S 13: Keep away from food, drink and animal feedingstuffs.
S 20/21: When using do not eat, drink or smoke.
S 23: Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer.
S 24: Avoid contact with skin.
S 26: In case of contact with the eyes, rinse immediately with plenty of water and seek medical advice.
S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S49: Keep only in the original container.

Herbex: "Glifogarde"

On the basis of the notifier's data submitted, a decision on classification and labelling of the preparation is not possible.

Luxan: "Glyphosate 360 SL"

Hazard symbol: Xi
Indication of danger: Irritant

Risk phrases:

R 41: Risk of serious damage to eyes.

Safety phrases:

S 26: In case of contact with the eyes, rinse immediately with plenty of water and seek medical advice.

Luxan: "Glycel 41 SL"

On the basis of the notifier's data, classification and labelling is not required.

Marubeni [Shinung]: "Glyphosate 360 SL"
All studies are in progress.
Therefore at present, a classification and labelling of the

preparation is not possible.

Nufarm:
No information submitted.

Sanachem: "Glyphosate 360"

Hazard symbol:		Xi
Indication of danger:		Irritant
Risk phrases:		
	R 36:	Irritating to eyes.
	R 43:	May cause sensitization by skin contact.
Safety phrases:		
	S 2:	Keep out of reach of children.
	S 13:	Keep away from food, drink and animal feedingstuffs.
	S 16:	Keep away from sources of ignition - No smoking.
	S 23:	Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer.
	S 28:	After contact with skin, wash immediately with plenty of...(to be specified by manufacturer).
	S 36/37:	Wear suitable protective clothing and gloves.
	S 45:	In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

I.Pi.Ci.: Ipiglyce 36 SL

Hazard symbol:		Xi
Indication of danger:		Irritant
Risk phrases:		
	R 36:	Irritating to eyes.
	R 43:	May cause sensitization by skin contact
Safety phrases:		
	S 2:	Keep out of reach of children.
	S 13:	Keep away from food, drink and animal feedingstuffs.
	S 20/21:	When using do not eat, drink or smoke.
	S 46:	If swallowed, seek medical advice immediately and show this container or label.

Annex for monographs of both Glyphosate and Glyphosate-Trimesium

Table 2.7.3-2 given below summarizes all MRL values of PMG-anion and TMS-cation existing in the EU and the MRL proposals from evaluation of the data submitted for glyphosate and glyphosate-trimesium separately together with the resulting MRL proposal for glyphosate. The proposals for AMPA from table B.7.3-1 are not listed again.

Table 2.7.3-2: Compliance with existing MRLs and MRLs proposed for Glyphosate and Trimesium-Cation

Commodity	Existing MRL [mg/kg] in EU or MS (indicated)		MRL proposal [mg/kg]			
			Glyphosate	Glyphosate-Trimesium		Resulting Glyphosate
	Glyphosate	TMS		PMG	TMS	
Citrus fruit	0.1*		0.5	0.1*	0.05*	0.5
Tree nuts	0.1*		0.1*	0.1*	0.05*	0.1*
Pome fruit	0.1*		0.1*	0.1*	0.05*	0.1*
Stone fruit	0.1*		0.1*	0.1*	0.05*	0.1*
Berries and small fruit						
Table grapes	0.1*		1	0.1*	0.05*	1
Wine grapes	0.1*		1	0.1*	0.05*	1
Strawberries (other than wild)	0.1*					
Cane fruit (other than wild)	0.1*					
Other berries and small fruit (other than wild)	0.1*		open	0.1*	0.05*	
Wild berries and wild fruit	0.1*			0.1*	0.05*	0.1*
Miscellaneous fruit						
Olives	open					
Olives (table consumption)			0.1*	0.1*	0.05*	0.1*
Olives (oil consumption)			20	0.5	0.5	0.5
Others	0.1*		0.1*	0.1*	0.05*	0.1*
Root and tuber vegetables	0.1*			0.1*	0.05*	
Beetroot			0.1*			0.1*
Others			0.1*			0.1*
Bulb vegetables	0.1*			0.1*	0.05*	
Onions			0.1*			0.1*
Others			0.1*			0.1*
Fruiting vegetables			0.1*	0.1*	0.05*	0.1*
Solanacea	0.1*					
Cucurbits-edible peel	0.1*					
Cururbits-inedible peel	0.1*					
Sweet corn	0.1*					
Brassica vegetables			0.1*	0.1*	0.05*	0.1*
Cauliflower	0.1*					
Head cabbage	0.1*					
Leafy brassica	0.1*					
Kohlrabi	0.1*					
Leaf vegetables and fresh herbs			0.1*	0.1*	0.05*	0.1*
Lettuce and similar	0.1*					
Water cress	0.1*					
Spinach and similar	0.1*					
Chicory	0.1*					
Fresh herbs	0.1*					
Legume Vegetables (fresh)	0.1*		0.1*	0.1*	0.05*	0.1*
Stem vegetable	0.1*			0.1*	0.05*	
Asparagus			open			open
Others			0.1*			0.1*
Fungi						
Mushrooms (other than wild)	0.1*		0.1*	0.1*	0.05*	0.1*
Wild mushrooms	50		50	50	20	50

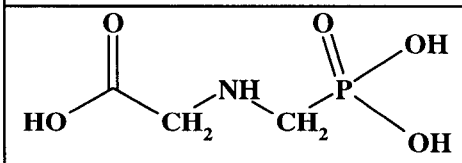
Commodity	Existing MRL [mg/kg] in EU or MS (indicated)		MRL proposal [mg/kg]			
	Glyphosate	TMS	Glyphosate	Glyphosate-Trimesium PMG	TMS	Resulting Glyphosate
Pulses						
Beans	open		1			1
Lentils	0.1*					0.1*
Peas	open		5	1	1	5
Others	0.1*		0.1*	0.1*	0.05*	0.1*
Oil seeds						
Linseed	10		10			10
Rape seed	10		10	5	5	10
Rape seed (glyphosate tolerant)			10			10
Soya beans	20		20			20
Soya beans (glyphosate tolerant)			20			20
Cotton seed (glyphosate tolerant)			5			5
Mustard seed	open		10			10
Others	0.1*		0.1*	0.1*	0.05*	0.1*
Potatoes	0.1*		0.5	0.1*	0.05*	0.5
Tea (black tea processed from the leaves of Camellia sinensis)	0.1*		1	0.1*	0.1*	1
Hops	0.1*		0.1*	0.1*	0.1*	0.1*
Cereals						
Wheat	5	5 DE	5	5	5	5
Wheat products (excl. raw bran)		5 DE				
Rye	5		10	5	5	10
Barley	20		20	20	10	20
Oat	20		20	20	10	20
Triticale	5		5	5	5	5
Bran (raw)	20 DE					
Bran (raw, of wheat)		10 DE				
Cereals products (except raw bran)	5 DE					
Maize			1			1
Maize (glyphosate tolerant)			0.2			0.2
Others	0.1* DE	0.1 DE	0.1*	0.1*	0.05*	0.1*
Other food of plant origin	0.1* DE	0.1 DE		0.1*	0.05*	0.1*
Sugar beets	0.2 DE		0.2	0.1*	0.05*	0.2
Sugar beets (glyphosate tolerant)			1			1
Foodstuffs of animal origin			0.1*			
Milks	0.1*	0.2 DE		0.1*	0.1	0.1*
Milk products	0.1*	0.2 DE				0.1*
Eggs	0.1*					0.1*
Eggs (without shell)	0.1*					0.1*
Egg yolk	0.1*					0.1*
Meat	0.1*					0.1*
Meat of cattle, goat, sheep, pig				0.1*	0.1	0.1*
Meat, except kidney of cattle, sheep, goat, liver of cattle, sheep, goat and meat of poultry, meat products except meat pro-ducts of poultry		0.2 DE				
Meat products	0.1*					0.1*
Kidney of cattle	2	0.5 DE		0.1*	0.2	0.1*
Liver of cattle		0.5 DE		0.1*	0.1*	0.1*
Kidney of sheep	2	0.5 DE		0.1*	0.2	0.1*
Liver of sheep		0.5 DE		0.1*	0.1*	0.1*
Kidney of goat	2	0.5 DE		0.1*	0.2	0.1*
Liver of goat		0.5 DE		0.1*	0.1*	0.1*
Kidney of pig	0.5			0.1*	0.1*	0.1*
Liver of pig				0.1*	0.1*	0.1*
Fat of cattle, goat, sheep, pig	0.1*			0.1*	0.05*	0.1*
Liver of poultry				0.1*	0.1	0.1*
Others	0.1*	0.05 DE		0.1*	0.05*	0.1*

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Chapter 2.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	glyphosate
Function (*e.g.* fungicide)	herbicide
Rapporteur Member State	Germany

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	*N*-(phosphonomethyl)-glycin
Chemical name (CA)	glycin, *N*-(phosphonomethyl)-
CIPAC No	0284
CAS No	1071-83-6
EEC No (EINECS or ELINCS)	213-997-4
FAO Specification (including year of publication)	AGP:CP/301/311 (1992/1994)
Minimum purity of the active substance as manufactured (g/kg)	950 ± 20
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	*N*-methylglyphosate: max. 28 g/kg aminomethyl-phosphonic acid: max. 17 g/kg hydroxymethyl-phosphonic acid: max. 12 g/kg phosphonomethylimino-di-acetic acid: max. 10 g/kg
Molecular formula	$C_3H_8NO_5P$
Molecular mass	169
Structural formula	

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	189.5 °C (999 g/kg)
Boiling point (state purity)	decomposition
Temperature of decomposition	> 200°C (199-231), purity not stated
Appearance (state purity)	colourless crystalls
Relative density (state purity)	1.705 (995 g/kg)
Surface tension	73.0 mN × m^{-1}
Vapour pressure (in Pa, state temperature)	$1.31 \bullet 10^{-5}$ Pa/25°C (acid)
Henry's law constant (Pa m^3 mol^{-1})	$2.1 \bullet 10^{-7}$
Solubility in water (g/l or mg/l, state temperature)	pH 2: 10.5 ± 0.2 g/l (20°C, 995 g/kg)
	pH_____:
	pH_____:
Solubility in organic solvents (in g/l or mg/l, state temperature)	acetone: 0.078 g/l dichloromethane: 0.233 g/l ethyl acetate: 0.012 g/l hexane: 0.026 g/l methanol: 0.231 g/l n-octanol: 0.020 g/l
	propan-2-ol: 0.020 g/l
	toluene: 0.036 g/l
Partition co-efficient (log P_{OW}) (state pH and temperature)	pH 5 – 9: - 3.2 at 25°C (999 g/kg)
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH__5____: stable (25°C)
	pH__7____: stable (25°C)
	pH__9____: stable (25°C)
Dissociation constant	pK_a: 2.34(20°C), 5.73(20°C), 10.2(25°C)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	ε: 0.086 (295nm)
Photostability (DT_{50}) (aqueous, sunlight, state pH)	33d (pH5), 69d(pH 7), 77d (pH9) (Xenon lamp).
Quantum yield of direct phototransformation in water at Σ > 290 nm	not determined
Flammability	not highly flammable
Explosive properties	not explosive

Listing of End Points

Summary of intended uses
* Maximum uses for certain application techniques (i.e. wet rope) are not possible to calculate.

