Conclusion regarding the peer review of the pesticide risk assessment of the active substance

**glufosinate**

**finalised: 14 March 2005**

(revision of 13 April 2005 with minor editorial changes)

**SUMMARY**

Glufosinate is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000\(^1\), as amended by Commission Regulation (EC) No 1490/2002\(^2\). This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Sweden being the designated rapporteur Member State submitted the DAR on glufosinate in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 3 January 2003. Following a quality check on the DAR, the peer review was initiated on 28 April 2003 by dispatching the DAR for consultation of the Member States and the sole notifier Bayer CropScience. Subsequently, the comments received were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting in January 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in April and May 2004.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 10 February 2005 leading to a full consensus on all issues and the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of 3 representative uses as proposed by the notifier, representing the 3 main types of use of the compound (apple for non-selective herbicide use in conventional crops, potatoes for use as crop desiccant and transgenic maize for use as selective herbicide) at application rate up 1.5 kg glufosinate-ammonium per hectare. The representative formulated products for the evaluation were “Basta SL 14”, “Basta SL 18” and “Liberty SL 18”, soluble concentrates (SL). The latter can be used in genetically modified glufosinate tolerant

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\(^1\) OJ No L 53, 29.02.2000, p. 25  
\(^2\) OJ No L 224, 21.08.2002, p. 25
organisms (such as maize, oil seed rape and sugar beets). Due to the fact that the ammonium salt, a variant of glufosinate, is used in the formulated product, it should be noted that the evaluated data belong to the variant glufosinate-ammonium, unless otherwise specified.

Adequate methods are available to monitor all compounds given in the respective residue definition except for blood.

Glufosinate-ammonium is poorly absorbed; the average was set to 10% (based on available data). The major metabolites were MPP\(^3\) and NAG\(^4\), minor amounts of MHB\(^5\), MPB\(^6\) and traces of MPA\(^7\). The oral LD\(_{50}\) was 1510 mg/kg bw in the rat and 416 mg/kg bw in the mouse (leading to a proposed classification with Xn; R22). Dermal LD\(_{50}\) was determined > 4000 mg/kg bw for the rat or 1500-2000 mg/kg bw for the female rabbit and > 2000 mg/kg bw for the male rabbit. According to the inhalatory LC\(_{50}\) 1.26 mg/l air a classification of Xn; R20 was proposed. Glufosinate-ammonium was mildly irritating to eyes but not to skin and showed no sensitising properties. Relevant oral short term no-observed adverse effect level (NOAEL) is 4.5 mg/kg bw/day, 1-year dog study, based on mortality and decreased glutamine synthetase activity and is an overall value for the studies in dog (proposed classification: Xn; R48/22). Relevant dermal NOAEL is 100 and 300 mg/kg bw/day for male and female rat, respectively. The NOAEL(C) was 0.012 mg/l air leading to a proposed classification of T; R48/23. There was no evidence of genotoxicity or carcinogenicity or direct effects on reproductive performance or fertility observed. The relevant NOAEL for reproduction is 120 ppm (7.5 and 9.6 mg/kg bw/day male and female) in rat based on reduced litter size. However, both pre- and post implantation losses to a high degree were noted and the NOAEL was set to 50 ppm (4.3 mg/kg bw/day). Glufosinate-ammonium induced pre- and post implantation losses, vaginal bleedings, abortions and dead foetuses not induced by maternal toxicity. The relevant developmental NOAEL is 6.3 mg/kg bw/day in the rabbit based on premature deliveries, abortions and dead foetuses (proposed classification: Cat. 2, T; R61/R62). No indications of delayed neurotoxicity. The metabolites (NAG, MPA and MPP) are all less toxic than glufosinate-ammonium.

The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) are based on the NOAEL of 6.3 mg/kg bw/day from the rabbit developmental toxicity study. Due to the severe art of effects seen both in the rat and rabbit an additional safety factor of 3 was added. The ADI is 0.021 mg/kg bw/day. The AOEL is 0.0021 mg/kg bw/day since a correction for 10% oral absorption (based on available data) is required. Two acute reference doses (ARfD) values are set; the first is based on the NOAEL from the rabbit developmental study for women of child bearing potential i.e. 0.021 mg/kg bw/day. The second is based on the NOAEL of 4.5 mg/kg bw/day from the 1-year dog study, without additional safety factor, i.e. 0.045 mg/kg bw/day is suggested to be used for the general population.

\(^3\) \text{3-methyl-phosphinico-propionic acid (MPP)}
\(^4\) \text{disodium L-2-acetamido-4-methylphosphinato-butyrate or N-acetyl-glufosinate (NAG)}
\(^5\) \text{2-hydroxy-4-methylphosphinico-butanoic acid (MHB)}
\(^6\) \text{4-methylphosphinico-butyanoic acid (MPB)}
\(^7\) \text{2-methylphosphinico-acetic acid (MPA)}
Dermal absorption of the formulations Basta SL14 and Basta SL18/Liberty SL18 were 16 % and 7 % for undiluted product and 14 % and 9 % for spraying dilution, respectively.
The estimated operator exposure levels for apple orchards using Basta SL14/SI18 were below the AOEL when personal protective equipment (PPE) was used. The estimated operator exposure both for potato desiccation using Basta SL14/SI18 and for weed control in transgenic maize using Liberty SL18 exceeded the AOEL even when PPE was used.

The metabolism of glufosinate-ammonium has been investigated on the three crops selected as representative uses by the notifier as well as in livestock. The residue definition proposed for monitoring and risk assessment for apples, potatoes and transgenic maize as well as for products of animal origin is the sum of glufosinate, its salts, MPP and NAG expressed as glufosinate equivalents. This definition protects adequately the consumer.

When the product is used according to the proposed good agricultural practice in apple and maize, no residues above the limit of quantification (LOQ) of 0.1 mg/kg are present at harvest. In potatoes, however, residues can be present up to 0.5 mg/kg and consist essentially of parent glufosinate. These residues are not altered by cooking in boiling water.

In a succeeding crop installed shortly after the use of glufosinate, one unknown metabolite of polar nature can be present but at extremely low levels (around 0.01 mg/kg). Further work should however be done to identify this metabolite.

Cattle liver and kidney can contain measurable levels of residues of MPP (up to 1 and 2 mg /kg respectively) when the animals are fed with potatoes and transgenic maize treated with glufosinate.

Chronic and acute risk assessments for the consumers were carried out according to usual methodologies. Based on the available data, the use on potatoes appeared to lead to an acute risk for toddlers (114 % of the ARfD for general population, including toddlers).

All studies on the fate and behaviour in the environment were performed with the ammonium salt of glufosinate (glufosinate-ammonium). Due to the fact the ammonium ion is ubiquitous in the environment; the fate of the ammonium resulting from the application of glufosinate-ammonium was not followed. Therefore, the results are referred to the fate of the anion glufosinate which is expected to be dissociated in aqueous media at environmentally relevant pH (5-9).

Glufosinate yields the two major metabolites MPP and MPA in soil under dark aerobic conditions. Glufosinate is stable towards photolytical degradation in soil.

Glufosinate is low persistent and metabolites MPP and MPA are low to moderate persistent in soil under aerobic conditions. Plant metabolite in transgenic plants, NAG, is very low persistent in soil. However, Member States may need to further assess this metabolite for uses were a larger portion of the plants is left in the field after cropping. Glufosinate is moderate to high mobile, MPP is high mobile and MPA is high to moderate mobile in soil.

Glufosinate is hydrolytically stable and it is not degraded by photolysis in water. Glufosinate is not readily biodegradable.
In the water phase, at 20 °C under aerobic conditions, the major metabolites were MPP, MPA, P-X, P-Y (= MPF) and NAG. The same metabolites were found under anaerobic conditions. Glufosinate reached levels above 10 % applied radioactivity (AR) in the sediment. An estimated theoretical maximum of 46 % AR was calculated for MPP in the sediment and used for calculation of the predicted environmental concentration in sediment (PEC sed). The dissipation half-lives of glufosinate in the water phase were 1.4 - 13 days at 20°C. The half life for MPP was estimated by extrapolation to be 150 d. Degradation of MPA and P-Y was slower. Further assessment of metabolites NAG and P-X may be needed for MS risk assessment.

Predicted environmental concentrations in surface water (PEC sw) and sediment (PEC sed) presented in the addendum were used for the ecotoxicological risk assessment. According FOCUS ground water (gw) PELMO 1.1.1. modelling MPP may have some potential to contaminate groundwater in vulnerable areas (trigger of 0.1 µg / L is exceeded in one of the nine scenarios). One field leaching study confirms leaching potential of MPP under vulnerable conditions at levels above 0.1 µg /L. Hence, for this metabolite an assessment with regard to potential relevance in ground water is warranted.

Concentrations of glufosinate-ammonium in the air compartment are expected to be negligible, due to low volatility and short persistence in the atmosphere.

Based on the data available at the EPCO expert meeting on ecotoxicology a high risk to mammals was identified. The acute and long term toxicity exposure ratio (TER) values are 3.5 and 0.13 respectively for the use in apples. The long term TER value is 0.86 in transgenic maize and the long term TER value for insectivorous mammals in potatoes would be 3.25 if the interception factor is disregarded as proposed by EFSA. Further data was submitted by the notifier after the EPCO expert meeting but this was neither evaluated by the RMS nor peer reviewed. The risk assessment can only be concluded when the outstanding data is evaluated.

The resulting TER-values for the acute and long term risk for aquatic organism were all higher than the Annex VI trigger value indicating a low risk to aquatic organisms for all representative uses (pending on a confirmatory data requirement for the long term risk to Daphnia magna from the metabolite MPP).

The risk is considered to be low for in-field populations of non-target arthropods (NTA) in potato and transgenic maize. A high risk is identified for off-crop populations of non-target arthropods in potatoes and maize which requires risk mitigation measures such as a 5 m bufferzone at Member State level. The available data at the EPCO expert meeting were not sufficient to demonstrate a safe use for non-target arthropods in orchards, since the tested doses in the field study were lower than those recommended in orchards (1.5 kg as/ha) and the risk assessment can only be concluded when the outstanding data is evaluated.

Based on the available data EFSA considers the risk to non-target plants from the use in orchards and maize as low when a buffer zone of 5 meter is taken into account. The risk from the use in potatoes can be regarded as low without the need for risk mitigation measures.

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8 3-methylphosphinico-acrylic acid (P-X)
9 methylphosphinico-formic acid (P-Y)
The risk to birds, bees, earthworms, other soil non-target macro-organisms, soil micro-organisms and biological methods for sewage treatment is considered to be low.

**Key words:** glufosinate, glufosinate-ammonium peer review, risk assessment, pesticide, herbicide