EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and Biocides

Glyphosate
SANTE/10441/2017 Rev 2
9 November 2017

Final

Review report for the active substance **glyphosate**
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 9 November 2017 in view of the renewal of the approval of glyphosate as active substance in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the evaluation of glyphosate, in accordance with Regulation (EC) No 1107/2009[2] and Commission Regulation (EU) No 1141/2010[3] following the submission of an application to renew the approval of this active substance expiring in December 2017.

Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing Regulation (EU) No 380/2013[4], lays down the procedure for the renewal of the second group of active substances in Annex I to Directive 91/414/EEC[5] and includes glyphosate.

Glyphosate is a substance that was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2001/99/EC[6]. Glyphosate is deemed to have been approved under Regulation (EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[7].

In accordance with the provisions of Article 5 of Directive 91/414/EEC, several companies notified the Commission of their wish to renew the approval of the active substance glyphosate, and of their decision to work together as a Glyphosate Task Force. Subsequently, an application for the renewal of the inclusion of the active substance glyphosate was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 within the time period provided for in that Article.

1 Review Report established in accordance with Art. 17 of Regulation (EU) No 1141/2010; does not necessarily represent the views of the European Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 322, 8. 12.2010, p. 10.
4 OJ L 116, 26.4.2013, p.4.
5 OJ L 230, 19.8.1991, p. 1.
6 OJ L 304, 21.11.2001, p. 14.
7 OJ L 153, 11.6.2011, p. 1.

Commission Directive 2010/77/EU[8] extended until 31 December 2015 the period of approval of glyphosate to allow the completion of its review.

Commission Implementing Regulation (EU) 2015/1885[9] extended until 30 June 2016 the period of approval of glyphosate to allow the completion of its review.

Commission Implementing Regulation (EU) 2016/1056[10] extended until "6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the European Chemicals Agency (ECHA) by the Commission or 31 December 2017, whichever is the earlier" the period of approval of glyphosate to allow the completion of the assessment of the dossier concerning the harmonised classification and the completion of its review. Given that the Opinion[11] of the Committee for Risk Assessment of ECHA was submitted to the Commission on 15 June 2017, the expiry date of glyphosate is 15 December 2017.

Commission Regulation (EU) No 1141/2010 designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For glyphosate the rapporteur Member State was Germany and the co-rapporteur Member State was Slovakia.

Germany finalised in December 2013 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and EFSA on 20 December 2013 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of glyphosate for the supported uses.

In accordance with Article 16 of Commission Regulation (EU) No 1141/2010, the Commission requested EFSA to arrange an expert consultation on the rapporteur Member State's renewal assessment report and to deliver its conclusions.

Therefore, EFSA organised a consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The International Agency for Research on Cancer (IARC) published a Monograph[12] containing detailed information on its evaluation as regards the carcinogenic potential of glyphosate in July 2015. The Commission mandated EFSA to review the underlying information and to include those findings in its conclusion. To allow for an appropriate evaluation of that information and the extraordinarily high number of comments received during the peer review and the public consultation, the Commission extended the deadline for the submission of the Authority's conclusion to 30 October 2015.

On 30 October 2015 EFSA sent to the Commission its conclusion on the risk assessment of glyphosate (Conclusions regarding the peer review of the pesticide risk assessment of the

[8] OJ L 293, 11.11.2010, p. 48.
[9] OJ L 276, 21.10.2015, p. 48.
[10] OJ L 173, 30.6.2016, p. 52.
[11] European Chemicals Agency (ECHA) (2017). Opinion of the Committee for Risk Assessment proposing harmonised classification and labelling of glyphosate (ISO); N-(phosphonomethyl)glycine (EC Number: 213-997-4; CAS Number: 1071-83-6).
[12] IARC Monographs on the evaluation of carcinogenic risks to humans; volume 112.

active substance)[13]. This conclusion refers to background document A (renewal assessment report and additional report) and background document B (EFSA peer review report).

Following a request from the Commission dated 19 November 2014, EFSA sent on 30 October 2015 to the Commission a statement on the co-formulant polyethoxylated (POE) tallowamine[14] based on the toxicological evaluation of POE-tallowamine (CAS No 61791-26-2) presented by the rapporteur Member State Germany in the context of the peer review of the active substance glyphosate.

The conditions of approval of the active substance were amended in light of the new scientific and technical knowledge by Commission Implementing Regulation (EU) 2016/1313[15].

Following the submission on 17 March 2016 by the rapporteur Member State, Germany, of a dossier concerning the harmonised classification of glyphosate under Regulation (EC) No 1272/2008[16], in accordance with Article 37 of that Regulation, including for the hazard class on carcinogenicity, on 15 June 2017 the European Chemicals Agency (ECHA) forwarded to the Commission the opinion adopted by its Committee for Risk Assessment on 15 March 2017. Subsequently the Commission published a Notice[17] in the Official Journal of the European Union to confirm receipt of this Opinion.

Following a request from the Commission dated 27 September 2016, EFSA sent to the Commission a conclusion on the potential endocrine disrupting properties of glyphosate[18] on 7 September 2017.