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
CITRUS FRUIT Citrus	Annual weeds, Perennial weeds, shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	Weeds actively growing. Before, during or immediately after blooming of the crop	1 - 5	-	200-400/ulv	0.72-4.32	Southern Europe	4.32
POME- AND STONE FRUIT Orchards	Couch-grass, Annual weeds, Perennial weeds, Root suckers	F	SL SG	spraying	14 days before harvest, after harvest, weed height >20cm, trees > 2 years old	1	-	100-400	0.72-4.32	Northern Europe	4.32
	Couch-grass, Annual weeds, Perennial weeds	F	SL SG	spot treatment	trees > 2 years old	1	-	-	2% or 2.94 g/l	Netherlands Luxemburg Belgium	
	Couch-grass	F	SL SG	spraying	-	1	-	-	1.08	France	1.08
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	actively growing, well developed weeds. Before, during or immediately after blooming. Trees > 2 years old.	1-3	-	80-400/ulv	0.72-4.32	Southern Europe	4.32
	Forestry orchards, non crop and aquatic areas	F	SL SG	spot treatment	actively growing, well developed weeds	1	-	-	33% dilution	United Kingdom, Ireland	

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
BERRIES AND SMALL FRUIT											
Grapes	Annual weeds, Perennial weeds	F	SL SG	spraying	vine > 4 years old	1	-	100-400	1.44-3.6	Luxemburg	3.6
	Annual weeds, Perennial weeds	F	SL	spraying	vine > 4 years old	1	-	100-400	1.08-4.32	Austria	4.32
	Annual weeds, Perennial weeds	F	SL	spraying	vine > 4 years old	2 (splitting)	-	100-400	1.80+1.80	Germany Luxemburg	3.60
	Annual weeds, Perennial weeds	F	SG	spraying	vine > 4 years old	2 (splitting)	-	100-400	1.68+1.68	Germany	3.36
	Annual weeds, Perennial weeds, Convulvulus	F	SL SG	spraying	vine > 4 years old	1	-	100-400	3.60	Germany	3.60
	Annual weeds, Perennial weeds, Convulvulus	F	SL SG	spraying	vine > 4 years old	1	-	100-400	3.36	Germany	3.36
	Annual weeds, Perennial weeds	F	SL	spraying	well developed weeds	-	-	200-300	1.08-4.32	France	4.32
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying;+ other (wet rope, drop boom, etc)*	Actively growing, well developed weeds. Before, during or immediately after blooming of the crops. Vine > 2 years old.	1-3	-	80-400	0.72-4.32	Southern Europe	4.32
Avocado	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-3	-	5-400	0.72-2.16	Spain	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Cherimoya	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-3	-	5-400	0.72-2.16	Spain	4.32
Fig	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-2	-	5-400	0.72-2.16	Spain	4.32
Pomegranate	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-3	-	5-400	0.72-2.16	Spain	4.32
Medlar	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-3	-	5-400	0.72-2.16	Spain	4.32
MISCELLA-NEOUS FRUIT											
Olives	a) Developed weeds b) Perennial weeds c) Growing weeds	F	SL SG	a) spray b) spot c) spray	Trees > 2 years old a) prebloom, postharvest b) immature fruit stage c) preharvest	a) 1 b) 1 c) 1	-	80-600	a) 2.16 b) 4.32 c) 0.54-1.08	Southern Europe	4.32
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	Weeds actively growing. Before, during or immediately after blooming of the crop	1-3	-	200-400/ulv	4.32 max.	Italy	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Walnuts	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	any	-	-	200-400/ulv	4.32	Italy	4.32
Hazelnuts	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-3	-	5-400	0.72-2.16	Spain	4.32
Almonds	Annual weeds, Perennial weeds	F	SL SG	spraying (directed) + wiping (directed)	post-emergence of weeds, pre-harvest of crop	1-2	-	5-400	0.72-2.16	Spain	4.32
ROOT AND TUBER VEGETABLES											
Beet root	Annual weeds, Wild potato shoots	F	SL	spraying	pre-emergence	1	-	80-250	1.08	Netherlands	1.08
Carrots	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
Witloof (chicory)	Annual weeds, Perennial weeds, Couch-grass	F	SL SG		pre-emergence	-	-	-400	1.44	Netherlands	1.44
BULB VEGETABLES											
Onions	Annual weeds, Wild potato shoots	F	SL SG	spraying	2-4 days before emergence	1	-	80-400	0.7-2.1	Northern Europe	2.1

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
STEM VEGETABLES											
Asparagus	Annual weeds, Perennial weeds, Couch-grass	F	SL SG	spraying	pre-emergence	1	-	80-400	2.16	Netherlands	2.16
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	pre-emergence according to weed stage, post-harvest	1-3	-	200-400/ulv	1.44-4.32	Italy	4.32
Artichoke	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
FIELD VEGETABLES											
	Annual weeds, Perennial weeds	F	SL	wiping	>10cm height difference	2	-	-	35-50%	Austria	
Tomatoes, eggplants	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
PULSES											
Pulses	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying and wiping	pre-emergence	1	-	80-400	0.54	Northern Europe	0.54
Beans	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	when ¾ of the pods has changed to black minimum 7 days before harvest (seeds > 30% humidity), full ripening	1	-	80-400	0.7-2.16	Northern Europe	2.16

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Broadbeans	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
	Orobanche spp.	F	SL	broadcast spraying	post-emergence of the crop	1-2	-	100-400	0.54-1.08	Spain	1.08
Frenchbeans	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
Soybeans	Annual weeds, Perennial weeds	F	SL SG	spraying + other (wet rope, drop boom, etc*) wiping	pre-plant, post-harvest	1-3	-	200-400/ulv	-	Italy	4.32
Peas	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	when 70-75% of the field has changed to yellow-brown colour min. 7 days before harvest (seeds > 30% humidity), full ripening	1	-	80-400	0.7-2.16	Northern Europe	2.16
	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
OIL SEEDS **Rape seed**	Annual weeds, Perennial weeds	F	SL SG	spraying	<30% moisture content in the seed, 2-3 weeks before harvest	1	-	100-250	1.44-1.47	Northern Europe	2.01

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Rape seed		F	SL SG	spraying	pre-emergence	1	-	-	0.54	United Kingdom, Ireland Northern + Southern Europe	2.01
	Harvest management	F	SL SG	spraying	<30% moisture content in the seed, 2-3 weeks before harvest	1	-	-	1.08-1.47	Sweden, United Kingdom, Ireland	2.01
Linseed	Annual weeds, Perennial weeds	F	SL SG	spraying	<30% moisture content in the seed, 2-3 weeks before harvest	1	-	80-250	1.44	United Kingdom, Ireland	1.44
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence	1	-	80-250	0.54	Northern Europe	1.98
	Harvest management	F	SL SG	spraying	-	1	-	-	0.36-0.54	United Kingdom, Ireland	1.08
Mustard seed	Annual weeds, Perennial weeds	F	SL SG	spraying	<30% moisture content in the seed, 8-10 days before harvest	1	-	80-250	1.44	United Kingdom, Ireland	1.44
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence	1	-	80-250	0.54	Northern Europe	1.98
	Harvest management	F	SL SG	spraying	-	1	-	-	1.08	United Kingdom, Ireland	1.08

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
POTATOES											
Potatoes	Annual weeds, Perennial weeds, Couch-grass, Wild potato shoots	F	SL EC GR SG	spraying	pre-drilling, pre-emergence	1	-	50-400	0.54-2.18	Netherlands Sweden	2.1
	Annual weeds, Perennial weeds	F	SL	wiping	>10cm height difference	2	-	-	35-50%	Austria	
	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
	Harvest management (pre-harvest)	F	SL	spraying	1 week before harvest, treatment only if potato tops destroyed or died naturally	1	-	80-250	1.44	Netherlands	1.44
CEREALS											
Cereals	Annual weeds, Perennial weeds, Couch-grass	F	SL SG	spraying	full ripening stage (BBCH stage 89), when moisture content of youngest crop grain is < 30%	1	-	40-400	0.7-2.16	Northern Europe	2.16
	Annual weeds, Perennial weeds	F	SL SG	spraying	before drilling	-	-	-	1.08-4.32	France	4.32
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence	1	-	40-250	0.54	United Kingdom, Ireland, Italy, Spain	2.70
	Annual weeds, Perennial weeds	F	SL SG	spraying; other (wet rope, drop boom, etc)*	pre-plant, post-harvest	1-3	-	200-400/ulv		Italy Greece	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Winter wheat and barley	Harvest management (pre-harvest)	F	SL	spraying	1 week before harvest and moisture content of grain is < 25%	1	-	-	2.16	France	2.16
Maize	Annual weeds, Perennial weeds	F	SL	spraying interrow equipment	till growth stage 36	1 or 2 (splitting)	-	100-300 100-300	1.80 or 0.90+0.90	Germany	1.80
	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence till 2 days before seeding	1	-	100-300	1.08	Germany	1.08
	Annual weeds, Perennial weeds	F	SL SG	spraying interrow equipment + wiping	any stage	1-3	-	200-400/ulv	-	Italy Greece	4.32
Rice	Annual weeds, Perennial weeds	F	SL SG	spraying; other (wet rope, drop boom, etc)*	pre-plant + post-harvest	multiple	-	200-400/ulv	-	Italy	4.32
OTHER FOODSTUFF											
Sugar and fodder beet	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	pre-emergence	1	-	100-400	0.7-2.1	Netherlands	2.1
Sugar beet	Annual weeds, Perennial weeds	F	SL SG	spraying; other (wet rope, drop boom, etc)*	pre-plant and post-harvest	1-3	-	200-400/ulv	-	Italy Greece	4.32
	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Sugar beet	Annual weeds, Perennial weeds	F	SL SG	spraying	pre-emergence till 2 days before seeding	1	-	100-300	1.08	Germany United Kingdom	1.08
localized	Thistle, wild beets	F	SL SG	wiping	sufficient height differences between weeds	2	-	-	33-50% concen-tration	Germany United Kingdom	
OTHER THAN FOODSTUFF											
Tobacco	Orobanche ramosa	F	SL SG	spraying	40 days after transplanting	1st	0.036	400	0.144	Greece	0.36
					60 days after transplanting	2nd	0.054	400	0.216		
OTHER SITUATIONS OF APPLICATION											
Annual spring crops (cotton, maize, tobacco)	Annual weeds, Perennial weeds	F	SL SG	spraying	interrow (hooded) application	1	-	80-300	1.80	Greece	1.80
Stubbles	Couch-grass, Annual weeds, Perennial weeds	F	SL SG	spraying	after harvest, autumn, 5-10 days before cultivation or drilling	1	-	80-400	0.54-2.94	Northern Europe	2.94
	Couch-grass	F	SL	spraying	developed weeds	1	-	200-400	2.16	France	2.16
	Couch-grass, Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying	developed weeds	1	-	80-300	1.44-4.32	Italy Greece	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Stubbles	Couch-grass, Annual weeds, Perennial weeds	F	SL SG	spraying	spring, before seeding of all crops			up to 400	-	Belgium Netherlands Luxemburg Greece	2.94
Stubbles of strawberries, vegetables, sugar beet, cereals, maize, rice, soybean, meadow, nurseries	Annual weeds, Perennial weeds	F	SL SG	spraying + other (wet rope, drop boom, etc)*	post-harvest	1-3	-	200-400/ulv	-	Italy Greece	4.32
PRE-PLANT of strawberries, vegetables, sugar beet, cereals, maize, rice, soybean, meadow, nurseries	Annual weeds, Perennial weeds	F	SL SG	spraying + other (wet rope, drop boom, etc)*	pre-drilling	multiple	-	200-400/ulv	-	Southern Europe	4.32
Pasture, meadows, grassland	Annual weeds, Perennial weeds, Couch-grass	F	SL SG	spraying	well developed weeds, application till to 5 days before use	1	-	100-400	1.08-3.60	Northern Europe	3.60
	Annual weeds, Perennial weeds	F	SL SG	weed-wiper	weeds taller than grassland	1-multiple (spot applica-tion)	-	-	33-50%	Austria Germany United Kingdom	
	Annual weeds, Perennial weeds	F	SL	spraying	well developed weed stage	1-multiple (spot applica-tion)	-	-	1-2%	Austria	

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Pasture, meadows, grassland	Renovation	F	SL SG	spraying	application before seeding, late summer	1	-	200-400	0.7-2.52	Germany Luxemburg Netherlands Belgium	2.52
	Short rotation ryegrass with Annual weeds	F	SL SG	spraying	between Jun.-Oct., before grazing or cutting, regrowth after grazing or cutting	1	-	150-250	1.08	United Kingdom, Ireland	
	Leys 2-4 years old with Perennial weeds	F	SL SG	spraying	between Jun.-Oct., before grazing or cutting, regrowth after grazing or cutting	1	-	150-250	1.44	United Kingdom, Ireland	
	Long leys 4-7 years old with Perennial broadleaved weeds	F	SL SG	spraying	between Jun.-Oct., before grazing or cutting, regrowth after grazing or cutting	1	-	150-250	1.80	United Kingdom, Ireland	
	Permanent pasture	F	SL SG	spraying	between Jun.-Oct., before grazing or cutting, regrowth after grazing or cutting	1	-	150-250	2.16	United Kingdom, Ireland	
	Annual weeds, Perennial weeds, shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	pre-plant and post-harvest	1-3	-	200-400/ulv	-	Italy	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Pasture, meadows, grassland	Grassland destruction, Perennial weeds	F	SL	spraying	min. 3-6 active leaves, min. 10 days before grazing or cutting	1	-	100-200	1.44	Denmark	1.44
Flower bulbs	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	middle of Aug. to middle of Sept., emerged weeds, spring : pre-emergence	1	-	200-400	1.44-2.16	Netherlands	2.16
	Annual weeds, Perennial weeds	F	SL	spot use	middle of Aug. to middle of Sept., emerged weeds	-	-	-	2% conc.	Netherlands	
	Annual weeds, Perennial weeds, shrubs	F	SL	spraying; other (wet rope, drop boom, etc)*	pre-emergence according to weed stage and post-harvest	1-3	-	200-400/ulv	-	Italy	4.32
Roses	Annual weeds, Perennial weeds	F	SL	wiping	-	-	-	-	-	Italy	4.32
Christmas trees	Annual weeds, Perennial weeds	F	SL SG	spraying	trees > 2 years, after mellowing	1	-	80-300	2.16	Belgium, Luxemburg, Netherlands	2.16
	Annual weeds, Perennial weeds	F	SL	spraying	over the top application	1	-	400-600	1.08-1.26	Denmark	1.26
	Annual weeds, Perennial weeds	F	SG	spraying	over the top application	1	-	400-600	1.05-1.26	Denmark	1.26
Forestry	Annual weeds, Perennial weeds, heather	F	SL SG	spraying	pre-planting, post-planting	1	-	80-400	1.08-3.60	Northern Europe	3.60

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Forestry	Tree stumps (chemical thinning)	F	SL SG	injecting	outside active sap flow, in spring/ early summer	-	-	-	0.72g per 10cm diameter of stem	United Kingdom, Ireland	
	Tree stumps (chemical thinning)	F	SL SG	spraying	application to saturate freshly cut stump	-	-	-	20% solution	United Kingdom, Ireland Netherlands	
	Tree stumps (chemical thinning)	F	SL SG	wiping, spraying	application to saturate freshly cut stump	-	-	-	5% solution	Netherlands Belgium	
Afforestation sites	Annual weeds, Perennial weeds	F	SL SG	spraying	weed height min. 15 cm, May-June	-	-	200-400	1.08-1.80	Germany, Austria	
Conifer sites	Annual weeds, Perennial weeds	F	SL	spraying	after finish of shoot elongation, Aug.-Oct.	-	-	200-400	1.08-1.80	Germany, Austria	
	Annual weeds, Perennial weeds	F	SG SL	spraying	after finish of shoot elongation, Aug.-Oct.	-	-	200-400	1.05	Germany, Austria United Kingdom	
Old forest sites	Annual weeds, Perennial weeds	F	SL	spraying	Aug-Sept	-	-	200-400	1.80	Germany, Austria	
	Annual weeds, Perennial weeds	F	SG	spraying	Aug-Sept	-	-	200-400	1.68	Germany, Austria	
Forestry	Annual weeds, Perennial weeds, shrubs	F	SL	spraying; other (wet rope, drop boom, etc)*	Weeds actively growing, well developed. Before, during or immediately after blooming of the crops	1-3	-	80-400/ulv	-	Southern Europe	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Forestry	Annual weeds, Perennial weeds, shrubs, Prunus serotina (max. 1.5m high)	F	SL SG	spraying	actively growing, at or near flowering	1	-	-	2%	Netherlands	2%
Home and garden sites	Annual weeds, Perennial weeds Couch-grass	F	SL	spraying	-	-	-	100-400	1.08-4.32	All EU countries	4.32
	Annual weeds, Perennial weeds Couch-grass	F	SG	localised spraying	-	-	-	200	1.47-3.36	Germany	3.36
	Annual weeds, Perennial weeds Couch-grass	F	AL	localised spraying	-	-	-	100-400	1.08-4.32	all EU countries	4.32
	Annual weeds, Perennial weeds Couch-grass	F	TB	localised spraying	-	-	-	100-400	1.08-4.32	United Kingdom France Germany	4.32
	Annual weeds, Perennial weeds shrubs	F	ready to use	localised spraying	emerged weeds	1-3	0.97	-	2.5-4.32	Italy	4.32
	Annual weeds, Perennial weeds shrubs	F	SL	spraying; other (wet rope, drop boom, etc)*	Weeds actively growing, well developed. Before, during or immediately after blooming of the crop	1-3	-	200-1000/ulv	-	Italy	4.32
	Annual weeds, Perennial weeds	F	SL	spraying	well developed weeds	-	-	200-1000	1.08-4.32	France	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Home and garden sites	Annual weeds, Perennial weeds	F	SG	spraying	-	2-3 (splitting)	-	100-600	-	Spain	4.32
Set-aside (temporarily removed from production)	Annual weeds, Perennial weeds, Couch-grass	F	SL SG	spraying	1 day before cultivation, at or near flowering	1-3	-	50-400	0.72-2.88	Northern + Southern Europe	2.88
	Annual weeds, Perennial weeds, Couch-grass	F	SL SG	spraying	add during vegetation period	1	-	50-400	0.72-2.88	Germany	2.88
Roads and walkways	Annual weeds, Perennial weeds	F	SL	spraying	March-April with soil herbicide	1	-	-	2.16	Netherlands	2.16
	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	March-April with soil herbicide	1	-	-	2.94	Belgium	2.94
	Annual weeds, Perennial weeds Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	Weeds actively growing, well developed. Before, during or immediately after blooming of the crop	1-3	-	200-1000/ulv	-	Italy Greece	4.32
	Annual weeds, Perennial weeds	F	SL SG	spraying	well developed weeds	-	-	80-300	1.44-4.32	France United Kingdom	4.32
	Annual weeds, Perennial weeds	F	SL	spraying	well developed weeds	1	-	-	3-33%	Germany	
Railways	Annual weeds, Perennial weeds	F	SL SG	spraying	spring or early summer (well developed weeds)	1-2 (splitting)	-	500-1000	3.60 or 1.80+1.80	Germany United Kingdom	3.60
	Annual weeds, Perennial weeds	F	SL SG	spraying	well developed weeds	-	-	-	3.24-4.32	France	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Railways	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	weeds actively growing	1-3	-	200-1000/ulv	-	Italy Greece	4.32
Irrigation and drainage channels + special aquatic situations	Aquatic weeds	F	SL SG	spraying	when weeds are actively growing	1	-	100-300	1.44-2.94	Northern Europe	2.94
	Emergent weeds Floating weeds	F	SL SG	spraying	when weeds are actively growing	1 1	- -	200-400 100-200	1.80 2.16	United Kingdom, Ireland, France	
	Aquatic weeds	F	SL	spraying	well developed weeds	1	-	-	2.16-3.60	Southern Europe	3.60
Drains	Annual weeds, Perennial weeds Couch-grass	F	SL SG	spraying	only if drain is dry	1	-	-	2.16	Netherlands	2.16
	Annual weeds, Perennial weeds, shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	Weeds actively growing, well developed. Before, during or immedi-ately after blooming of the crop	1-3	-	200-1000/ulv	-	Italy	4.32
Other non-crop land (industrial sites, urban areas, cemeteries, etc)	Annual weeds, Perennial weeds	F	SL SG	spraying	well developed weeds	-	-	100-400	0.7-4.32	Northern Europe	4.42

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Other non-crop land (industrial sites, urban areas, cemeteries, etc)	Annual weeds, Perennial weeds, shrubs	F	SL SG	spraying	according to weed stage	1-2	-	80-400	0.72-4.32	Southern Europe	4.32
	Annual weeds, Perennial weeds, Shrubs	F	SL SG	spraying; other (wet rope, drop boom, etc)*	Weeds actively growing, well developed. Before, during or immedi-ately after blooming of the crop	1-3	-	200-1000/ulv	-	Italy	4.32
Spot use in public green / all crops localised treatment	Annual weeds, Perennial weeds, Couch-grass	F	SG SL	spraying				-	2%	Netherlands Belgium	
All arable land	killing erosion protection crops (grass, rye, barley,...); killing green manure	F	SL SG	spraying	1 week before soil turning			200-400	0.7-2.1	Netherlands	2.1
All arable crops and grassland and industrial sites and vegetables	Annual weeds, Perennial weeds, Couch-grass	F	SL	wiping	for as long as there is min. 10cm distance between protected crop and weed to be killed			-	up to 33% up to 50%	Netherlands Belgium Italy	
All arable crops and grassland and industrial sites	Annual weeds, Perennial weeds, Couch-grass	F	SG	wiping	for as long as there is min. 10cm distance between protected crop and weed to be killed			-	30-45%	Belgium Luxemburg	

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
All arable crops, grassland, industrial sites and nurseries	Annual weeds, Perennial weeds	F	SL	wiping	for as long as there is min. 10cm distance between protected crop and weed to be killed	max. 2		-	33-50%	Austria	
NURSERIES	Annual and Perennial weeds	F	SL	spraying	well developed weeds	1	-	-	3%	Germany	
	Annual and Perennial weeds	F	SG	spraying	well developed weeds	1	-	-	2.14	Germany	
Flower, poplar, shrubs, ornamentals, forestals	Annual weeds, Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32
FORAGE CROPS											
Alfalfa	Annual and Perennial weeds	F	SL	wiping		-	-	-	-	Italy	4.32

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
GLYPHOSATE TOLERANT CROPS											
Winter oilseed rape	Annual weeds, Perennial weeds	F	SL SG	high volume spraying, broadcast application	4-12 leaves in fall (BBCH14-19)	2	-	200-300	0.72	Northern and Southern Europe	1.44
					stem elongation (BBCH30-31) in fall and spring	2	-	200-300	1.08	Northern and Southern Europe	2.16
Spring oilseed rape	Annual weeds, Perennial weeds	F	SL SG	high volume spraying, broadcast application	BBCH14-16	1	-	200-300	0.72	Northern and Southern Europe	0.72
Maize	Annual weeds, Perennial weeds	F	SL SG	high volume spraying, broadcast application	6-8 leaves (BBCH16-18)	2	-	200-300	1.08	Northern Europe	2.16
	1) Annual weeds	F	SL	high volume spraying, broadcast application	4-8 leaves (BBCH14-18)	1) 1	-	200-300	1) 1.08	Southern Europe	3.24
	2) Perennial weeds					2) 1 or 2	-		2) 1.44 0.72		
Soybean	Annual weeds, Perennial weeds	F	SL SG	high volume spraying, broadcast application	1-12 leaves (BBCH11-19)	2	-	200-400	0.72 -1.08	Northern and Southern Europe	1.44

Crop and/or situation	Pests or Group of pests	F or G	Type of Form.	Application			Application rate per treatment			Country	Appl. max/season kg as/ha
				method kind	growth stage	number (max.)	kg as/hl	water l/ha	kg as/ha		
Sugar beet and fodder beet	Annual and Perennial weeds	F	SL SG	high volume spraying, broadcast application	cotyledon-18 leaves (BBCH10-19)	2	-	200-300	1.08	Northern and Southern Europe	2.16
						3	-		0.72		2.16
Sugar beet	Annual and Perennial weeds	F	SL	high volume spraying, broadcast application	cotyledon-18 leaves (BBCH10-19)	2	-	200-300	1.08	Southern Europe	2.16
						3	-		0.72		2.16
Cotton	Annual grass weeds and broadleaf weeds	F	SL	high volume spraying, broadcast application	Before 4 leaf stage	1 or 2	-	200-400	1.08 or 0.72	Southern Europe	1.08 1.44
	Annual weeds, Perennial weeds	F	SL	high volume spraying, directed application	8-10 leaf stage	1	-	200-400	1.80	Southern Europe	1.80
	Annual or Perennial weeds	F	SL	high volume spraying, broadcast application	after 50% of cotton bolls are open	1	-	200-400	1.80	Southern Europe	1.80

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	none
with regard to toxicological data	R 41 (Risk of serious damage to eyes)
with regard to fate and behaviour data	
with regard to ecotoxicological data	R 52/53

Chapter 2.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	AOAC-CIPAC method: HPLC with anion exchange column, UV detection at 195 nm, or amino phase column, UV detection at 210 nm.
Impurities in technical as (principle of method)	Most of them HPLC with RP18, anion exchange or Dionex columns. Detection UV, fluorescence, conductivity. LC-Ms and GLC.
Plant protection product (principle of method)	AOAC-CIPAC method: As for technical as.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	**Glyphosate:** HPLC-Fluorescent-detector (FluD), 0.03-2 mg/kg, diverse crops. GC-ECD, -FPD, -MS 0.01-0.1 mg/kg, various crops **AMPA**: HPLC-FluD: *ditto* GC-ECD, -MS: *ditto*
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	**Glyphosate**: HPLC-FluD, 0.025-0.05 mg/kg, eggs, milk, fat, muscle, liver, kidney GC-MS, 0.02 mg/kg, eggs, milk, pork **AMPA**: HPLC-FluD: *ditto*; GC-MS: *ditto*
Soil (principle of method and LOQ)	**Glyphosate**: HPLC-FluD, 0.02 mg/kg GC-MS, 0.02 mg/kg, eggs, milk, pork **AMPA**: HPLC-FluD: *ditto*
Water (principle of method and LOQ)	**Glyphosate**: HPLC-FluD, 0.05 µg/l, drinking water GC-ECD, 0.05 µg/l, drinking water **AMPA**: HPLC-FluD: *ditto*; GC-ECD: *ditto*
Air (principle of method and LOQ)	**Glyphosate**: HPLC-FluD, 8 µg/m³ GC-ECD, 7 µg/m³ **AMPA**: HPLC-FluD: *ditto*
Body fluids and tissues (principle of method and LOQ)	

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Chapter 2.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption:	Rapidly but only to a limited extent (approx. 30%)
Distribution:	Generally low residues occurring in all tissues
Potential for accumulation:	No evidence of accumulation (< 1% after 7 days)
Rate and extent of excretion:	Rapid and nearly complete (approx. 30% via urine)
Metabolism in animals	Very limited (< 0.5%) if occurring at all
Toxicologically significant compounds (animals, plants and environment)	Parent compound; main plant metabolite, aminomethyl-phosphonic acid (AMPA), also detected in rats (< 0.5%)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 2000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 5 mg/l air (4-hour exposure)
Skin irritation	Not irritating
Eye irritation	Acid: moderately to severely irritating, **R 41;** Salts: slightly or not irritating, no classification
Skin sensitization (test method used and result)	Not sensitizing (M&K test, Buehler test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Liver, gastrointestinal mucosa, salivary glands
Lowest relevant oral NOAEL / NOEL	90 days, rat: 2000 ppm (equal to 150 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL	21 days, rat: >1000 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL	2 weeks, rat: >3.8 mg/l

Genotoxicity (Annex IIA, point 5.4)	Not genotoxic

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	Liver (organ weight↑, clinicial chemistry, histology); salivary glands (organ weight↑, histology); stomach mucosa and bladder epithelium (histology); eye (cataracts)
Lowest relevant NOAEL / NOEL	2 years, rat: 31 mg/kg bw/d
Carcinogenicity	No evidence of carcinogenicity

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Reduced pup weight at parentally toxic doses
Lowest relevant reproductive NOAEL / NOEL	10000 ppm (equal to 700 mg/kg bw/d)
Developmental target / critical effect	Lower number of viable fetuses and reduced fetal weight; retarded ossification, higher incidence of skeletal and/or visceral anomalies; effects confined to maternally toxic doses
Lowest relevant developmental NOAEL / NOEL	Rat: 300 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

No relevant effects

Other toxicological studies (Annex IIA, point 5.8)

Toxicological studies on AMPA revealing the metabolite to be less toxic than the parent compound, no evidence of mutagenicity and teratogenicity; toxicity studies in farm animals: no risk to be expected; mechanistic study on salivary gland findings

Medical data (Annex IIA, point 5.9)

Comprehensive database, mainly related to accidental or intentional oral intake of glyphosate products

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.3 mg/kg bw	Long-term studies in rats	100
AOEL	0.2 mg/kg bw/day (systemic)	Rabbit teratogenicity study, NOEL for maternal toxicity (30% oral absorp-tion)	100
ARfD (acute reference dose)	Not allocated (not necessary)		

Dermal absorption (Annex IIIA, point 7.3)

Less than 3%

Acceptable exposure scenarios (including method of calculation)

Operator	Acceptable for proposed uses (German model)
Workers	Acceptable for proposed uses
Bystanders	Acceptable for proposed uses

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Chapter 2.4a: Residues in plants non-tolerant to Glyphosate

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	citrus mitis, walnut, almond, pecan trees, apple trees, grapes, carrots, cabbage, lettuce, peas, beans, potatoes, soya beans, beets, wheat, barley, oat, rice, sorghum, cotton, maize, sugar beets, sugar cane, coffee plants, pasture crops (fescue, alfalfa, clover, grass)
Rotational crops	carrots, lettuce, barley
Plant residue definition for monitoring	glyphosate
Plant residue definition for risk assessment	glyphosate
Conversion factor (monitoring to risk assessment)	---

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	lactating goats, laying hens
Animal residue definition for monitoring	glyphosate
Animal residue definition for risk assessment	glyphosate
Conversion factor (monitoring to risk assessment)	---
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	Only very low levels of glyphosate and AMPA are present in the soil and plant tissues of rotational crops. Residues in emergency replant and rotational crops will be less than those found in the primary crop.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	Storage stability studies of glyphosate and AMPA residues have been carried out on corn grain, soya bean forage, sorghum stover, clover, tomatoes and of AMPA additionally in alfalfa seed and potatoes. Endogenous and exogenous glyphosate and AMPA residues are stable in these crops for 2-5 years at frozen storage. Storage stability studies on tissues and fat of swine, dairy cow and laying hens indicate a slight decrease of residues which has a negligible effect on the results of the feeding studies.

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes/~~no~~	Poultry: yes/~~no~~	Pig: yes/~~no~~
Muscle	< 0.05	< 0.05	0.06
Liver	< 0.05 – 0.2	< 0.05 – 0.61	< 0.05 – 0.6
Kidney	0.24 – 3.0	0.32 – 7.63	0.36 – 7.63
Fat	< 0.05	0.07	< 0.05
Milk	< 0.025		
Eggs		0.026 – 0.03	

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Grapefruit	S	Glyphosate: 5 x <0.05 AMPA: 2 x <0.05	5 Residue trials were conducted in the US. The data are sufficient to evaluate the residue situation in Southern Europe. PHI: 1, 21 days	0.5	0.05
Lemons	S	Glyphosate: 8 x <0.05, 2 x <0.06, 2 x 0.08 AMPA: 6 x <0.05	4 Residue trials were conducted in the US. The data are sufficient to evaluate the residue situation in Southern Europe. PHI: 1, 7 and 21 days	0.5	0.05
Orange	S	Glyphosate: 17 x <0.05, 0.06, <0.07, 0.08, <0.1, <0.11, 0.11, 0.13, 0.17, 0.19, 0.46, 0.47 AMPA: 14 x <0.05	Residue trials were conducted in the US. The data are sufficient to evaluate the residue situation in Southern Europe. PHI: 1, 7, 21 days	0.5	0.05
Hazelnuts	S	Glyphosate: 4 x <0.05 AMPA: 4 x <0.05	application rates: 4.32 and 8.64 kg as/ha PHI: 67 and 90 days	0.1*	0.05
Apples	N	Glyphosate: 12 x <0.02, 32 x <0.05 AMPA: 32 x <0.05	application rates: 1.44 to 3.6 kg as/ha PHI: 0 to 354 days	0.1*	0.02
	S	Glyphosate: 16 x <0.03, 20 x <0.05 AMPA: 20 x <0.05	application rates: 3.38 to 9 kg as/ha PHI: 26 to 90 days	0.1*	0.03
Pears	S	Glyphosate: 4 x <0.05 AMPA: 4 x <0.05	application rates: 4.32 to 8.64 kg as/ha PHI: 32 to 84 days	0.1*	0.05
Raspberries (wild growing)	N	Glyphosate: 1.4, 2.2, 9, 15 AMPA: 2 x <0.05, 0.1, 2.1	application rates: 0.72 to 1.44 kg as/ha PHI: 7 to 18 days Residue data are not sufficient to evaluate the residue situation in berries.		
Grapes	N	Glyphosate: 12 x <0.01, 38 x <0.05, 0.2, 0.7 AMPA: 38 x <0.05	application rates: 0.72 to 3.72 kg as/ha PHI: 0 to 85 days	1.0	0.05
	S	Glyphosate: 24 x <0.05, 0.07, 0.1, 0.2, 2 x 0.3, 0.4 AMPA: 30 x <0.05	application rate: 0.72 kg as/ha PHI: 0 to 21 days	1.0	0.05

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (continued)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Olives	S	Glyphosate: 6 x <0.05, 0.08, 5 x 0.1, 0.2, 0.3, 4 x 0.4, 0.5, 0.8, 3 x 0.9, 2 x 1.1, 1.2, 1.8, 2, 4.3, 5.8, 5.9, 6, 6.4, 6.7, 9.2, 9.3, 9.8, 12, 2 x 13 (ground-lying olives); 45 x <0.05, 0.08 (olives from tree)	application rates: 0.36 to 4.32 kg as/ha PHI: 0 to 41 days All residue data for AMPA are below the LOD (0.05 mg/kg).	0.1* table olives	from tree: 0.05; ground-lying: 0.85
Salads	S	Glyphosate: 10 x <0.05, 4 x 0.05, 0.06 AMPA: 15 x <0.05	application rates: 1.44 to 8.64 kg as/ha PHI: 54 to 89 days	0.1*	0.05
Turnips	N	Glyphosate: 3 x <0.05 AMPA: 3 x 0.05	application rate: 2.16 kg as/ha PHI: 89 to 106 days	0.1*	0.05
Swedes	N	Glyphosate:4 x <0.05 AMPA: 4 x <0.05	application rates: 1.44 to 3.6 kg as/ha PHI: 199 to 229 days	0.1*	0.05
Kale	N	Glyphosate: 9 x <0.05 AMPA: 9 x <0.05	application rates: 1.44 to 3.6 kg as/ha PHI: 59 to 148 days	0.1*	0.05
Carrots	S	Glyphosate: 10 x <0.05, 0.07, 0.08 AMPA: 12 x <0.05	application rates: 1.44 to 8.64 kg as/ha PHI: 101 to 140 days	0.1*	0.05
Beetroots	N		No residue trials have been conducted in beetroot cultures; extrapolation from sugar beets is possible. These data are sufficient to evaluate the residue situation.	0.1*	
Onions	N	Glyphosate:13 x <0.05, 0.05 AMPA: 14 x <0.05	application rates: 1.44 to 8.64 kg as/ha PHI: 80 to 181 days	0.1*	0.05
Asparagus	N		No residue trials were conducted according to the critical GAP. Data are required.	open	
	S		No residue trials were conducted according to the critical GAP. Data are required.	open	

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (continued)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Wild Mushrooms	N	Glyphosate: <0.05, 0.25, 0.27, 0.5, 1, 1.39, 2.2, 3.1, 3.5, 3.7, 4.4, 5.2, 5.5, 6.41, 6.5, 9.27, 10.4, 18.5, 24.2, 28, 29.4, 34, 37.3, 56 AMPA: 9 x <0.05, 2 x 0.05, 0.06, 0.07, 0.08, 2 x 0.1, 0.25, 0.3, 0.34, 0.4, 0.44, 0.48, 0.5, 0.77	application rate: 1.8 kg as/ha PHI: 0 to 20 days Residue data for new growth are 0.1 or <0.1 mg/kg for Glyphosate and below the LOD (0.05 mg/kg) for AMPA. No trials according to GAP. MRL could be proposed based on the available data.	50	4.82
	S		No residue trials from Southern Europe. MRL could be proposed based on the available data. As GAP is not clearly defined further data might be required after defining the application conditions.	50	
Field Beans	N	Glyphosate: 4 x <0.05, 0.05, 4 x 0.1, 0.13, 0.14, 0.15, 0.16, 0.18, 4 x 0.2, 0.21, 0.23, 2 x 0.30, 0.33, 0.50, 0.53, 1.80 (seed, dry) AMPA: 16 x <0.05 (seed, dry)	application rates: 1.44 to 2.88 kg as/ha PHI: 7 to 10 days	1	0.17
Peas, dry	N	Glyphosate: 8 x <0.05, 5 x 0.05, 4 x 0.06, 0.07, 0.08, 7 x <0.1, 0.13, 0.14, 4 x 0.2, 0.23, 3 x 0.3, 2 x 0.4, 5 x 0.5, 0.65, 0.7, 2 x 0.8, 1.1, 1.2, 1.4, 1.5, 2 x 1.7, 2 x 1.8, 2.1, 2.3, 2.4, 2.5, 5.7, 6.9, 7.62, 8.0, 8.3 (seed) AMPA: 44 x <0.05, 0.11 (seed)	application rates: 0.72 to 2.88 kg as/ha PHI: 4 to 15 days	5	0.27
Linseed	N	Glyphosate: 1.27, 1.29, 2.23, 3.97, 4.6 AMPA: 4 x <0.05	application rates: 1.44 or 2.88 kg as/ha PHI: 5 to 7 days; The available residue data are insufficient. The MRL was proposed by extrapolation from rape seed.	10	2.23
	S		GAP is not residue relevant compared to the GAP in Northern Europe.	10	

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (continued)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Mustard Seed	N	Glyphosate: 0.2, 0.5, 2.6, 3.2	The available residue data are insufficient. The MRL was proposed by extrapolation from rape seed.	10	
Rape Seed	N	Glyphosate: 0.05, 0.1, 0.15, 2 x 0.2, 2 x 0.3, 0.35, 11 x 0.4, 0.43, 0.45, 5 x 0.5, 0.55, 11 x 0.6, 2 x 0.7, 0.73, 4 x 0.8, 0.88, 0.9, 0.95, 2 x 0.98, 1.0, 1.05, 1.08, 4 x 1.2, 4 x 1.3, 1.4, 3 x 1.5, 1.57, 1.6, 1.78, 3 x 1.8, 1.85, 2.0, 2.07, 2.4, 2.7, 2 x 2.8, 2.9, 3.1, 3.19, 3.2, 3.4, 2 x 3.5, 3.6, 3.7, 4.0, 2 x 4.4, 5.41, 5.73, 2 x 6.3, 6.53, 8.40, 10.0, 11.6 (seed) AMPA: 86 x <0.05, 0.05, 2 x 0.06, 0.08, 0.1, 0.13, 0.15 (seed)	application rates: 1.0 to 2.88 kg as/ha PHI: 7 to 17 days	10	0.98
	S		GAP is not residue relevant compared to the GAP in Northern Europe.	10	
Potatoes	N	Glyphosate: 11 x <0.05, 0.05, 0.07, 0.08, 0.09, 0.11, 0.12, 0.21, 0.59, 0.7 AMPA:14 x <0.05	application rates: 0.72 to 2.88 kg as/ha PHI: 6 to 7 days	0.5	0.05
Barley	N	Glyphosate: 0.09, 2 x 0.4, 2 x 0.6, 0.74, 0.9, 1.0, 1.16, 3 x 1.2, 1.3, 1.4, 1.5, 2 x 1.6, 2 x 1.7, 4 x 1.8, 2 x 1.9, 2.0, 2 x 2.1, 4 x 2.2, 2.28, 2.3, 2.37, 2.4, 2.5, 2 x 2.7, 2.8, 3 x 3.0, 3 x 3.2, 3.3, 3.5, 3 x 3.6, 3.7, 2 x 3.8, 4.0, 3 x 4.1, 2 x 4.2, 4.3, 3 x 4.4, 4.5, 3 x 4.6, 2 x 4.7, 3 x 4.8, 5.0, 5.1, 2 x 5.2, 5.3, 2 x 5.4, 5.8, 5.89, 2 x 5.9, 6.0, 2 x 6.2, 6.3, 3 x 6.4, 6.7, 6.8, 6.99, 3 x 7.0, 3 x 7.2, 2 x 7.3, 3 x 7.4, 3 x 7.6, 7.9, 2 x 8.0, 8.1, 8.5, 8.6, 8.9, 3 x 9.6, 10.83, 3 x 11.0, 11.8, 3 x 12.0, 12.6, 3 x 13.0, 13.2, 2 x 14.0, 2 x 18.0, 21.0 AMPA: <0.05 - 0.7	application rates: 1.8 to 2.2 kg as/ha PHI: 5 to 16 days Residues in straw: Glyphosate <0.05 – 255 mg/kg; AMPA <0.05 – 2.38 mg/kg. Further trials were conducted using lower or exaggerated application rates.	20	4.65

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (continued)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Oat	N	Glyphosate: 0.3, 2 x 1.2, 1.3, 2.1, 2.2, 2.4, 2.6, 2 x 3.2, 3.4, 2 x 3.6, 2 x 3.8, 4.3, 5.1, 5.3, 5.5, 5.7, 5.9, 6.4, 7.1, 7.4, 8.4, 8.5, 8.7, 10.4, 10.7, 13.8, 17.0, 17.1, 17.3, 18.2, 18.4, 21.4 AMPA: <0.05 - 0.33	application rates: 1.8 to 2.16 kg as/ha PHI: 5 to 15 days Residues in straw: glyphosate: 8.1 – 157 mg/kg; AMPA <0.05 – 1.07 mg/kg.	20	5.40
Rye	N	Glyphosate: 1.9, 2.3, 2 x 2.8, 2.86, 2.9, 3.0, 3.1, 3.5, 3.86, 4.05, 4.25, 4.6, 4.74, 5.3, 5.4, 5.44, 15.6, 16.7 AMPA: <0.05 – 0.35	application rates: 1.8 to 2.16 kg as/ha PHI: 7 to 15 days Residues in straw: Glyphosate 16.4 – 30.5 mg/kg; AMPA 0.361 - 0.563 mg/kg.	10	3.86
Wheat	N	Glyphosate: <0.05, 0.1, 0.15, 0.17, 5 x 0.2, 2 x 0.24, 4 x 0.3, 0.32, 6 x 0.4, 0.45, 0.46, 3 x 0.5, 0.51, 6 x 0.6, 0.61, 0.63, 0.67, 4 x 0.7, 2 x 0.75, 4 x 0.8, 0.83, 2 x 0.85, 4 x 0.9, 2 x 0.93, 1.0, 1.09, 1.1, 1.11, 1.12, 4 x 1.2, 2 x 1.3, 1.39, 1.4, 5 x 1.5, 1.57, 2 x 1.6, 4 x 1.7, 3 x 2.1, 2 x 2.2, 2.6, 2 x 3.9, 4.2, 4.6, 2 x 4.8, 6.69, 7.41, 8.81, 9.83, 11.4, 16.9 AMPA: <0.05 – 0.664	application rates: 1.6 to 2.2 kg as/ha PHI: 5 to 15 days Residues in straw: Glyphosate 3.3 – 140 mg/kg; AMPA <0.05 - 2.2 mg/kg. Further trials were conducted using lower or exaggerated application rates.	5	0.85
Maize	N	Glyphosate: <0.05, 0.05, 0.07, 0.08, 2 x 0.1, 0.18, 0.20, 0.27, 0.33, 0.5, 0.6 AMPA: <0.05	application rates: 2.16 to 4.32 kg as/ha PHI: 8 to 64 days Residues in straw: Glyphosate 0.4 – 3.3 mg/kg; AMPA <0.05 mg/kg.	1	0.14
	S	Glyphosate: 13 x <0.05, 0.05, 0.07, 9 x 0.1, 0.13, 6 x 0.2, 0.21, 0.27, 5 x 0.3, 0.8, 2 x 1.0, 1.6, 2.4, 2.6, 3.8 AMPA: <0.05 – 0.07	application rates: 2.16 to 4.32 kg as/ha PHI: 8 to 64 days Residues in straw: Glyphosate 0.87 – 15.5 mg/kg; AMPA <0.05 – 0.13 mg/kg.	1	0.10
Sugar Beets	N	Glyphosate: 23 x <0.05, 7 x 0.1, 0.5 AMPA: 31 x <0.05	application rates: 20 to 50 % (wiping)	0.2	0.05

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (continued)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Grass	N	Glyphosate: 1.0, 1.2, 2 x 1.4, 1.7, 4 x 1.8, 2.0, 2.4, 2 x 2.5, 2.9, 2 x 3.1, 2 x 3.2, 3.5, 3.6, 3.8, 3.9, 4.2, 4.3, 2 x 4.4, 4.6, 4.7, 5.5, 5.6, 6.2, 7.0, 7.1, 7.3, 7.4, 7.7, 8.1, 8.3, 8.8, 3 x 9.2, 9.6, 9.8, 10.6, 11.0, 13.0, 13.9, 14.3, 14.6, 14.9, 2 x 15.7, 17.3, 17.5, 3 x 19.6, 2 x 20.4, 20.9, 21.2, 23.9, 24.2, 27.2, 28.5, 29.0, 34.4, 36.8, 38.4, 39.8, 40.0, 44.0, 45.0, 46.4, 2 x 47.9, 48.3, 49.8, 51.0, 51.5, 59.5, 60.6, 67.3, 72.1, 2 x 75.0, 2 x 78.0, 84.1, 87.6, 88.1, 88.9, 90.4, 91.9, 93.7, 107.3, 110.9, 131.0, 2 x 134.0, 138.7, 142.8, 237.6, 252.3 AMPA: <0.05 – 1.2	Residues of glyphosate in hay: 0.1 – 166 mg/kg; residues of glyphosate in silage: 0.73 – 80.6 mg/kg.	-	16.5
	S		No residue trials carried out in Southern Europe	-	
Tea Leaves		Glyphosate: 4 x <0.08, 0.08, 2 x 0.1, 4 x 0.11, 0.15, 0.18, 0.2, 0.21, 0.23, 2 x 0.24, 0.25, 0.32, 0.35, 0.4, 2 x 0.43, 0.53, 0.56, 0.64, 0.75, 0.8, 0.82, 1.08, 1.09, 1.18, 1.25, 2.12, 2.36, 2.58, 2.8, 4.5, 5.71, 7.35, 11.51, 13.57, 17.04 AMPA: <0.08 (LOD) – 0.22	Trials were conducted in India (6), Taiwan (3) and Sri Lanka (7).	1	0.42

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.3 mg/kg bw/day
TMDI (European Diet) (% ADI)	WHO Global diet: 15 % BBA model: 23 %
NEDI (% ADI)	
Factors included in NEDI	
ARfD	not assessed
Acute exposure (% ARfD)	

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Grapefruit/juice, peel, press liquor, feed meal	7	no residues above the LOD	
Lemons/press liquor	5	0.25 – 3	
Lemons/juice	2	0.9	
Lemons/peel	6	1.1 – 9	
Lemons/feed meal	10	1.1 – 9	
Oranges/press liquor	27	0.8 – 18.5	
Oranges/juice	28	0.3 – 0.6 (most residues < LOD)	
Oranges/peel	28	1.5 – 4.1 (most residues < LOD)	
Oranges/feed meal	27	0.8 – 19.5 (most residues < LOD)	
Olives/oil	44	no residues above the LOD	
Linseed/oil	4	no residues above the LOD	
Linseed/cake	4	1.1 – 1.7	
Oilseed rape/cake	7	1.1 – 7.0	
Oilseed rape/crude oil	7	no residues above the LOD	
Oilseed rape/refined oil	7	no residues above the LOD	
Soya bean/fat-free meal	3	1	
Soya bean/hulls	3	5	
Soya bean/crude oil	3	< 0.02	
Soya bean/soapstock	3	< 0.02	

Processing factors (continued)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Potatoes/chips	4	no residues above the LOD	
Potatoes/flakes	4	no residues above the LOD	
Potatoes/granules	4	no residues above the LOD	
Potatoes/flake raw stock feed	4	1x33; 3x<LOD	
Potatoes/flake dry stock feed	4	1x4.5; 3x<LOD	
Tea leaves/brewed tea	16	0.2 – 1.1	
Tea leaves/instant tea	16	1.3 – 5.6	
Barley/malt	59	< 0.5	
Barley/wort	44	< 0.1	
Barley/beer	14	< 0.1	
Oat/groats	8	0.2 – 0.8	
Oat/hulls	8	0.8 – 8.3	
Wheat/whole meal flour	5	0.1 – 3.3	
Wheat/whole meal loaf	5	0.1 – 3.0	
Wheat/white flour	14	0.06 – 0.8	
Wheat/white loaf	8	0.03 – 0.08	
Wheat/bran	18	1.6 – 9	
Maize/meal	4	1 – 1.2	
Maize/crude oil	6	0.01 – 0.03	
Maize/refined oil	4	0.01 – 0.03	
Maize/soapstock	2	0.01 – 0.03	
Maize/steep grain	4	0.03 – 0.2	
Maize/large grits	2	0.7 – 1.1	
Maize/medium grits	2	0.6 – 0.9	
Maize/flour	4	0.9	
Sugar cane/bagasse	28	0.1 – 0.9	
Sugar cane/molasses	28	3.2 – 27.8	
Sugar cane/raw sugar	28	0.3 – 5.4	
Sugar cane/refined sugar	28	0.01 – 2.2	

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Citrus Fruit	0.5
Tree Nuts	0.1*
Pome Fruit	0.1*
Stone Fruit	0.1*
Berries and Small Fruit	
Table grapes	1
Wine grapes	1
Other berries and small fruit (other than wild)	open
Miscellaneous Fruit	
Olives (table consumption)	0.1*
Olives (oil consumption)	20
Others	0.1*
Root and Tuber Vegetables	
Beetroot	0.1*
Others	0.1*
Bulb Vegetables	
Onions	0.1*
Others	0.1*
Fruiting Vegetables	0.1*
Brassica Vegetables	0.1*
Leaf Vegetables and Fresh Herbs	0.1*
Legume Vegetables	0.1*
Stem Vegetables	
Asparagus	open
Others	0.1*
Fungi	
Mushrooms (other than wild)	0.1*
Wild mushrooms	50
Pulses	
Beans	1
Peas	5
Others	0.1*
Oil Seeds	
Linseed	10
Rape seed	10
Soya bean	20
Mustard seed	10
Others	0.1*

Proposed MRLs (continued)

Potatoes	0.5
Tea	1
Hops	0.1*
Cereals	
Barley	20
Oat	20
Rye	10
Triticale	5
Wheat	5
Maize	1
Others	0.1*
Other food of plant origin	0.1*
Sugar beets	0.2
Foodstuffs of animal origin	0.1*

Chapter 2.4b: Residues in plants tolerant to Glyphosate

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	tolerant maize, tolerant cotton, tolerant soya, tolerant rape
Rotational crops	
Plant residue definition for monitoring	AMPA besides Glyphosate
Plant residue definition for risk assessment	AMPA besides Glyphosate
Conversion factor (monitoring to risk assessment)	---

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	lactating goats, laying hens
Animal residue definition for monitoring	Glyphosate
Animal residue definition for risk assessment	Glyphosate
Conversion factor (monitoring to risk assessment)	---
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	Storage stability studies of glyphosate and AMPA residues have been carried out on different crops non-tolerant to glyphosate . Endogenous and exogenous glyphosate and AMPA residues are stable for 2-5 years at frozen storage. Storage stability studies on tissues and fat of swine, dairy cow and laying hens indicate a slight decrease of residues which has a negligible effect on the results of the feeding studies

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical GAP information for residues

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pest or Group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Glyphosate in Glyphosate tolerant plants														
Cotton seed	S-EU-MS		F		SL	360		50% boll opening	1			1.8	20	
Rape Seed	N-EU-MS S-EU-MS		F		SG	420		BBCH 30-31: fall and spring	2			1.08	120	
Soya Beans	N-EU-MS S-EU-MS		F		SL/SG	360/ 420		BBCH 11-19	2			0.72	90	
Maize	N-EU-MS S-EU-MS		F F						2 3			1.08 1.08	110 110	
Sugar Beets	N-EU-MS S-EU-MS		F F						2 3			1.08 0.72	120 120	

Remarks: (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4) including where relevant, information on season time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - pre-harvest interval (minimum)
(m) Remarks may include: Extent of use/economic importance/restrictions

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Cotton seed from plants tolerant to glyphosate	US	Glyphosate: 0.1, 4 x 0.3, 6 x 0.4, 6 x 0.5, 3 x 0.6, 2 x 0.7, 2 x 1.0, 1.2, 1.3, 1.4, 1.8, 1.9, 2 x 2.0, 2.1, 2.2, 2.4, 2 x 2.5, 2.7, 2 x 2.9, 3.0, 3.4, 3.5, 2 x 3.6, 2 x 4.0, 4.3, 4.6, 5.0 AMPA: 30 x <0.05, 4 x 0.05, 0.06, 0.07, 4 x 0.08, 6 x 0.1, 3 x 0.2	application rates: up to 8.80 kg as/ha PHI: 6 to 17 days Data are sufficient to propose an import tolerance.	Glyphosate: 5; AMPA: 0.2	Glyphosate: 1.20; AMPA: 0.05
	S		No GAP does exist, but it is intended to be applied for. 2 trials have been carried out in Spain, but not according to the intended GAP.		
Rape Seed from plants tolerant to glyphosate	N	Glyphosate: 24 x <0.05, 0.08 AMPA: 7 x <0.05, 2 x 0.06, 0.09, 2 x 0.1, 3 x 0.2, 2 x 0.3, 0.4, 0.5	application rates: 2 x 0.72 kg as/ha (fall + spring) or 1.44 kg as/ha in spring	Glyphosate: 10; AMPA: 0.5	Glyphosate: 0.05; AMPA: 0.09
Maize tolerant to glyphosate	N	Glyphosate: 20 x <0.05 AMPA: 6 x <0.05, 0.05, 2 x 0.06, 0.09, 0.1, 4 x 0.2, 4 x 0.3, 0.5	maximum application rates: 3.33 kg as/ha PHI: 86 to 140 days	Glyphosate: 1; AMPA: 1	Glyphosate: 0.05; AMPA: 0.1
	S	Glyphosate: 8 x <0.05 AMPA: 5 x <0.05, 2 x 0.06, 0.09		Glyphosate: 1; AMPA: 1	Glyphosate: 0.05; AMPA: 0.05
	US	Glyphosate: 19 x <0.05, 0.06, 0.07, 0.35 AMPA: 2 x <0.05, 5 x 0.1, 3 x 0.2, 6 x 0.3, 2 x 0.4, 0.5, 0.7, 1.0, 1.4	maximum application rates: 8.90 kg as/ha PHI: 6 to 8 days		Glyphosate: 0.05; AMPA: 0.30

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Summary of critical residues data (continued)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Soya Beans tolerant to glyphosate	S	Glyphosate: 0.07, 2 x 0.2, 3 x 0.3, 4 x 0.4, 2 x 0.5, 3 x 0.6, 3 x 0.7, 0.8, 0.9, 3 x 1.0, 3 x 1.1, 1.2, 1.8 AMPA: 0.09, 2 x 0.4, 4 x 0.5, 4 x 0.6, 0.8, 3 x 0.9, 3 x 1.0, 2 x 1.1, 3 x 1.2, 1.3, 1.7, 1.8, 2.0, 2.2, 2.5	application rates: 2.16 to 2.88 kg as/ha; PHI: 83 to 109 days	Glyphosate: 20; AMPA: 5	Glyphosate: 0.60; AMPA: 0.90
	US	Glyphosate: 2 x <0.05, 0.05, 0.06, 0.07, 5 x 0.1, 7 x 0.2, 9 x 0.3, 3 x 0.4, 4 x 0.5, 5 x 0.6, 4 x 0.7, 0.9, 6 x 1.0, 1.1, 1.3, 4 x 1.4, 2 x 1.5, 2 x 1.6, 1.7, 1.8, 5 x 1.9, 2.0, 2.1, 4 x 2.3, 2.4, 2.7, 2 x 3.0, 3.3, 3.5, 4.4, 5.6 AMPA: 2 x <0.05, 0.05, 2 x 0.07, 4 x 0.1, 7 x 0.2, 4 x 0.3, 4 x 0.4, 5 x 0.5, 3 x 0.6, 2 x 0.7, 0.8, 2 x 0.9, 2 x 1.0, 3 x 1.1, 1.2, 3 x 1.3, 2 x 1.4, 1.6, 2 x 1.7, 1.8, 3 x 1.9, 2 x 2.0, 2.1, 2.2, 2.3, 2.4, 2 x 2.6, 2 x 2.7, 2 x 2.8, 3.0, 3.1, 3.2, 2 x 3.3, 2 x 3.4, 2 x 3.6, 4.5, 5.0, 5.4, 7.6	application rates: 7.22 to 8.90 kg as/ha PHI: 66 to 108 days		Glyphosate: 0.70; AMPA: 1.10
Sugar Beets tolerant to glyphosate	N	Glyphosate: <0.05, 2 x 0.05, 0.09, 5 x 0.1, 10 x 0.2, 10 x 0.3, 4 x 0.4, 4 x 0.5, 3 x 0.6, 3 x 0.7, 1.3, 1.5, 2 x 2.3 AMPA: 46 x <0.05, 0.05	application rates: 1.5 to 3.0 kg as/ha PHI: 89 to 125 days	Glyphosate: 1; AMPA: 0.1	Glyphosate: 0.30; AMPA: 0.05
	S	Glyphosate: <0.05, 3 x 0.05, 2 x 0.06, 3 x 0.08, 0.09, 0.1, 8 x 0.2, 2 x 0.3, 0.6 AMPA: 22 x <0.05	application rates: 1.5 to 3.0 kg as/ha PHI: 89 to 125 days	Glyphosate: 1; AMPA: 0.1	Glyphosate: 0.15; AMPA: 0.05

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Oilseed rape/meal	1	1	
Oilseed rape/crude oil	1	no residues above the LOD	
Oilseed rape/refined oil	1	no residues above the LOD	
Soya bean/meal	3	0.8 – 1	
Soya bean/crude oil	3	0.01	
Soya bean/refined oil	1	0.01	
Soya bean/soapstock	3	0.01 – 0.02	
Sugar beets/thin juice, thick juice, molasse, raw sugar, refined sugar	2	no residues above the LOD	
Cotton/delinted cotton seed	1	0.17	
Cotton/kernels	1	0.07	
Cotton/hulls	1	0.33	
Cotton/meal	1	0.11	
Cotton/crude oil	1	0.006	
Cotton/soapstock	1	0.006	
Cotton/refined oil	1	0.006	
Cotton/bleached, deodorized refined oil	1	0.006	

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

	Glyphosate [mg/kg]	AMPA [mg/kg]
Rape seed (glyphosate tolerant)	10	0.5 (N-EU)
Soya bean (glyphosate tolerant)	20	5
Cotton seed (glyphosate tolerant)	5	0.2
Maize (glyphosate tolerant)	1	1
Sugar beet (glyphosate tolerant)	1	0.1

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Chapter 2.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days	up to 80%
Non-extractable residues after 100 days	up to 20%
Relevant metabolites - name and/or code, % of applied (range and maximum)	Aminomethylphosphonic acid (AMPA) 26-29% after 14 days

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	not submitted
Soil photolysis	DT50: 96d (90d dark); 101d (1236d dark)

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Timme/Frehse calculation, first order kinetics
Laboratory studies (range or median, with n value, with r^2 value)	DT_{50lab} (20°C, aerobic): 4 – 180 d (20°C), mean 49d, n=7
	DT_{90lab} (20°C, aerobic): 40 – 280 d (20°C), mean 159d,n=4
	DT_{50lab} (10°C, aerobic): not submitted (see field studies)
	DT_{50lab} (20°C, anaerobic): not submitted
	degradation in the saturated zone: not submitted
Field studies (state location, range or median with n value)	DT_{50f}: Germany 5;8 d, Switzerland 3;16d, USA: Tennesee 12d, California 13;68d, Georgia 8d, Canada: 6;8;21d. **AMPA DT_{50f}**: USA: California 958d, Georgia 896d; Canada: 353d, 237d.
	DT_{90f}: Germany 123;208d, Switzerland 85;172d, USA: Tennesee 38d, California 92d, Georgia 76d, Canada: 44;66d.
Soil accumulation and plateau concentration	< 0.05 – 9.5 ppm

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f / K_{oc}

K_d

pH dependence (yes / no) (if yes type of dependence)

Glyphosate

soil type	1/n	Koc
silty clay loam	1.16	60000
silt loam	0.8	3800
loamy sand	0.92	22300
sand	*)	32830
sand loam	*)	50660
sandy clay loam	*)	3598
loamy sand	*)	884
silt loam	*)	3404
loam(sediment)	*)	17819

*)The advanced adsorption isotherm test wasn't conducted due to insignificant degree of chemical adsorptivity in the screening test

No pH-dependence

AMPA

soil type	1/n	Koc
clay loam	0.786	3640
sand	0.904	8310
sand	0.752	1160
clay loam	0.791	3330
loamy sand	0.769	6920
sand	0.788	24800

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	0.12 – 1.45% as of applied in leachate
Aged residues leaching	not submitted
Lysimeter/ field leaching studies	not submitted

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	First order kinetics, 20% cover, DT50: 150d; intervall: 60d.
Application rate	single application: 4320 g as/ha; multiple application: 2 x 4320 g as/ha.

$PEC_{(s)}$		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		4.608 mg/kg	4.608 mg/kg	8.100 mg/kg	8.100 mg/kg
Short term	24h	4.587 mg/kg	4.597 mg/kg	8.063 mg/kg	8.081 mg/kg
	2d	4.566 mg/kg	4.587 mg/kg	8.026 mg/kg	8.063 mg/kg
	4d	4.524 mg/kg	4.566 mg/kg	7.952 mg/kg	8.026 mg/kg
Long term	7d	4.461 mg/kg	4.534 mg/kg	7.842 mg/kg	7.970 mg/kg
	28d	4.049 mg/kg	4.322 mg/kg	7.117 mg/kg	7.598 mg/kg
	50d	3.657 mg/kg	4.114 mg/kg	6.429 mg/kg	7.232 mg/kg
	100d	2.903 mg/kg	3.690 mg/kg	5.103 mg/kg	6.486 mg/kg

AMPA: (based on study results):

application rates (kg/ha)	maximum concentrations (mg/kg)	period (d)	concentrations at the end of study (mg/kg)
3.6-4.5	0.06 – 0.64	7-95	0.04 – 0.19*)

*)after up to 18 months

In some cases maximum concentrations of 0.17 – 0.835 mg/kg were reached only after 300 days.

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH__5____: stable (25°C)
	pH__7____: stable (25°C)
	pH__8____: stable (25°C)
Photolytic degradation of active substance and relevant metabolites	DT50: 33d (pH 5), 69d(pH 7), 77d (pH 9).
Readily biodegradable (yes/no)	no
Degradation in water/sediment - DT_{50} water - DT_{90} water	1 - 4 days -
- DT_{50} whole system - DT_{90} whole system	27,31,124 and 146 days -
Mineralization	6 – 26 % after 100 days
Non-extractable residues	14 - 35% after 100 days
Distribution in water / sediment systems (active substance)	after 1 day: 47-64% in water, 31-44% in sediment; after 100 days 3% in water, 29-44% in sediment. In sediment: maximum 50-60% after 7 and 14 days, resp. and 30-50% after 100 days.

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Distribution in water / sediment systems (metabolites)	AMPA: if found, only in the water phase: maximum 16% after 14 days and 0.5 % after 100 days.

PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation	OVERSPRAY: Model pond (1m^2 surface area, 30 cm in deep, 300 l). Spray drift values according to Ganzelmeier et al. (1995) and dissipation/degradation taking into account results of water/sediment studies (Möllerfeld and Römbke 1993)(PEC $_{actual}$) and DT50=4days (PEC $_{twa}$)..
Application rate	4320 g as/ha
Main routes of entry	spray drift

PEC$_{(sw)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1440 µg/l	1440 µg/l		
Short term 24h	922 µg/l	1322 µg/l		
2d	720 µg/l	1217 µg/l		
4d	533 µg/l	1039 µg/l		
Long term 7d	331 µg/l	834 µg/l		
14d	202 µg/l	541 µg/l		
21d	158 µg/l	385 µg/l		
28d	115 µg/l	294 µg/l		
42d	72 µg/l	198 µg/l		

AMPA (only in water phases detected): 3% (day 1), 5%(day 2), 11% (day 7), 16% (day 14), 12 % (day 30), 5% (day 61), 0.5% (day 100).

PEC (sediment)

Method of calculation	Results of water/sediment studies (Muttzall 1993).
Application rate	3.6 kg as/ha

PEC$_{(sed)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				
Short term	5 % (day 0)			
Long term	51% (day 14) 52% (day 28) 55% (day 56) 52% (day 91)			

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Glyphosate and its relevant metabolite AMPA are very strongly bound to soil.This places glyphosate and AMPA in the 'immobile' category of the McCall classification scheme for potential mobility in soil. For this reason there is no possibility that glyphosate or AMPA will pass through soil and result in a concentration in ground water, so the predicted environmental concentration of glyphosate and AMPA $PEC_{(gw)}$ is zero. -
Application rate	
$PEC_{(gw)}$	
Maximum concentration	
Average annual concentration	

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air	33d (pH 5), 69 d (pH 7), 77d (pH 9)
Quantum yield of direct phototransformation	not determined.
Photochemical oxidative degradation in air	DT50: 1.6 d (Atkinson estimation)
Volatilization	from plant surfaces: no significant volatilization
	from soil: not significant volatilization

PEC (air)

Method of calculation	The PEC_{air} is negligible based on Henry's law constant of glyphosate and no significant volatilisation rates from soil and plants. Once in the atmosphere rapid photochemical oxidative degradation of glyphosate in the troposphere will occur.
$PEC_{(a)}$	
Maximum concentration	

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Glyphosate and Aminomethylphosponic acid (AMPA).

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	
Surface water (indicate location and type of study)	

Listing of End Points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Ground water (indicate location and type of study)	United Kingdom, 1991 – 1996; 1991-1994: no detection of glyphosate in drinking water derived from groundwater (total number of determinations > 0.1 µg/l: 61,138,1217,1347; number of determinations of glyphosate > 0.1 µg/l in drinking water derived from surface water: 3 in 1993, 3 in 1994, maximum concentrations 0.35 and 0.37 µg/l, respectively. Total number of determinations in 1995 and 1996, respectively: 1374 and 1169,respectively. Number of determinations exceeding 0.1 µg/l: 3 (1995), 1 (1996).
Air (indicate location and type of study)	

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Chapter 2.6: Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	lowest LD 50 > 2000 mg/kg
Acute toxicity to birds	LD 50 > 2000 mg/kg
Dietary toxicity to birds	LD 50 > 4640 mg/kg
Reproductive toxicity to birds	NOEC 200 ppm

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
5.0	all uses	grazing bird	acute	>14	10
5.0	all uses	grazing bird	short-term	>8	10
5.0	all uses	grazing bird	long-term	9	5
5.0	all uses	grazing mammal	acute	>14	10
5.0	all uses	grazing mammal	long-term	9	5

Restrictions/Conditions necessary on member state level ? No

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish	Glyphosat - Isopropylaminsalt	acute	EC 50	>1000
Fish	Glyphosat - Isopropylaminsalt	chronic	NOEC	917
Daphnia	Glyphosat - Isopropylaminsalt	acute	EC 50	930
Daphnia	Glyphosat - Isopropylaminsalt	chronic	NOEC	455
Algae	Glyphosat - Isopropylaminsalt	chronic	EC 50	41.1
Fish	as	acute	EC 50	38
Fish	as	FLC-test	NOEC	25.7
Daphnia	as	acute	EC 50	40
Daphnia	as	chronic	NOEC	9
Algae	as	chronic	EC 50	0.6
Fish	AMPA	acute	EC 50	>180
Daphnia	AMPA	acute	EC 50	>180
Algae	AMPA	chronic	EC 50	89.8
Microcosm or mesocosm tests				

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
1.44 – 4.32	aquatic uses	algae	chronic	1	1.2 – 0.7	10
0.54 – 4.32	all uses	algae	chronic	1	86 - 10	10

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Bioconcentration

Bioconcentration factor (BCF)	Not relevant
Annex VI Trigger for the bioconcentration factor	—
Clearance time (CT_{50})	—
(CT_{90})	
Level of residues (%) in organisms after the 14 day depuration phase	—

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	100 µg as/bee
Acute contact toxicity	> 100 µg as/bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
4.32	orchards	oral	<50	50
4.32	orchards	contact	<50	50

Field or semi-field tests

Restrictions/Conditions necessary on member state level ? No

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
Typhlodromus pyri	lifecycle	360 g/l	4.3	Mortality	100	30
Aphidius rhopalosiphi	adult	360 g/l	4.3	Mortality	100	30
Chrysoperla carnea	larval stage	360 g/l	0.7	Mortality	53	30
Aleochara bilineata	lifecycle	360 g/l	1.9	Parasitization-capacity	1	30
Bembidion lampros	adult	360 g/l	3.6	Mortality	0	30
Poecilus cupreus	adult	360 g/l	4.3	Mortality	0	30
Poecilus cupreus	adult	360 g/l	4.3	Food uptake	31	30
Trechus quadristriatus	adult	360 g/l	3.6	Mortality	14	30
Pardosa spp.	adult	360 g/l	4.3	Mortality	56	30

Restrictions/Conditions necessary on member state level ? Yes

Field or semi-field tests
No data

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	December 1998	Glyphosate

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	LC50 > 480 mg as/kg
Reproductive toxicity	—

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
1 x 2.16 *	cereals	acute	> 155	10
1 x 5.07 **	vine, orchards	acute	>67	10
2 x 4.32 ***	pasture, stubble	acute	> 59	10

PEC: 3.1 mg as/kg *
7.2 mg as/kg **
8.1 mg as/kg ***

Restrictions/Conditions necessary on member state level ? No

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization	No effects up to 18 kg as/ha
Carbon mineralization	No effects up to 18 kg as/ha

Restrictions/Conditions necessary on member state level ? No