According to the provisions of Article 17 of Regulation (EU) No 1141/2010, the Commission referred a draft review report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 28 January 2016. The draft review report on renewal of approval was finalised in the meeting of the Standing Committee on 9 November 2017.

This review report on renewal of approval contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA, and the comments and clarifications submitted after the conclusion of EFSA (part of background document C), these documents are also considered to be part of this review report.

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[13] EFSA Journal 2015; 13(11): 4302. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. doi:10.2903/j.efsa.2015.4302. Available online: www.efsa.europa.eu/efsajournal.

[14] EFSA Journal 2015; 13(11): 4303. Statement of EFSA on the request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine. doi:10.2903/j.efsa.2015.4303. Available online: www.efsa.europa.eu/efsajournal.

[15] Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (OJ L 208, 2.8.2016, p. 1).

[16] OJ L 353, 31.12.2008, p.1.

[17] OJ C 204, 28.6.2017, p. 5.

[18] EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate. EFSA Journal 2017;15(9):4979, 20 pp. https://doi.org/10.2903/j.efsa.2017.4979.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2017/2324**[19] concerning the renewal of approval of glyphosate as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing glyphosate they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011[20].

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011[21], submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 18 of Regulation (EU) No 1141/2010, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing glyphosate will still fulfil the safety requirements laid down in Article 4(1) to (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each glyphosate containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

The following reference values have been finalised as part of this evaluation:

ADI: 0.5 mg/kg bw per day,
ARfD: 0.5 mg/kg bw,
AOEL: 0.1 mg/kg bw per day.

[19] OJ L 333, 15.12.2017, p. 10.
[20] OJ L 155, 11.6.2011, p. 127.
[21] OJ L 155, 11.6.2011, p. 1.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The highest Theoretical Maximum Daily Intake (TMDI) for all considered consumer groups is 3% of the Acceptable Daily Intake (ADI), and the highest International Estimated Short-Term Intake (IESTI) is 9% of the Acute Reference Dose (ARfD), based on EFSA PRIMo Model.

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

The review has identified acceptable exposure scenarios for operators, workers, bystanders and residents, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The following points could not be finalised or were considered as a critical area of concern by EFSA in their conclusion on glyphosate:

- *Glyphosate is not classified or proposed to be classified as carcinogenic or toxic for the reproduction category 2 in accordance with the provisions of Regulation (EC) No. 1272/2008 (harmonised classification supported by the present assessment) and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. Apical studies did not show adverse effects on the reproduction, however as an endocrine-mediated mode of action could not be ruled out. Data gaps for the full battery of Tier I screening assays according to the EDSP, or the Level 2 and 3 tests currently indicated in the OECD Conceptual Framework, are identified and the assessment could not be finalised.*

  Pertinent additional information has meanwhile become available and was assessed by EFSA. In its conclusion of 7 September 2017, EFSA concluded that the weight of evidence indicates that glyphosate does not have endocrine disrupting properties through oestrogen, androgen, thyroid or steroidogenesis mode of action based on a comprehensive database available in the toxicology area. The available ecotoxicology studies did not contradict this conclusion. Therefore the data gap has been adequately addressed.

- *Eight out of the 24 applicants presented specifications that were not supported by the toxicological assessment.*

  Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies, during renewal or first authorisation of plant protection products containing material from those sources (see section 6 below).

  For the source of Industrias Afrasa S.A., it appears that two different labels have been assigned to the same batch. This prevented a final conclusion on equivalence during the renewal assessment. Equivalence of this source should be confirmed during renewal or first authorisation of plant protection products containing material from that source.

In their statement concerning POE-tallowamine EFSA concluded that compared to glyphosate, a significant toxicity of POE-tallowamine (CAS No 61791-26-2) was observed on all endpoints investigated. Additional concerns were highlighted as regards the potential of POE-tallowamine to negatively affect human health. It is hence appropriate to exclude POE-tallowamine (CAS No 61791-26-2) from the use in plant protection products containing glyphosate.

As outlined in the EFSA conclusion on glyphosate, the peer review recognised that some genotoxicity studies on formulations presented positive results, and therefore, that the genotoxic potential of formulations should be addressed during renewal or first authorisation of plant protection products.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity of glyphosate is given in Appendix I.

The active substance shall have a minimum purity of 950 g/kg.

The manufacturing impurities formaldehyde and *N*-Nitroso-glyphosate are of toxicological concern and must be present below 1 g/kg and 1 mg/kg, respectively, in the active substance as manufactured.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of EFSA.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing Glyphosate

Only uses as herbicide may be authorised.

On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses;
- the protection of operators and amateur users*;

- the risk to terrestrial vertebrates and non-target terrestrial plants;
- the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions*;
- compliance of pre-harvest uses with good agricultural practices.

Conditions of use shall include risk mitigation measures, where appropriate.

Member States shall ensure that use of plant protection products containing glyphosate is minimised in the specific areas listed in Article 12(a) of Directive 2009/128/EC.

Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies.

Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).

Member States shall ensure that the genotoxic potential of formulations containing glyphosate is addressed before granting authorisations for plant protection products containing glyphosate.

** N.B During the Appeal Committee held on 27 November 2017, two further conditions were added in the final text voted by Member States concerning amateur users and biodiversity.*

7. List of studies to be generated

No further information was identified which was at this stage considered necessary in relation to the approval of glyphosate under the current approval conditions specified in Regulation (EU) 2017/2324.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (pages 23-24).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State (Germany) will keep available a document which gives information about the studies for which the applicant has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

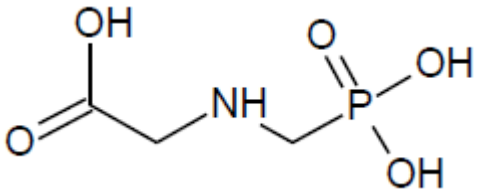
9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for glyphosate.

APPENDIX I

Main identity

GLYPHOSATE

Common name (ISO)	Glyphosate
Chemical name (IUPAC)	N-(phosphonomethyl)glycine
Chemical name (CA)	N-(phosphonomethyl)glycine
CIPAC No	284
CAS No	1071-83-6
EC No (EINECS or ELINCS) ‡	213-997-4
FAO SPECIFICATION	284/TC (2014) applicable to material of Monsanto, Cheminova, Syngenta and Helm Glyphosate: ≥ 950 g/kg Formaldehyde: maximum 1.3 g/kg of the glyphosate acid content found *N*-Nitroso-glyphosate: maximum 1 mg/kg Insolubles in 1 M NaOH: maximum 0.2 g/kg
Minimum purity	950 g/kg Impurities: Formaldehyde, less than 1 g/kg *N*-Nitroso-glyphosate, less than 1 mg/kg
Molecular formula	$C_3H_8NO_5P$
Molecular mass	169.1 g/mol
Structural formula	

APPENDIX II

List of uses supported by available data

GLYPHOSATE*

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc a.s. (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	L/ha product min-max	Water L/ha min-max	kg a.s./ha min max		
All crops** (all seeded or transplanted crops)	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Pre planting of crop	1-2	21 d (see remark)	1-6	100-400	0.36-2.16		Spring & autumn after harvest (incl. stubble and/or seedbed prep.) For all crops: Max. application rate 4.32 kg/ha glyphosate in any 12 month period across use categories, equivalent to the sum of pre-plant, pre-harvest and post-harvest stubble applications. The interval between applications is dependent on new weed emergence after the first treatment, relative to the time of planting the crop.
All crops** (all seeded crops)	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Post planting/ pre emergence of crop	1		1-3	100-400	0.36-1.08		

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc a.s. (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	L/ha product [#] min-max	Water L/ha min-max	kg a.s./ha min max		
Cereals (pre-harvest) wheat, rye, triticale,	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Crop maturity < 30 % grain moisture	1		2-6	100-400	0.72-2.16	7	Max. application rate 4.32 kg/ha glyphosate in any 12 month period across use categories, equivalent to the sum of pre-plant, pre-harvest and post-harvest stubble applications Pre-harvest uses in all crops include uses for weed control (higher doses) and harvest aid, sometimes referred to as desiccation (lower doses). The critical GAP is the high dose recommended used for weed control.
Cereals (pre-harvest) barley and oats	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Crop maturity < 30 % grain moisture	1		2-6	100-400	0.72-2.16	7	
Oilseeds (pre-harvest) rapeseed, mustard seed, linseed	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Crop maturity < 30 % grain moisture	1		2-6	100-400	0.72-2.16	14	

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc a.s. (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	L/ha product min-max	Water L/ha min-max	kg a.s./ha min max		
Orchard crops, vines, including citrus & tree nuts	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	Spray	Post emergence of weeds	1-3	28 d	2-8	100-400	0.72-2.88	N/A	Stone & pome fruit, olives Applications to avoid contact with tree branches. Maximum cumulative application rate 4.32 kg/ha glyphosate in any 12 month period Note: Because applications are made to the intra-rows (inner strips between the trees within a row), application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will roughly only be 33 %
Orchard crops, vines, including citrus & tree nuts	EU	MON 52276	F	Emerged annual, perennial and biennial weeds	SL	360 g/L	(ULV) Sprayer or Knapsack use (spot treatment)	Post emergence of weeds	1-3	28d	2-8	0-400	0.72-2.88		Stone & pome fruit, olives Applications made round base of trunk [0.0 L/ha water addresses ULV application of the undiluted product] Max. cumulative application rate 4.32 kg/ha glyphosate in any 12 month period Note: Because

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc a.s. (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	L/ha product min-max	Water L/ha min-max	kg a.s./ha min max		
															applications are made round base of trunk and to the intra-rows , (inner strips between two trees within a row), application rates per ha are expressed per 'unit of treated surface area' the actual application rate per ha orchard or vineyard will roughly only be 33 % - 50 %

Remarks:

* For uses where the column 'Remarks' is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

** Crops including but not restricted to: root & tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- & fodder beet; before planting fruit crops, ornamentals, trees, nursery plants etc.

(a) For crops, the EU and Codex classifications (both) should be taken into account; 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 sucking 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 plant - 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 at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

former information on kg a.s.s/hl replaced by RMS

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions