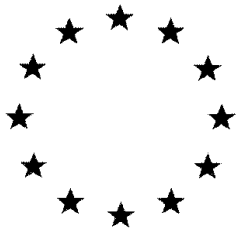
COMMENTS ON THE DRAFT ASSESSMENT REPORT ON PICOLINAFEN
DISCUSSED UNDER THE CO-RAPPORTEUR SYSTEM

Date	**Supplier**	**File name**
07 March 2001	BASF	01-picolinafen_com_basf-1.doc
07 March 2001	BASF	02-picolinafen_com_basf-2.doc
07 March 2001	BASF	03-picolinafen_com_basf-3.doc
07 March 2001	BASF	04-picolinafen_com_basf-4.doc
30 March 2001	Greece	05-picolinafen_com_gr.doc
30 March 2001	United Kingdom	06-picolinafen_com_uk.doc
30 March 2001	Denmark	07-picolinafen_com_dk-1.doc
30 March 2001	Finland	08-picolinafen_com_fin.doc
02 April 2001	Denmark	09-picolinafen_com_dk-2.doc

European Commission

Peer Review Programme



ECCO Peer Review Meetings

Full Report on
Picolinafen

- Reports of the meetings
- Comments on the draft assessment report
- Other documents considered at the meetings

ECCO-Team, at: Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig
11.09.2002

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address)	:	BASF
Pesticide (s) (common name (s))	:	Picolinafen (proposed)
CAS No	:	137641-05-5
Trade name (s)	:	Pico™
Main uses e.g. insecticide, fungicide	:	Herbicide
CROP TYPE	**:**	**Cereals**
COUNTRY	**:**	**Germany**

Use Pattern

1	2	3	4	5	6				7			8	9
Crop and/or situation (a)	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d-f)	Conc. of a.s. (i)	Method, kind (f-h)	Growth stage & season (j)	Number (min max)	interval between applications (min)	kg a.s./ha	water l/ha	kg a.s. /hl		
Winter Wheat, Winter Barley, Winter Rye, Triticale (autumn only)	F	Weeds	WG	750 g/kg	over plant spray	Post-em to BBCH 29	1	n/a	0.1	200	0.05	n/a	

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), or 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 concentration (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
(I) g/kg or g/L
(j) Growth stage at last treatment (BBCH) including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address)	:	BASF
Pesticide (s) (common name (s))	:	Picolinafen (proposed)
CAS No	:	137641-05-5
Trade name (s)	:	Pico™
Main uses e.g. insecticide, fungicide	:	Herbicide
CROP TYPE	**:**	**Cereals**
COUNTRY	**:**	**France**

Use Pattern

1	2	3	4	5	6				7			8	9
Crop and/or situation (a)	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d-f)	Conc. of a.s. (i)	Method, kind (f-h)	Growth stage & season (j)	Number (min max)	interval between applications (min)	kg a.s./ha	water l/ha	kg a.s. /hl		
Winter Wheat, Winter Barley, Winter Rye, Triticale (autumn only)	F	Weeds	WG	750 g/kg	over plant spray	Post-em to BBCH 29	1	n/a	0.1	200	0.05	n/a	

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), or 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 concentration (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
(I) g/kg or g/L
(j) Growth stage at last treatment (BBCH) including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address)	:	BASF Gosport, Hampshire PO13 0AS
Pesticide (s) (common name (s))	:	Picolinafen (proposed)
CAS No	:	137641-05-5
Trade name (s)	:	Pico™
Main uses e.g. insecticide, fungicide	:	Herbicide
CROP TYPE	**:**	**Cereals**
COUNTRY	**:**	**UK**

Use Pattern

1	2	3	4	5	6				7			8	9
Crop and/or situation (a)	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d-f)	Conc. of a.s. (i)	Method, kind (f-h)	Growth stage & season (j)	Number (min max)	interval between applications (min)	kg a.s./ha	water l/ha	kg a.s. /hl		
Winter Wheat, Winter Barley	F	Weeds	WG	750 g/kg	over plant spray	Post-em (BBCH11) to BBCH 29	1	n/a	0.05-0.1	200	0.025 - 0.05	n/a	

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), or 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 concentration (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
(I) g/kg or g/L
(j) Growth stage at last treatment (BBCH) including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address)	:	BASF
Pesticide (s) (common name (s))	:	Picolinafen (proposed)/IPU
CAS No	:	137641-05-5
Trade name (s)	:	Pico™
Main uses e.g. insecticide, fungicide	:	Herbicide
CROP TYPE	**:**	**Cereals**
COUNTRY	**:**	**France**

Use Pattern

1	2	3	4	5	6				7			8	9
Crop and/or situation (a)	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d-f)	Conc. of a.s. (i)	Method, kind (f-h)	Growth stage & season (j)	Number (min max)	interval between applications (min)	kg a.s./ha	water l/ha	kg a.s. /hl		
Winter Wheat, Winter Barley, Winter Rye, Triticale (autumn only)	F	Weeds	SC	25/500 g/kg	over plant spray	Post-em to BBCH 29	1	n/a	0.05/1	200	0.025/0.5	n/a	

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), or 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 concentration (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
(I) g/kg or g/L
(j) Growth stage at last treatment (BBCH) including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address)	:	BASF
Pesticide (s) (common name (s))	:	Picolinafen (proposed)/Pendimethalin
CAS No	:	137641-05-5 / 21725-46-2
Trade name (s)	:	To be advised
Main uses e.g. insecticide, fungicide	:	Herbicide
CROP TYPE	**:**	**Cereals**
COUNTRY	**:**	**Italy**

Use Pattern

1	2	3	4	5	6				7			8	9
Crop and/or situation (a)	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d-f)	Conc. of a.s. (i)	Method, kind (f-h)	Growth stage & season (j)	Number (min max)	interval between applications (min)	g a.s./ha	water l/ha	g a.s. /hl		
Winter Wheat, Winter Barley,	F	Weeds	SC	16/320 g/l	over plant spray	Post-em to BBCH 29	1	n/a	48/960	200-500	24/480 – 9.6/192	N/a	

*** NOTE: Southern European GAP is based on an AC 900001/ cyanazine co-formulation. A full Annex III dossier on the co-formulation will be submitted for evaluation at the Member State level for country specific approvals. The solo formulation has been submitted for evaluation for Annex I listing as this represents the 'worst case GAP' with the highest potential application rate.**

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), or 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 concentration (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
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(j) Growth stage at last treatment (BBCH) including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

ECCO PEER REVIEW PROGRAMME

FULL REPORT ON **PICOLINAFEN**

CONTENTS

PART 1: REPORTS

PART 2: COMMENTS AND OTHER DOCUMENTS

Attachment 2

Picolinafen -

EU Toxicology Response to B.6.14.1.1

A dermal AOEL of 0.5 mg/kg b.w./day was established for technical picolinafen to be used in operator risk assessments. A NOAEL of 50 mg/kg b.w./day for technical picolinafen was demonstrated in a 28-day dermal toxicity study. The latter study measures both dermal penetration and toxicity via the dermal route of exposure on a repeated basis and thereby, negates the need for a separate dermal absorption study. However, a systemic AOEL was also calculated to be 0.03 mg/kg b.w./day, based on a systemic NOAEL of 5.2 mg/kg b.w./day from the 90-day timepoint of the one-year dog study, a safety factor of 100, and an approximate 60% oral absorption rate. For a systemic AOEL to be used in operator risk assessments, an estimate of dermal absorption is required for calculating operator exposure. Dermal absorption based on a comparison of systemic and dermal LOAELs in the rat was estimated to be about 10%. This is in contrast to the estimated 60% dermal absorption used by the EU in calculating operator exposure.

Dermal absorption was estimated in rats to be about 10% by comparing LOAELs after repeated exposure by the dietary route (corrected for oral absorption) with the LOAEL from the 28-day dermal study. Because the dietary concentrations were selected with a 10-fold differential, i.e. 100 ppm and 1000 ppm, in the 28-day rat toxicity study, the LOAEL of 1000 ppm for anemia should not be considered the lowest LOAEL for this end-point. In fact, the 3 month LOAEL for hematological effects in the 2-year chronic toxicity in rats showed a LOAEL for hemolytic anemia of 250 ppm (approximately 12.6 mg/kg b.w. in males and 15.9 mg/kg b.w. in females, calculated from food consumption data) and a NOAEL of 50 ppm (the next lowest dose in the study). Because the 3 month rat LOAEL of 250 ppm is 2.5-fold greater than the NOAEL for anemia of 100 ppm in the 28-day rat toxicity study or about 3-fold greater than the NOAEL of 80 ppm (at 30, 60, or 90-days) in the 90-day rat toxicity study, it is difficult to predict whether the true LOAEL may actually be somewhere between dietary concentrations of 100 to 250 ppm, e.g. 150 ppm.

In contrast, incrementals in dosing were very close, i.e. 25, 50, 75, 100, 200 and 1000 mg/kg b.w./day, in the 28-day dermal toxicity study. In fact the LOAEL for slight anemia was 75 mg/kg b.w./day, which was only 1.5-fold the NOAEL of 50 mg/kg b.w./day. Nevertheless, a conservative estimate of dermal absorption can be made by comparing the most sensitive LOAEL for anemia of 250 ppm or 12.6 mg/kg b.w./day or 7.56 mg/kg b.w./day (after correcting for a 60% oral absorption), with the LOAEL of 75 mg/kg b.w./day in the dermal toxicity study, supporting a maximum dermal absorption in the rat of approximately 10%.

Therefore, picolinafen can be categorized as a medium skin penetrant for which a default 10% dermal absorption can be assigned. Further, the relatively large molecular weight of picolinafen, namely 376, would limit its penetration through the pores in the epidermis. Therefore, the use of a 10% default, as proposed by the EU, would be sufficiently conservative based on the above comparison of toxicities via the oral and dermal routes.

However, a more appropriate approach for estimating worker risk assessments for picolinafen is to use the 28-dermal study in the rat to set a dermal AOEL. Additionally, metabolism of picolinafen can be predicted to be similar for both farmers/contractors potentially exposed to picolinafen and for rats treated with picolinafen in the short-term dermal toxicity study, because, in both cases, exposure to picolinafen is via the dermal route, a route of exposure which bypasses the first-pass effect of the liver. This further supports the inclusion of a dermal AOEL in risk assessments for farmers/contractors mixing/loading/applying picolinafen formulations.

The AOEL for picolinafen technical is based, in part, on the NOAEL from the short-term (4-week) dermal toxicity study in rats with picolinafen technical. The NOAEL for this study is 50 mg/kg b.w./day, based on hematological changes indicative of a slight anemia for both sexes at 75 mg/kg b.w./day, the next highest dose tested. The inclusion of data from this short-term dermal toxicity study in rats is justified because the route and length of exposure in this study are consistent with the route and length of potential exposure of farmers/contractors to picolinafen. For example, the exposure models presented in the Annex III, Tier II summaries for the picolinafen formulations show that inhalation exposure to picolinafen is negligible (less than 1% of the total dermal exposure). As such, total dermal exposure can be considered representative of total exposure during mixing/loading/applying picolinafen formulations. Moreover, picolinafen formulations are intended for application by farmers only once per year, typically from early post-emergence to growth stage day 30 for the cereal crop to ensure optimal performance. As such, potential exposure to the farmer will be a maximum of one time per year. However, because contractors will be treating more than one field, a worst case scenario for a professional spray operator with unlimited access to cereal crops has been developed supporting a maximum period of consecutive exposure for a single autumn herbicide to not exceed 30 days. As such, potential exposure of picolinofen to the contractor will not likely exceed 30 days. Moreover, it is noteworthy that there is no apparent increase in toxicity after 28 days of treatment compared to 90 days of treatment. This is supported from an evaluation of results from the 28-day and 13-week dietary toxicity studies in rats with picolinafen technical which shows similar endpoints of toxicity in both studies (i.e., anemia) and comparable NOAELs for both studies (NOAEL of 100 ppm from the 28-day study and 80 ppm from the 13-week study).

As indicated from the exposure models (Annex III, Tier II), the potential for dermal exposure to the operator is mainly during application (following dissolving/diluting the end-use products in water), rather than during mixing/loading. Three of the 4 end-use formulations of picolinafen are wettable granule (WG) formulations which are dissolved in water prior to application. Similarly, water is the main component (approximately 45%) in the suspension concentrate (SC) end-use product of picolinafen. This end-use formulation will be even further diluted in water prior to application. The vehicle used in the short-term dermal toxicity study with picolinafen technical was water. Therefore, the use of the NOAEL from the short-term dermal toxicity study with picolinafen technical to derive the AOEL for workers is also justified because the vehicle used in this dermal toxicity study is representative of actual in-use situations. Using the NOAEL from the short-term dermal toxicity study with picolinafen to derive the AOEL for farmers/contractors is further justified because the endpoints noted in this dermal toxicity study (i.e., body weight gain reductions, hematological changes indicative of anemia, increased spleen weights, and

microscopic splenic changes) are similar to those noted following short- and long-term oral administration of picolinafen technical to rats, mice and dogs.

An analysis of NOAELs obtained after 90 days of treatment in the rat, mouse and dog shows that the mouse is the least sensitive species to picolinafen technical, while the rat and dog are equally sensitive to picolinafen technical (see Table 2 below).

Table 2
NOAELs from Data after 90 Days of Treatment with Picolinafen Technical in Rats, Mice and Dogs

Study Type	NOAEL ppm or (mg/kg b.w./day)[a]
13-week Rat Study	80 (6.6)
13-week Mouse Study	50 (11.4)
90-day timepoint in One-year Dog Study	150 (5.9)

[a]Calculated from food consumption data

These data indicate that because the rat and dog are equally sensitive to picolinafen technical, and both the rat and the dog are more sensitive than the mouse, a highly sensitive species was tested in the short-term dermal toxicity study with picolinafen technical. This further supports the use of the NOAEL from the short-term (4-week) dermal toxicity study in rats with picolinafen technical to derive the AOEL for farmers/contractors.

In the absence of genotoxicity, reproductive toxicity, teratogenicity or oncogenicity, an uncertainty factor of 100 is applied to the NOAEL of 50 mg/kg b.w./day from the short-term dermal toxicity study with picolinafen technical in rats, resulting in a dermal AOEL of 0.5 mg/kg b.w./day.

The results of a microcosm study with picolinafen have shown that the Environmentally Acceptable Concentration (EAC) of picolinafen for aquatic systems is 7 ppb.

The potential exposures of aquatic organisms to picolinafen through spray drift were calculated using the 95% Drift Values from Ganzelmeier. The Predicted Initial Environmental Concentrations (PIEC) of picolinafen in a 30 cm deep body of water were calculated based on an application of 100 g a.i./ha. The results are shown in the table below.

Base-case: Direct Overspray = 33.3 ppb

Buffer (m)	% Drift	Initial Water Conc. (ppb)	Mesocosm Conc. (ppb)
			7.03
			2.81
1	4.0	1.33	
			1.13
2	1.6	0.533	
			0.45
3	1.0	0.333	
4	0.9	0.300	
5	0.6	0.200	
			0.18
10	0.3	0.100	
			0.072
15	0.2	0.067	
20	0.1	0.033	

Based on an EAC of 7 ppb, a buffer of less than 1 meter would be needed. A 1 or 2 meter buffer would provide a 5 and 13X safety factor, respectively.

Page	Section	Comments
VOLUME 1 – LEVEL 1		
3	1.3.1	Under Contact person, the telephone and fax number are modified as follow: T- *32-81-625332 F- *32-81-625340 e-mail- catherine.deprez@central-europe.basf.org
4	1.3.4	Further to the acquisition by BASF, a new code has been allocated to the active ingredient, Picolinafen: BAS 700 H
5	1.4.1	Further to the acquisition by BASF, a new code has been allocated to the plant protection product, Picolinafen 750 g/kg WG: BAS 700 00 H
VOLUME 1 – LEVEL 2		
13	2.2.3	▪ Enforcement method for the air allows a LOQ of 2 µg/l. Based on the reviewed of the AOEL systemic to 0.03 mg/kg bw/day. I would like to have the comment "*based on a proposed AOELsystemic of 0.008 mg/kg bw/d*" removed. ▪ Could you delete the last sentence "Validation data for air down to the toxicological relevant concentration of 2.4 µg/m^3 are missing"? The report RES 00-0021 (in Volume A, Annex 2, page 11) was sent with the tier summaries to the BBA, one copy with cover letter dated 15 June 2000 and 3 additional copies on the 29 June 2000.
24	2.5.2	In the sentence starting "The soil photolysis study showed that picolinafen **is relatively stable**" instead of in relativ stable.
25	2.5.4	We would like you to add the $t_{1/2}$ of 2 days for 12 hour day
26	2.6.3.1	Sentence before the last: write "all hazard quotient are **clearly** below 50 instead of **chearly.**
26	2.6.3.2	What is the meaning of **wrt** associated to BBCH 11 to BBCH 29 wrt winter cereal... as it is not in Appendic I, "2.8 appendices, pages 37-46"?
26	2.6.4	▪ Would it be possible to include the new study on effect on eathworm reproduction submitted to the BBA on the 26 October 2000 [Lührs U (2000) Effects of AC 900001 in a 750 g/kg water dispersible granule formulation (RL 123357) on reproduction and Growth of earthworms *Eisenia fetida* (Savigny 1826) in Artificial soil, BASF Agro Research, PT – US; Report No ETX-00-167, GLP]. This study confirms the NOEL value used in the monograph and left the issue around the validity criterion. Subsequently, we would also like you to review the explanation and conclusion with regard to that study in the monograph, as well as have the study reference included in Volume 2 Annex A
VOLUME 1 – LEVEL 2 – APPENDIX 3, END POINTS		
55	-	List of intended uses: As monograph will be on internet at some stage of the EU evaluation and since BASF intention is to not support Cyanazine EU re-registration under Commission Regulation 421/2000/EC, we would like to have the table revised – See attachment I BASF is also supporting uses as a co-formulation with other active ingredient such as Pendimethalin and Isoproturon. An Annex III dossier will be submitted at Member State Level.

57	2.8.3.3	"Toxicologically significant compounds"- Based on the available data, the metabolites (above the trigger value of 0.1 mg/kg or 10%TRR of the applied dose) are not of toxicological significance. This statement is also given in the final draft, Volume 3B-7.3.1 (Definition of the residue, page 189). Therefore, could you revised the answer under *Toxicologically significant compounds (animals, plants and environment)* as **None** instead of **Parent compound and metabolites**
65	2.8.3.5	Fate and behaviour in air (Annex IIA, point 7.2.2) We would like you to add the $t_{1/2}$ of 2 days for 12 hour day
66	2.8.3.6	Toxicity data for aquatics species: should the Latin name in the table be in italic?
67	2.8.3.6	Bioconcentration : would you add the CT50 (clearance time) in the end point list? The CT50 is less than 2 days (See EU dossier, MII-section 6 under 8.2.3 submitted to support Annex I according to Commission Directive 91/414/EC).
VOLUME 1 – LEVEL 3		
49	4.2	The 2-year storage stability for Picolinafen 750 g/kg WG report was submitted on the 26 October 2000 to the BBA [Baker I. (2000).Generation of Chemical and Physical Stability Data on a Batch of Picolinafen 750 g/kg WG – 104 week interim report; BASF PLC – BASF Agro Research Gosport, UK;Report No RLG 4589, GLP (Including Tier I and Tier II summaries)]. We would like you to include the results and reference of this study in the monograph.
VOLUME 2- ANNEX A – LIST OF TESTS AND STUDIES		
3-8	IIIA 2.7.3	The 2-year storage stability for Picolinafen 750 g/kg WG report was submitted on the 26 October 2000 to the BBA [Baker I. (2000).Generation of Chemical and Physical Stability Data on a Batch of Picolinafen 750 g/kg WG – 104 week interim report; BASF PLC – BASF Agro Research Gosport, UK;Report No RLG 4589, GLP (Including Tier I and Tier II summaries)]. We would like you to include the results and reference of this study in the monograph.
3-8	IIA 2.10	We would like you to update the monograph with results of this study and add this reference in the reference list: "Mangels G. (2000) Picolinafen (AC 900001): Estimation of the Photochemical Oxidation Rate in the Atmosphere; BASF Agro Research, PT – US; Report No. EXA 00-0222". The report was sent to the BBA on the 26 October 2000.
15-19	-	Within the reference of the report, the symbol "!" is used. Should it not be a coma? Could you correct adequately?
32-40	IIA 8.2.6	We would like you to add this reference in the reference list since it is used in the monograph: "Kranzfelder J., Bussard J, Wa rd GS, Barker C. (2000) Effect of AC 900001 on Growth of *Anabaena flos-aquae* BASF (formely American BASF (Prior Cyanamid)) Report No.: ETX99-270 GLP, Unpublished"
32-40	IIA 8.4.2 IIIA 10.6.2	We would like you to update the monograph with results of this study and add this reference in the reference list: "Lührs U (2000) Effects of AC 900001 in a 750 g/kg water dispersible granule formulation (RL 123357) on reproduction and Growth of earthworms *Eisenia fetida* (Savigny 1826) in Artificial soil, BASF Agro Research, PT – US; Report No ETX-00-167, GLP". The report was sent to the BBA on the 26 October 2000.
35	AIIA-8.3.1	Year is missing, we would like you to add the year of 1998 in the relevant column

VOLUME 3 – B-1:IDENTITY		
3	B.1.1.1	Under the Contact person, the telephone and fax number are modified as follow: T- *32-81-625332 F- *32-81-625340 e-mail- catherine.deprez@central-europe.basf.org
3	B.1.1.4	Further to the acquisition by BASF, a new code has been allocated to the active ingredient, Picolinafen: BAS 700 H
3	B.1.2.1	Further to the acquisition by BASF, a new code has been allocated to the plant protection product, Picolinafen 750 g/kg WG: BAS 700 00 H
VOLUME 3 - B-2:PHYSICAL AND CHEMICAL PROPERTIES		
20	B.2.2.7.3	The 2-year storage stability for Picolinafen 750 g/kg WG report was submitted on the 26 October 2000 to the BBA [Baker I. (2000).Generation of Chemical and Physical Stability Data on a Batch of Picolinafen 750 g/kg WG – 104 week interim report; BASF PLC – BASF Agro Research Gosport, UK;Report No RLG 4589, GLP (Including Tier I and Tier II summaries)]. We would like you to include the results and reference in the monograph.
24	B.2.2.11	1st sentence: please write "AC 900001 **750 g/kg WG**"
24	B2.3	Update with the study reference listed above and covering IIA 2.10 and III 2.7.3
VOLUME 3B - 3:DATA ON APPLICATION AND FURTHER INFORMATION		
34	B.3.2.4	As monograph will be on internet at some stage of the EU evaluation and since intention not to support Cyanazine EU re-registration under Commission Regulation 421/2000/EC, would it be possible to keep the content of the second sentence more open? BASF proposal: "In intended combination with other active ingredients, 50 g ai was reached."
36	B.3.3	List of intended uses: As monograph will be on internet at some stage of the EU evaluation and since BASF intention is to not support Cyanazine EU re-registration under Commission Regulation 421/2000/EC, we would like to have the table revised – See attachment I BASF is also supporting uses as a co-formulation with other active ingredient such as Pendimethalin and Isoproturon. An Annex III dossier will be submitted at Member State Level.
VOLUME 3B - 5:METHOD OF ANALYSIS		
53	B.5.2.1	Please write **NPD** instead of PND in the sentence starting Quantification is performed…
54	B.5.2.2	2nd sentence- Could you write "In contrast to S19,…" instead of In difference,?
54	B.5.3.5	In table 5.3-6, 2nd column – last comment : could you write **35**°C and **80**% rel. humidity instead of 35°C and 84% rel. humidity
56	Table B.5.3-3	Please write **NPD** instead of PND
57	Table B.5.3-4	Please write **NPD** instead of PND
57	B.5.3.4	Last sentence: units for LOQ at 0.5 is missing. Could you update?

59	B.5.5.2	Enforcement method for the air allows a LOQ of 2 µg/l. Based on the reviewed of the AOEL systemic to 0.03 mg/kg bw/day, I would like to have the comment "*based on a proposed AOELsystemic of 0.008 mg/kg bw/d*" removed.
60	Table B.5.5-1	Please write **NPD** instead of PND
60	B.5.5.2	Table B.5.5-2 - The studies referred in this section were used to generate the EU dossier submitted to the RMS and subsequently to MSs for Provisional approval. Therefore, we would like to claim data protection for those studies. Could you have them mention in *B.5.6, references relied on?*
VOLUME 3B - 6:TOXICOLOGY AND METABOLISM		
77	B. 6.1	Conclusion, 2nd paragraph, 1st sentence, Could you write: "**AC 900,001** was almost." (a "0" is missing in the current text in the final draft)
163	B.6.14.1.1	Determination of the tolerable exposure (AOELdermal) to run UK-POEM We would like to re-iterate the use of AOEL dermal of 0.5 mg/kgbw/day whatever the operator exposure model used (See attachment 2)
VOLUME 3B - 7:RESIDUE DATA		
179	7.2	Table B.7.2-1, should the values for urine + faeces after 2 days be in normal character instead of being in bold?
190	7.4	List of intended uses: As monograph will be on internet at some stage of the EU evaluation and since BASF intention is to not support Cyanazine EU re-registration under Commission Regulation 421/2000/EC, we would like to have the table revised – See attachment I BASF is also supporting uses as a co-formulation with other active ingredient such as Pendimethalin and Isoproturon. An Annex III dossier will be submitted at Member State Level.
202	7.9	1st Paragraph, 1st Sentence, Could you write: "A confined rotational crop study (Chiu, 1998, **MET 98-007**) in *carrots, soya bean, lettuce, sugar beet, peas* ***and sunflower***
203	7.9	Table 7.9-1, column *Radiochemical Purity* – Last row, Could you write **99.45 %** instead of 97.95% (see Page 31 of the study report)
209	7.15	Table B.7.15-1 – At the present time, the application of picolinafen for Annex I listing concerns the cereal crop. Why does the TMDI calculation cover wine, tea, hops and coffee for the 36-50 Yr old Woman. Could you clarify in the text?
VOLUME 3B - 8:E-FATE AND BEHAVIOUR		
239	Table B.8.1-11	We would like you to complete the table (empty cell) with NA for not applicable.
242	Table B.8.1-12	the average temperature for report 1997-074 and 1998-005 are 8.1 and 16.3, respectively. We would like you to update the table B.8.1-12
248	B.8.2	Under Comments: By the following we would like to explain why the ratio 1:40 was used in study *ENV 97-010.01 (1998)*. "The use of the1 g soil:40 mL solution was necessitated by the strong adsorption of picolinafen to soil. If a lower soil:water ratio was used it would not have been possible to measure the concentration in the water. In order to meet the recommended goal of 75-25% remaining in the water so that accurate water concentrations could be measured, this soil:water ratio was needed."
250	8.2.1.1	Table B.8.2-5, Soil segment 0-5CM/Speyer 2.3, Could your write: "**95.9/85.7** instead of 95.9/80.7

VOLUME 3B - 9:ECOTOXICOLOGY		
283	B. 9.1.5	In the avian risk assessment, the RMS used the following assumptions when calculating acute oral exposure; herbivorous birds would consume 40% of their body weight per day and insectivorous birds would consume 25% of their body weight per day. These values are slightly different than those used in ECPA and EPPO risk assessment schemes, where the values are 10% for large birds and 30% for small birds. Are the values used by the RMS standard values for Germany? Are they specific for certain crops, such as cereals? Is there any written reference that specifies these criteria? Despite our confusion over the daily food consumption figures used for the acute oral risk assessment, BASF is encouraged by the RMS's use of actual measured residues in cereal shoots to estimate residues on potential avian food items, as opposed to strictly relying on the values in the Kenaga nomogram.
285	Table B9.2-2	Metabolite: CL153815, last row Write ***S. Capricornutum*** instead of *O. Mykiss (results related to 72-h, ref. 1999-524)*
287	B9.2	We would like you to take in consideration the microcosm study conducted during 2000-2001 [report ETX-00229, Schäfers C. & al., 2001] to review the proposed buffer zone. Based on the EAC, *Environmentally Acceptable Concentration* and the PEC calculation (see Attachment 3), we believe than a buffer zone of 1 m can be supported. We would also like to have this study report included in the reference lists of the monograph (Volume 2 Annex A and Volume 3 Annex B9.11) and claim for data protection.
296	B.9.8.3	Risk assessment for earthworms Would it be possible to include the new study on effect on eathworm reproduction submitted to the BBA on the 26 October 2000 [Lührs U (2000) Effects of AC 900001 in a 750 g/kg water dispersible granule formulation (RL 123357) on reproduction and Growth of earthworms *Eisenia fetida* (Savigny 1826) in Artificial soil, BASF Agro Research, PT – US; Report No ETX-00-167, GLP]. This study confirms the NOEL value used in the monograph and removed the issue around the validity criterion. Subsequently, we would also like you to review the explanation and conclusion with regard to that study in the monograph, as well as have the study reference included in Volume 2 Annex A and Volume 3 Annex B9.11.
308	B.9.11	Could the repeat acute *Anabaena* toxicity study presented in the Monograph on p. 285 under 9.2 (reference WAAT-nr 2000-35) be added to the reference list under Annex IIA - 8.2.6 ?

05-Picolinafen_Com_GR

MINISTRY OF AGRICULTURE
GENERAL DIRECTORATE OF
PLANT PRODUCE
DIRECTORATE OF PLANT PRODUCE PROTECTION
DEPARTMENT OF PESTICIDES
Address: 3-5 Hippokratous str.
10164 Athens - Ellas.
Inf:Mrs H. Panagopoulou
Tel: 0030-1-2124511
Fax : 0030-1-3617103
e-mail: h.panagopoulou@minagr.gr

Athens: 30 / 3 / 2001
File No: 91487

To: ECCo-Team (BBA)
(Att:) Mrs Franziska Huttenlocher
e-mail : ecco@bba.de

RE: Comments on the Draft assessment reports on the new a.s. Dimethenamid-p and Picolinafen

Dear Madam

Please find attached our comments on the above mentioned subject

Yours sincirely

The Director

C. Louskas

PICOLINAFEN.

Comments on residue section

In general, we agree with the evaluation made by the rapporteur.

However, we have the following comments:

Annex B.7

- **Point B.7.12.2 MRL proposal for animal products (p. 208)** In order to be consistent with the conclusions of point B.7.8-2, the fact that feeding studies on domestic animals are not necessary, should also be stated in the first sentence of point B.1.12.2.

- **Point B.7.12-2 (p. 208) and B.7.15 (p.209)** To our opinion, it is not necessary to set an MRL at the LOQ for products of animal origin, as animal intakes, based on the use according to the critical GAP, are insignificant.

As a consequence of the above comment, at

Point B.7.15, **Table B.7.15-2 (p.209)** Products of animal origin should not be listed in the commodities for TMDI calculation

Comments on ecotoxicology section

Could you please clarify the GAP (Table B.3.3), because the estimated kg as/ha from the column of kg as/hL and the water L/ha are not correct? The actual application rate is x10.

a. Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.4)

Risk Assessment for honeybees

Could you please clarify the results on Table B.9.4-6?

According to article 10.4 (Annex III of Directive 91/414/EEC) and the worst case scenario:

Q_{HO}=Dose (gr/ha)/LD_{50} oral (μg a.i./bee) = 100/100 = 1

Q_{HC}= Dose (gr/ha)/LD_{50} contact (μg a.i./bee) = 100/200 = 0.5

b. Effects on other arthropod species (Annex IIA 8.3.2; Annex IIIA 10.5)

Could you please justify why there is no study of any foliage dwelling predator, while there are studies for the other relevant arthropods species? During autumn there is a quite large number of foliage dwelling predators in the fields that are still active or hibernate.

c. Effects on other non-target organisms (flora and fauna) believed to be at risk (IIA 8.6 and IIIA 10.8)

Risk Assessment

Results in pre emergence and post emergence indicate that sugar beets and oilseed rape are very sensitive (100%) to the maximum field rate (100gr a.i./ha). Its good to know these results but according to the fact that there is not any acceptable Guideline for higher plant, how can we interpret further? There must a residue definition in order to estimate the relevance to the environment.

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

Could you please justify why the effects on biological methods of sewage treatment are “not relevant”. According to the other herbicide, dimethenamid-P, one study was included.

PESTICIDES SAFETY DIRECTORATE
Mallard House, Kings Pool, 3 Peasholme Green, York YO1 7PX, UK
Website: www.pesticides.gov.uk
Switchboard: 01904 640500 GTN: 5138 5836
Direct Dial: 01904 455836 Fax: 01904 455722
International: (+44) 1904 455836 International Fax: (+44) 1904 455722
Email: matthew.burns@psd.maff.gsi.gov.uk

Mr H Bruno,
Federal Biological Research Centre
for Agriculture and Forestry (BBA),
Dept for Plant Protection Products
and Application Techniques,
Messeweg 11/12,
D-38104 Braunschweig,
Germany

Your ref.: 11445/ECCO/BBA/00
FH/Sz

Our ref.: ASY 153

29 March 2001

Dear Mr Bruno,

RE: ECCO PEER REVIEW OF NEW ACTIVE SUBSTANCES UNDER DIRECTIVE 91/414/EEC

UK COMMENTS ON THE PICOLINAFEN DRAFT ASSESSMENT REPORT

On behalf of the Pesticides Safety Directorate of the Ministry of Agriculture, Fisheries and Food, please find attached our comments (page 1-6) on the draft assessment report on picolinafen, provided under the peer review process. If you have any queries, please do not hesitate to contact me.

As already discussed, I shall shortly send you PSD's draft evaluation of picolinafen for a national registration.

We look forward to fulfilling our role as Co-Rapporteur and working with the BBA on this project.

Yours sincerely

Matthew Burns

Matthew Burns
New Substances Branch
Approval Group

cc: [Franziska Huttenlocher], ECCO Team – [BBA]

Picolinafen

The Pesticides Safety Directorate agrees with the technical evaluation given in the draft assessment report **except** in the areas detailed below (all comments refer to Volume 3 except were indicated):

B.2.1 Physical and chemical properties of the active substance

It would appear that there is decomposition occurring at 135 °C, which is before the decomposition point proposed in the monograph.

There is an unexpected difference in solubility in organic solvents between the pure active substance and the technical material, which can not be explained by the difference in purity. The tests should to be repeated.

B.5 Methods of analysis

For impurities A19 and A30 in the technical material there is no evidence to demonstrate that they can be accurately quantified using the calibration curves for A26 and A27. Validation data is now available for these impurities and this could be included in the monograph.

The LC-MS-MS methods can now be accepted as the requirements have recently changed.

It is stated that the limit of quantification for air at 2 $\mu g/m^3$ is too high as the toxicological relevant concentration is 2.4 $\mu g/m^3$. It is not clear why the Limit of Quantification is to high as the toxicological significant level is higher than 2 $\mu g/m^3$. A short explanation would be helpful.

B.6 Mammalian Toxicology

In general we agree with the ADI.

We agree with concentrations at which most NOAELs set, although exact figures may vary between UK and rapporteur evaluations, as we believe the applicant has over estimated achieved daily intakes in the studies. The rapporteur appears to have taken the applicants estimation of achieved daily intakes at face value, whereas we have recalculated many of them from the food consumption data provided. However, we have some comments as follows:

Critical areas affecting AOEL, ADI etc.

B.6.3.7 Interim 90 day AOEL in the 1 year dog study.

In the <u>one year</u> dog study at the <u>90 day time point</u> the rapportuer set the NOAEL at 5.2 mg/kg based on reduced body weights and weight gains; and reductions in RBC parameters. It is considered that the NOAEL is one dose lower at 1.8 mg/kg bw as the reductions in bodyweight (11%), weight gain (30%) and food efficiency

(25%) were of sufficient magnitude at 5.2 mg/kg in males to be considered adverse.

If it is possible to agree what the NOAEL should be at this time point then it would be possible to agree on the Short Term AOEL which is based on the NOAEL at the 90 day time point in the one year dog study.

B.6.12 Dermal absorption

In the absence of submission of dermal penetration studies, the rapportuer has concluded that at worst-case, dermal absorption would be similar to oral absorption with value of 60%, used a comparison of the LOAELs for the 28 day rat dermal study with that for the 28 day rat dietary study to support this value. It is not considered that this gives an accurate estimation of dermal absorption because of the uncertainty of the LOAEL/NOAEL boundary in the 28 day rat dietary study (due to wide spacings in dose level). The rapporteur considered that at minimum, dermal absorption would be 20% based on a similar comparison of the 28 day rat dermal study LOAEL with that from the 2 year rat chronic study. It is not considered appropriate to make a comparison between two studies of such different duration.

In the UK evaluation it was considered appropriate to assume a default dermal penetration value in man of 10%. This is appropriate as no additional toxicological effects were observed on dermal administration compared to dietary administration and the large molecular weight of picolinafen (376) would also limit dermal penetration. Hence a 10% dermal absorption value in man may be considered conservative.

This is a critical issue as it may impact on the Operator Exposure assessment.

B.6.10 AOEL

The rapportuer along with a short term systemic AOEL, proposed a dermal AOEL (similar to the applicant) of 0.5 mg/kg bw. It is not considered that it is appropriate to set a dermal AOEL as at a significant proportion (30%) of systemic exposure comes from inhalation.

Non critical areas not affecting AOEL ADI etc:

B.6.5.1 The rapporteur has set a NOAEL of 2.4 mg/kg bw/day (50ppm) in the 24 month rat chronic tox/carc study. We have set a more refined NOAEL of 1.93 mg/kg bw/day based on the same dietary concentration of 50 ppm based on an effect which was present in the first 12 months of the study when achieved daily intakes at 50 ppm were approx. 2.3 mg/kg bw/day (as calculated by PSD), but which was absent up to termination when achieved daily intakes at 50 ppm were approx. 1.93 mg/kg (as calculated by PSD). The effect in question was haemosiderin deposition in the spleen. This is not a major disagreement or critical as it does not impinge on the overall reference values.

B.6.6.3 In the Rabbit teratology study, the rapporteur has set a fetal/developmental NOAEL of 5 mg/kg bw/day, whereas we have set it at one dose level higher. The rapporteur based their NOAEL on decreased mean fetal bodyweight at 20 mg/kg bw/day, however this was not a dose related effect, fetal bodyweights increasing again at 50 mg/kg bw. We based the rabbit fetal/developmental NOAEL on the increased total number of resorptions and mean resorption rate at the top dose.

B.6.14.1.1 Estimation of Operator Exposure

It is noted that exposure estimates for 'AC 900001' have been predicted using UK POEM. As UK POEM does not have the appropriate data to estimate the level of exposure arising during mixing and loading a WG formulation these calculations may be unreliable. In these situations a combination of the German and UK POEM models may be used; the German model to obtain a figure for exposure during mixing and loading and POEM to derive an estimate for application exposure.

The RMS's estimates of exposure using the German Model and UK POEM assume dermal absorption of 60% when predicting the total systemic dose. Should a (default) dermal absorption value of 10% be used when estimating systemic exposure, exposures of 0.012 mg/kg bw/day are predicted from the German Model (no PPE worn) and 0.026 mg/kg bw/day for the German Model/UK POEM exposure model (protective gloves when mixing and loading and when handling contaminated surfaces). These exposures are within the RMS's proposed AOEL of 0.3 mg/kg bw/day.

The applicant has proposed using a route specific (dermal) AOEL. However, German Model/POEM estimates of exposure indicate inhalation exposure may account for up to 25% of the total systemic dose (depending on PPE regime). Comparison of predicted exposures with a short-term systemic AOEL rather than a route specific (dermal) AOEL, as made by the RMS, is therefore considered appropriate.

B.6.14.3 Worker Exposure

Workers may be exposed to picolinofen foliar residues as they may enter crops shortly after they have been treated with 'AC 900001' to perform tasks such as crop inspections. Worker exposure to dislodgeable foliar residues of 'AC 900001' may be predicted using an exposure model proposed by Krebs *et al*, (1996). Based on an 8-hour working day, a transfer coefficient of 4,500 cm^2/person/hr (extrapolated from carnations, van Hemmen and Brouwer (1997)), the daily dermal exposure to a worker crop inspecting cereal crops treated at 0.01 kg as/ha is calculated to be 0.36 mg a.s./person/day. Assuming 60 kg body weight and 10 % dermal absorption, systemic exposure is estimated to be 0.0006 mg/kg bw/day (2% of AOEL proposed by RMS). This value is based on a worker performing crop inspections for 8 hours per day. On this basis no minimum re-entry period is expected to be required.

References cited

van Hemmen J.J. and Brouwer D.H. (1997) Exposure Assessments for Pesticides: Operators and harvesters risk evaluation and risk management. Med. Fac. landbouvww. Univ. Gent 62/2a 113-131.

Krebs, B.,Maasfeld, W.,Schrader, J.,Wolf, R. (1996). Uniform Principles for Safeguarding the Health of Workers Re-entering Crop growing Areas after Application of Plant Protection Products,1996

B.7 Residue data

B.7.1 In the wheat metabolism study interpretation would be helped if it was made clear that it is only the lower part of the straw that is being analysed. A sentence could be added at the start of the straw analysis to make this clear.

B.7.2/6 From the available residues data that support the GAP residues in grain were <0.05 mg/kg and in straw did not exceed 0.12 mg/kg (higher levels found after application at later growth stages have been excluded). From these residues it can be calculated that the trigger for animal studies of 0.1 mg/kg diet as received has not been exceeded. It can therefore be concluded that the animal metabolism study was not required and MRL's for products of animal origin should not be set.

B.8 Environmental fate and behaviour

In **table B.8.1-13**, the dissipation DT50 for CL 153815 of 82 days for study 4385 was modelled using PRZM. We have been notified by the applicant that this modelling exercise did not take into consideration the difference in molecular weight between the parent and the metabolite, which invalidates this modelled value. A further modelling submission has been submitted by the applicant using 'ModelMaker' version 4 simulating a three compartment system, which takes into consideration the difference in molecular weights. A DT50 value of 107 days for the metabolite has been derived from this modelling, which is true dissipation rate and does not include any element of simultaneous formation from the parent.

Table B.8.3-2 gives PECsoil values for CL153815. The longest DT50 value used was 82 days. As described above, the applicant has stated that this is an incorrect value. If only taking true dissipation into account, the recalculated value of 107 days would be a more appropriate value to use. However, in order to give a more representative indication of exposure experienced by soil organisms and plants, a more appropriate value would be the dissipation figure which is derived from both formation and dissipation, and calculated from the peak concentrations of metabolite in study 4385. This would give a 1st order DT50 of 180 days. In addition, the assumptions of 100% conversion of parent to metabolite are too worst case, the UK using a worst case value from the field studies.

Table B.8.6-2 gives the short term PECsw for picolinafen has not been calculated for 1m distance that we consider ought to have been done. In addition, a similar calculation ought to have been performed for the metabolite.

Table 8.6-5 give the calculated PECsed values. Have these been calculated in line with ECCO guidance on PECsed?

B.8.6.3 This section summarises the applicant's groundwater modelling. It is not entirely clear how the RMS has concluded that the metabolite is unlikely to exceed 0.1 micrograms/litre in groundwater given the criticism with certain input parameters. The RMS may wish to note that the applicant has submitted revised modelling with more appropriate input parameters that confirm that contamination above 0.1 micrograms/litre is not expected.

Vol. 1 Environmental fate and behaviour

2.5.2 We are not entirely in agreement with the RMS that the metabolite CL153815 is unlikely to accumulate. On the basis of the field dissipation DT50 of 107 days from the UK field study, it is a borderline case whether the DT90 would be less than or greater than 1 year. However taking the overall decline from the peak concentration in the UK study, it is clear that the metabolite would have a DT90 of >1 year an thus accumulation ought to be considered.

With respect to the end points for fate and behaviour:

i) has the RMS included the lab. DT50 values calculated from the soil route of degradation studies. These studies give values of 44-49 days with reasonable fit to 1st order kinetics.

ii) the RMS must take note that applicant has admitted that the DT50 value of 82 days is incorrect. This ought to be amended to 107 days, with the proviso that this value is suitable for modelling, but does not take into account true exposure within soil as it excludes the effect of simultaneous formation from the parent.

iii) It has been noted that the Kd/Koc values for the parent exclude the lowest values of Kd of 248 and Koc of 15,000 for the parent. These must be included.

iv) it would be useful if the assumptions used in the PECsoil calculation could be given. In addition, it would be useful for PECsoil for the metabolite to be given.

v) a minor point, but the maximum level of parent in sediment was 68.6% AR, not 68.8% AR.

vi) Why hasn't the PECsw been calculated at 1m distance?

vii) Does the PECsed calculation conform to the criteria agreed in the ECCO process?

B.9 Ecotoxicology

As a general comment it was considered that the Ecotoxicology section of Vol. 3 was perhaps too brief in the details presented, and the basis of some risk assessment scenarios were difficult to follow. Were it not for the fact that we are currently considered our own National registration for this compound it is likely that we would have had to raise a number of issues for clarification.

B.9.1 **Effects on birds.** Picolinafen is of low toxicity to birds and poses a low risk. In theory some adjustments to the food intakes are required to take into account the water content of the food (Kenaga data are dry weight values). Picolinafen has the potential to bioaccumulate, therefore some consideration of the risk to fish-eating birds would have been useful. Some comment to confirm that no major metabolites were identified in plants would have shown that this area had been considered. In practice these points do not change the overall conclusion that the risk to birds is acceptable, but would provide reassurance that these areas had been adequately covered.

B.9.2 **Aquatic life.** We agree that this represents the main area of concern for this compound. We also agree with the most of the endpoints chosen, but ask that you check the following points:

In Table B.9.2.1, the NOEC and LC50 for *L macrochirus* should be 0.57 and >0.57 mg a.s./l respectively.

In Table B.9.2.2. the species tested in Reference 1999-524 was *Selenastrum capricornutum* and not *O mykiss* as stated.

You will be aware that some new studies have been submitted to the UK. These were an acute algal study using *A judayi* (Wenzel 2001) and a microcosm study (Schafers *et al* 2001). Our evaluation of these studies is included in the draft UK evaluation document you will be sent shortly. PSD are of the opinion that these data are sufficient to demonstrate that restrictive aquatic buffer zone labelling is not required for the proposed use on cereals (confirmation of this decision is subject to consideration by UK National Committees). If you are in agreement that this is the case then this should be made clear to the Commission and hence to other Member States.

B 9.6 **Summary and risk assessment for earthworms**. We agree that the risk posed by the parent picolinafen is low. There is some evidence to indicate that the major soil metabolite CL153815 may have a field DT90 >365 days (Ref. UK national evaluation section 7.1.3). If this proves to be the case then long term risk from this metabolite will need to be considered further. {The field soil macro-organism study (Sankanu *et al* 1999) offers some indirect support to the belief that significant impacts on earthworm populations are unlikely}.

MILJØ & ENERGI
MINISTERIET

Mr. Clive Edmunds
SANCO B.II.1, office 1/44
European Commission
Rue de la Loi 86
B-1049 Bruxelles
Belgium

DANISH ENVIRONMENTAL PROTECTION AGENCY

Pesticide division

J.no. M 7042-0195
Ref. ABA/11

Regarding 50/50 evaluation of Picolinafen

Monday, 26 March 2001

Danish comments on the monograph on Picolinafen prepared by the Germany to the European Commission September 2000 - the section concerning: "Toxicology and metabolism"

Classification of the active substance

The Danish EPA is of the opinion that active substance Picolinafen should be classified R48/22; Danger of serious damage to health by prolonged exposure due to haemolytic anaemia.
Haemolytic anaemia or signs of haemolytic anaemia were seen in all tested animals species.
In several studies the effects were seen in doses below the limit values for subchronic studies 50 mg/kg bodyweight/day and in the subacut oral rat study (28 days study) haemolytic anaemia were seen at 107 mg/kg bodyweight/day (limit value 150 mg/kg bodyweight/day according to 3.2.3 in Council Directive 67/548/EEC).

Conclusion:
The Danish EPA find that Picolinafen should be classified R48/22; Danger of serious damage to health by prolonged exposure due to haemolytic anaemia.

Ministry of Environment and Energy
Danish Environmental Protection Agency
Strandgade 29
DK 1401 Copenhagen K

Phone + 45 32 66 01 00
Fax + 45 32 66 04 79
Telex 31 209 miljodk
E-mail (X-400): I=mst; S=Miljoestyrelsen;O=Miljoestyrelsen; OU1=mst;P=sdn;A=dk400;C=dk;
E-mail (Internet): mst@mst.dk
Internet: www.mst.dk

Yours Sincerely

Annika Boye Andersen

c.c. Rapporteur Member State, Germany
ECCO-Team (BBA), Germany

27 March 2001

To: ECCO-Team (BBA)
Biologische Bundesanstalt für
Land- und Forstwirtschaft
Abteilung für Pflanzenschutzmittel
und Anvendungstechnik
Messeweg 11/12
D-38104 Braunschweig
Germany
e-mail: ecco@bba.de

Comment to the Monograph on Picolinafen prepared by Germany to the European Commission

B.6.10 Acute reference dose (ARfD)

The reviewers are of the opinion that setting of an ARfD is not necessary. There are, however, observations of hematological effects consistent with (hemolytic) anemia in practically all of the repeated dose studies. Studies in rats yield a lowest NOAEL for hematological effects consistent with slight anemia at a dose level of 6.4 mg/kg/day (13-week study in SD rats; Fischer, 1998a). In mice the NOAEL for hematological effects was 10.2 mg/kg/day (13-week study in CD-1 mice; Fischer, 1998b). In dogs the overall NOAEL for hematological effects was 5.2 mg/kg/day from 90-day and 1-year studies (Kelly, 1999a and 1999b). Based on these studies one may conclude that dog is the most sensitive species for the observed hematological effects. The anemia caused by picolinafen seems to be fairly mild, and the effects on red blood cell parameters are likely to be reversible after cessation of exposure. The induced anemia may therefore be considered as an acute reversible effect. With a safety factor of 100, an ARfD of 0.05 mg/kg/day may be set for acute hematological effects (chemically induced hemolytic anemia), based on the NOAEL of 5.2 mg/kg/day in dog which seems to be the most sensitive species for these type of effects.

Yours respectfully,

Lars Nylund
Senior Officer
National Product Control Centre for Welfare and Health
Chemicals Department
P.O.Box 210
FIN-00531 Helsinki
Finland
Tel +358-9-3967 2775
e-mail lars.nylund@sttv.fi

cc. Plant Production Inspection Centre, Finland
Finnish Environment Institute, Finland

Danish Environmental Protection Agency
Pesticide Division

J.nr. 7042-xxxx
2. April 2001
STM/11

Danish comments on the monograph on **Picolinafen** prepared by Germany concerning **fate and ecotoxicology**.

Overall comment

We generally agree with the work done by the RMS and only have some minor comments, please see below.

Specific comments

The comments are all related to the end points.

Non-extractable residues and major metabolites

It would be informative to present the maximum concentrations together with the time point for the observations, and to present the concentration in the end of the study (or at another illustrative time point) together with the time point.

Bioconcentration

Are there information available on the clearance CT_{50} and/or CT_{90} for the active ingredient and for ^{14}C-compounds?

Algae

In the risk assessment a TER value of 11 in a distance of 20 meter is presented. This value is a higher tier assessment using a time weighted average concentration (PECtwa of 0,016 µg/l). It would be informative to mention the arguments for using this value, and to present the tier 1 TER value of 5,5.

Earthworms

The 8 week TER value of 2,5 is lesser than the Annex VI trigger value of 5. Please specify the arguments (NOEC based on increase in body weight) for accepting this value.

Check list Full Report CoRAP

Picolinafen

,

Conclusions WG (eval)	,	
Evaluation table rev. 1-2	,	
List of end points	,	
List of studies not cited	,	
Classification and labelling	,	
Report all sections	,	
Report	,	
Reporting table	,	
List of end points	,	
List of studies not cited	,	
Classification and labelling	,	
All comments	,	
Date to be checked		

Conclusions of the Working Group 'Plant Protection Products' (evaluation)
11-12 October 2001

Peer Review Programme under Directive 91/414/EEC

Subject: **Picolinafen**

Rapporteur Member State: **DE**

Co-Rapporteur Member State: **UK**

The meeting agreed that all points are fulfilled pending evaluation and submission of draft assessment report addendum 2.

Applicant to distribute algae study (data requirement 3.1) to all MS.

COM to schedule picolinafen for next meeting of WG Evaluation on 10/11 December 2001.

Appendix 1: Evaluation table rev. 1-2: picolinafen

Appendix 2: complete list of end points: picolinafen

Appendix 3: List of studies which were submitted during the evaluation process and were not cited in the draft assessment report: picolinafen

Appendix 4: Suggested classification and labelling: picolinafen

WORKING DOCUMENT – DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

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

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
				Section 1 : Data requirements : 2 Open points : 0
1.1	CoRMS: Repeat tests should be conducted on the technical active substance and purified active substance to confirm the correct solubility in organic solvents. RMS: No agreement. The necessity for the requirement cannot be seen. (AIIA 2.7) **A**	28 September 2001 The solubility in organic solvent for the technical and pure active ingredient will be repeated. Since this data was requested by PSD to support full approval in July 2004, we expect to have the report for that submission.	(i) (ii) 04.10.2001 If the applicant want to repeat the experiments: okay, but if this requirement is regarded as essential, the proposed data for submission is not acceptable. However, the RMS still cannot see the necessity.	Working Group (evaluation) 11. – 12.10.2001: Data requirement confirmed. The applicant should communicate timelines for the submission of the study as soon as possible.

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
1.2	Validation data for the impurities A19 and A30 are required. (AIIA 4.1.3) **A**	28 September 2001 Validation data for impurities A 19 and A 30 is given as Attachment 1. This data are to be considered as confidential data.	(i) (ii) 04.10.2001 Data have been submitted (Jones, 2001, BASF report No. APBR 1160). Summary will be provided after evaluation	Working Group (evaluation) 11. – 12.10.2001: Data requirement fulfilled-pending evaluation by the RMS. RMS to evaluate and report in an addendum to the draft assessment report.

2. Environmental fate and behaviour

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
				Section 2 : Data requirements : 2 Open points : 0
2.1	New PEC_{soil} calculations for metabolite CL153815 with more realistic assumptions (DT_{50}: 107 days, initial conc. = 54 % of applied a.s.) are required. (AIIIA 9.1.3) **A**	28 September 2001 The new PECsoil calculation for the metabolites CL151815 is given as attachment 2. Considering a DT50 of 107 days and 54% of applied a.s. give a PIEC of 0.072 mg/kg.	(i) (ii) 04.10.2001 Data have been submitted (Mangels, 2001, BASF report No. EXA 01-036). The study was evaluated and reported in the addendum 2.	Working Group (evaluation) 11. – 12.10.2001: Data requirement fulfilled.
2.2	Revised modelling of potential for groundwater contamination of metabolite CL 153815 with more appropriate input parameters (amendment to study of Mangels, 2001) is required. (AIIIA 9.2.1) **A**	28 September 2001 Revised modelling for ground water contamination for CL151815 is given as attachment 3. PECgw for CL 153815 is < 0.1 ug/l	(i) (ii) 04.10.2001 Data have been submitted (Mangels, 2001, BASF EXA 01-010-01). The study was evaluated and reported in the addendum 2. The study shows no leaching potential of metabolite CL 153815 to groundwater (< 0.1 µg/l under worst case conditions).	Working Group (evaluation) 11. – 12.10.2001: Data requirement fulfilled.

3. Ecotoxicology

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
				Section 3 : Data requirements : 2 Open points : 1
3.1	The notifier is requested to submit data on the question how representative *Ankyra judayi* for other algae species is. (IIA-8.2, IIIA-10.2) **MS**	28 September 2001 Of the algal species that have been tested thus far, *Ankyra judayi* is the most sensitive to picolinafen. *A. judayi* is a relatively slow-growing species, as evidenced by the relatively extended time for recovery for some treatment levels in the microcosm study. If the microcosm systems were dominated by a less sensitive and more rapidly growing species (e.g., *Selenastrum*), the NOEC from the study would be higher, and recovery in the higher treatments would have been more rapid. Therefore, an aquatic risk assessment for picolinafen, based on effects observed on *A. judayi* in the microcosm study, would be a highly conservative assessment.	(i) (ii) 04.10.2001 Agreement. The algae *Ankyra judayi* is considered suitable for final risk assessment. Data requirement fulfilled.	Working Group (evaluation) 11. – 12.10.2001: Data requirement probably fulfilled, pending detailed discussion at the next meeting. RMS to ask the applicant to distribute the algae study to all Member States so that a detailed discussion can be held.

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
3.2	a) Notifier is requested to submit a new calculation of the field DT_{90} for the metabolite CL 153815. b) If the metabolite CL 153815 should have a field DT_{90} > 365 days the long term risk will need to be considered further. (IIA-8.4, IIIA-10.6) **A**	28 September 2001 a) Based on the 1st order constant for the UK soil dissipation [attachment 4, report EXA 01-029, Mangels G. 2001], DT90 is 355 days [log ln 0.1/rate constant = 2.303/0.00649 = 355] b) The DT90 is below 100 days, therefore no further data is required for the metabolite 153815.	(i) (ii) 04.10.2001 Data have been submitted. Summary will be provided after evaluation	Working Group (evaluation) 11. – 12.10.2001: Data requirement fulfilled-pending evaluation by the RMS. RMS to evaluate and report in an addendum to the draft assessment report.
	Open point 3.1: RMS to amend the list of end points. This open point was proposed at the Working Group (evaluation).			Working Group (evaluation) 11. – 12.10.2001: Open point still open.

4. Mammalian Toxicology

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
				Section 4 : Data requirements : 1 Open points : 1
	Open Point 4.1: CoRMS: Final dermal absorption value to be used for assessment in the range 10-25%. RMS: The proposed range of 10–25% as estimate for dermal absorp–tion is not supported for practi–cal reasons. For the purpose of exposure assessment a dermal absorption value of 12% is proposed (based on the com-parison of the NOAELs from the 28 day rat dermal (50 mg/kg bw/d) and 28 day rat dietary study (10.5 mg/kg bw/d), and taking into account 60% oral absorption)	28 September 2001 We support the proposed 12% dermal absorption.	(i) (ii) 04.10.2001 No comment	Working Group (evaluation) 11. – 12.10.2001: MS to clarify their position concerning the proposed dermal absorption rate of 12% to be discussed at the next meeting.

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
4.1	The Notifier to clarify the purity and imputity profile of the test material used in the toxicology studies and compare with current specification. This data requirement was proposed at the Working Group (evaluation)			Working Group (evaluation) 11. – 12.10.2001: New data requirement

5. Residues

No.	Column A Conclusions of the Accelerated ECCO-Peer Review	Column B Comments from the applicant	Column C Rapporteur Member State and Co-rapporteur Member State comments on applicant comments	Column D Conclusions of the evaluation group
				Section 5 : Data requirements : 0 Open points : 0

Conclusions of the Working Group (evaluation) 11. – 12.10.2001:

- The meeting agreed that all major points (except 1.1) are probably fulfilled pending evaluation and distribution of draft assessment report addendum 2.
- Applicant to distribute algae study (data requirement 3.1) to all MS, clarify impurity profile of test material (4.1) and provide timelines to fulfill requirement 1.1.
- RMS and ECCO to provide a first draft Review Report and List of Endpoints.
- MS to inform on provisional authorisations.
- COM to schedule picolinafen for next meeting of WG Evaluation on 10/11 December 2001.

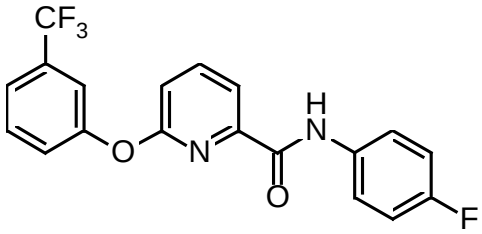
LIST OF USES SUPPORTED BY AVAILABLE DATA (date: 20.09.2001)

Crop and/ or situation	**Member State or Country**	**F G or I**	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Remarks:**
(a)		(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	(l)	(m)
Winter Wheat Winter Barley Winter Rye Triticale (autumn only	Northern Europe	F	Weeds	WG	750 g/kg	Over plant spray	Post- em (BBCH11) to BBCH 29	1		0.025-0.05	200-400 (max.400 applied for in DE)	0.05-0.1		
Winter Wheat Winter Barley	Southern Europe	F	Weeds			Over plant spray	Post-em to BBCH 29	1			200	0.05		Notifier intends only combinations with other active substances

(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 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
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	4'-Fluoro-6-[(α,α,α-trifluoro-m-tolyl)oxy]picolinanilide
Chemical name (CA)	N-(4-Fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]-2-pyridinecarboxamide
CIPAC No	639
CAS No	137641-05-5
EEC No (EINECS or ELINCS)	not assigned
FAO Specification (including year of publication)	not available
Minimum purity of the active substance as manufactured (g/kg)	> 950 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	none
Molecular formula	$C_{19}H_{12}F_4N_2O_2$
Molecular mass	376.3
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	Melting range: 107.2 - 107.6 °C (PAS 98.7 %)
Boiling point (state purity)	No defined boiling point observable, decomposition at > 230 °C (PAS 98.7 %)
Temperature of decomposition	No defined boiling point observable, decomposition at > 230 °C
Appearance (state purity)	fine crystalline white to chalky solid with musty smell (PAS 98.7 %)
Relative density (state purity)	1.45 g/cm^3 (PAS 98.7 %)
Surface tension	72.3 mN/m
Vapour pressure (in Pa, state temperature)	$1.7 \cdot 10^{-7}$ Pa (20 °C, extrapolated, PAS 99.5 %)
Henry's law constant (Pa m^3 mol^{-1})	$1.6 \cdot 10^{-3}$ Pa m^3 mol^{-1} (20 °C)

Solubility in water (g/l or mg/l, state temperature)	pH 5 buffer: $3.8 \cdot 10^{-5}$ g/l pH 7 buffer: $4.7 \cdot 10^{-5}$ g/l pH 9 buffer: $3.8 \cdot 10^{-5}$ g/l DI water: $3.9 \cdot 10^{-5}$ g/l (at 20 °C:)
Solubility in organic solvents (in g/l or mg/l, state temperature)	TAS (97.8 %), 20 °C acetone: 557 g/l dichloromethane: 764 g/l ethyl acetate: 464 g/l n-hexane: 3.8 g/l methanol: 30.4 g/l toluene: 263 g/l
Partition co-efficient (log P_{OW}) (state pH and temperature)	solvent — log P_{OW} DI water — 5.37 pH 5 buffer — 5.36 pH 7 buffer — 5.43 pH 9 buffer — 5.36
Hydrolytic stability (DT_{50}) (state pH and temperature)	Stable at pH 4, 7 and 9 (5 d, 50 °C)
Dissociation constant	No dissociation between pH 2 – 12
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	202 nm: ε=39500 [l mol^{-1} cm^{-1}] 230 nm: ε=14600 [l mol^{-1} cm^{-1}] (shoulder) 290 nm: ε=13000 [l mol^{-1} cm^{-1}]
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Xe-lamp (λ > 290 nm), continuos irradiation pH 5 buffer: 25 d pH 7 buffer: 31 d pH 9 buffer: 23 d
Quantum yield of direct phototransformation in water at λ > 290 nm	$2.14 \cdot 10^{-6}$
Flammability	not highly flammable
Explosive properties	not explosive

List of uses supported by available data

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	(l)	(m)
Winter Wheat Winter Barley Winter Rye Triticale (autumn only	Northern Country		F	Weeds	WG	750 g/kg	Over plant spray	Post-em (BBCH 11) to BBCH 29	1		0.025-0.05	200-400 (max.400 applied for in DE)	0.05-0.1		
Winter Wheat Winter Barley	Southern Country		F	Weeds			Over plant spray	Post-em to BBCH 29	1			200	0.05		Notifier intends only combinations with other active substances

(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 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
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	none
with regard to toxicological data	none
with regard to fate and behaviour data	none
with regard to ecotoxicological data	R50/53

2 Appendix III.2: Chapter 2 (methods of analysis)

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

Technical as (principle of method)	HPLC-UV; 290 nm; RP18 - column
Impurities in technical as (principle of method)	HPLC-UV; 230 nm; RP18 - column GC-FID; DB5 fused silica column
Plant protection product (principle of method)	HPLC-UV; 290 nm; RP8 - column

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	GC-ECD GC-PND GC-MS	0.01 mg/kg (wheat, barley) 0.05 mg/kg (cereals) 0.05 mg/kg (barley)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	GC-ECD	0.01 mg/kg (milk) 0.02 mg/kg (meat, eggs, fat)
Soil (principle of method and LOQ)	GC-ECD	0.01 mg/kg
Water (principle of method and LOQ)	**drinking** GC-PND GC-ECD **surface** GC-PND/MS	 0.05 µg/l 0.1 µg/l 0.1 µg/l
Air (principle of method and LOQ)	HPLC-UV	2 µg/m³
Body fluids and tissues (principle of method and LOQ)	-	

3 Appendix III.3: Chapter 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 absorbed (60% based on urinary and biliary excretion within 48 h for males at low dose)
Distribution	Widely distributed
Potential for accumulation	No evidence for accumulation (<0.5% after 7 days: highest residues of the aniline-label in blood and spleen)
Rate and extent of excretion	Rapidly excreted, ca. 88% within 48 h via urine (48/62% for males/females) and feces
Metabolism in animals	Extensively metabolised (>87%) by hydrolytic cleavage (to substituted picolinic acid and *p*-fluoroaniline), oxidation, acteylation, and subsequent glucuronide and sulfate conjugations

Toxicologically significant compounds (animals, plants and environment)	Parent compound and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 4000 mg/kg bw
Rat LC_{50} inhalation	> 5.9 mg/L (4 h, dust, nose only)
Skin irritation	Non-irritating
Eye irritation	Non-irritating
Skin sensitization (test method used and result)	Non-sensitizer (M & K)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Red blood cells, spleen, liver (hemolysis); thyroid (hypertrophy, dog)
Lowest relevant oral NOAEL / NOEL	90d overall dog (90 d + 1yr): 150 ppm (5.2 mg/kg bw/d) 1yr dog: 50 ppm (1.4 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL	28d rat: 50 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL	No data - not required

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential

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

Target / critical effect	Red blood cells, spleen (hemolysis); liver (hypertrophy)
Lowest relevant NOAEL / NOEL	2yr rat: 50 ppm (2.4 mg/kg bw/d)
Carcinogenicity	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	No effects on reproduction
Lowest relevant reproductive NOAEL / NOEL	2gen rat: > 500 ppm (43 mg/kg bw/d)
Developmental target / critical effect	Increased resorption rate; decreased fetal body weights at maternal toxic doses (rabbit)
Lowest relevant developmental NOAEL / NOEL	Rabbit: 5 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

No data - not required

Other toxicological studies (Annex IIA, point 5.8)

No data - not required

Medical data (Annex IIA, point 5.9)

Limited; new compound

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.014 mg/kg bw	1yr dog	100
AOEL systemic	0.03 mg/kg bw/d	90d + 1y dog, 60% absorption	100
Drinking water limit			
ARfD (acute reference dose)	0.05 mg/kg bw/d	developmental rabbit	100

Dermal absorption (Annex IIIA, point 7.3)

28d dermal and oral rat studies	10 % (based on comparison of oral and dermal toxicity)

Acceptable exposure scenarios (including method of calculation)

Operator	Intended use acceptable (German model; with PPE)
Workers	Intended use acceptable
Bystanders	Intended use acceptable

4 Appendix III.4: Chapter 4 (residues)

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

Plant groups covered	wheat
Rotational crops	lettuce, peas, carrots, soya bean, sugar beet
Plant residue definition for monitoring	picolinafen
Plant residue definition for risk assessment	picolinafen
Conversion factor (monitoring to risk assessment)	none

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

Animals covered	lactating goat
Animal residue definition for monitoring	picolinafen
Animal residue definition for risk assessment	picolinafen
Conversion factor (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	yes

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

.....	Uptake of residues after 30 days from treated soil or after 11 months replant after wheat treatment reveals no or very low TRR in the succeeding crops. Highest TRR were found at 0.006 mg/kg in carrot (DAT 78) or soya bean straw (DAT 159).

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

.....	Storage stability of residues of picolinafen in is proven over the period of 21 months. The samples collected in the residue trials have been analysed within 14 d and 8 months being covered by the storage stability tests.

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	no study conducted	no study conducted	no study conducted
Liver	no study conducted	no study conducted	no study conducted
Kidney	no study conducted	no study conducted	no study conducted
Fat	no study conducted	no study conducted	no study conducted
Milk	no study conducted	no study conducted	no study conducted
Eggs	no study conducted	no study conducted	no study conducted

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)
winter wheat	N S	12 x <0.05 mg/kg 5 x <0.05 mg/kg		0.05 mg/kg	0.05 mg/kg
winter barley	N S	12 x <0.05 mg/kg 2 x <0.05 mg/kg			

(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

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

ADI	0.014 mg/kg bw/d
TMDI (European Diet) (% ADI)	0.0015 mg/kg bw → 11 %
NEDI (% ADI)	not calculated
Factors included in NEDI	not applicable
ARfD	not assigned
Acute exposure (% ARfD)	not applicable

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
no study conducted			

* 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)

0.05 mg picolinafen/kg cereals grain

5 Appendix III.5: Chapter 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	aniline label: 17.4 % (61 d) (n=1) pyridine label: 22.8 - 43.0 % (100 d) (n=4)
Non-extractable residues after 100 days	aniline label: 43.9 % (61 d), max. 65 % (134 d); pyridine label: 21.2 % (100 d), max. 22.7 (60 d) (n=1)
Major metabolites - name and/or code, % of applied (range and maximum)	CL 153815 (range 23.9 (14 d) – 43.6 % (30 d), max. 43.6 %), end of study: 1.4 - 4.9 % (150 d, 122 d), (n=4)

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

Anaerobic degradation	DT_{50}: 6 – 7 days (2nd order) DT_{90}: 58 – 73 days (2nd order) CL 7693 (range 0 - 8 %, max. 8 %, day 120) CL 153815 (range 35 - 88 %, max. 88 %, day 63)
Soil photolysis	stable to photolysis (DT50: 30.2 days)

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

Method of calculation	picolinafen: Bayer program (version 2.0) method of Timme & Frehse (best-fit) CL 153815: linear regression
Laboratory studies (range or median, with n value, with r^2 value)	DT_{50lab} (20°C, aerobic): 1-14 d (n=4), r^2= >0.95 (√1st order), recalculation by 1st order: Speyer 2.2 (aniline-^{14}C): 46 d (r^2= 0.9574) Speyer 2.2 (pyridine-^{14}C): 50 d (r^2= 0.8198) Engelstadt/Benz: 51d (r^2= 0.4937) Ingelheim/Moers: 47 d (r^2= 0.5475) Kloppenheim/Untere Gewann: 46 d (r^2= 0.5656) CL 153815 (20°C, aerobic): 30-77 days (n=4), r^2= >0.96
	DT_{90lab} (20°C, aerobic): 34-149 d (n=4), r^2=>0.95
	DT_{50lab} (8°C, aerobic): pyridine label, 7 d (√1st order), n=1, r^2= >0.95
	DT_{50lab} (20°C, anaerobic): aniline label, 7 d (√1st order), r^2=0.98, n=1, pyridine label, 6 d, r^2=0.99, n=1 (2nd order)
	degradation in the saturated zone: not measured
Field studies (state location, range or median with n value)	DT_{50f}: 9-64 d (n=8), average 30 d (1st order) locations: 4 in Germany, 3 in France, 1 in UK CL 153815: 19-107 ~~82~~ d (N=8)
	DT_{90f}: 56-212 d (n=8) average, 107 d
Soil accumulation and plateau concentration	DT_{50} is < 3 months and DT_{90} is < 1 yr., picolinafen is not expected to accumulate in the soil

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_d /K_{oc}	picolinafen k_d: 248 - 764 l/kg , K_{OC}: 15,000 - 31,800 l/kg (n = 4) CL 153815 k_d: 6.3 - 16.2 l/kg, K_{OC}: 160 - 783, mean 440 kg/l (n = 4)
pH dependence (yes / no) (if yes type of dependence)	Yes. Stronger binding was observed in acidic soils

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

Column leaching	column leaching study with picolinafen 750 g ai/kg WG formulation showed <0.1 % applied radioactivity in leachate (~200 mm percolate).
Aged residues leaching	leachates contained 0 - 0.09 % of applied radioactivity (~200 mm percolate)
Lysimeter/ field leaching studies	not required. Field studies showed no picolinafen in depth below 10 cm

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	actual: C = Co * e^{-kt}, twa: Initial PECs * (1 - e^{-k*t})/(k*t)
Application rate	0.1 kg as/ha (750 g as/kg WG), DT_{50}: 64 days

$PEC_{(s)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.133	0.133	intended use = single application	intended use = single application
Short term				
24 h	0.132	0.133		
2 d	0.130	0.132		
4 d	0.127	0.130		
Long term				
7 d	0.123	0.128		
28 d	0.098	0.115		
50 d	0.077	0.103		
100 d	0.045	0.081		

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)	Stable at pH 4, 7 and 9 (5 d, 50 °C)
Photolytic degradation of active substance and relevant metabolites	Xe-lamp (λ > 290 nm), continuous irradiation, DT_{50}: pH 5 buffer: 25 d pH 7 buffer: 31 d pH 9 buffer: 23 d
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT_{50} water	1.1 – 1.4 d (sqrt 1st order, n = 2)

- DT_{90} water - DT_{50} whole system - DT_{90} whole system	6.2 d (1st order, n = 2)
Mineralization	2.5 % AR after 100 d
Non-extractable residues	64 – 83 % AR after 100 d
Distribution in water / sediment systems (active substance)	Water: 22.7 – 52.2 % AR (day 0 sample), 0 % AR after 30 d; sediment: max. 39 – 68.6 % AR (day 0 sample), 0 – 1.9 % AR after 100 d
Distribution in water / sediment systems (metabolites)	Metabolite CL 153815 Water: max. 31.5 – 41.4 % AR (day 7), 0 – 9.3 % AR after 100 d; sediment: max. 83.1 % AR (day 100) and 47.9 % AR (day 62)

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

Method of calculation	4 % spray drift at 1 m and 0.6 % at 5 m distance, 30 cm deep static water body (300 l/m²); Active substance: DT_{50} = 1.4 d, sqrt 1st order; Metabolite: 100 % conversion, DT_{50} = 25 d, 1st order CL 153815: Consideration of molar mass ratio (376:283)
Application rate	1 x 0.1 kg as/ha
Main routes of entry	Spray drift

$PEC_{(sw)}$ (µg/l)	Picolinafen				Metabolite CL 153815			
	Single application Actual		Single application Time weighted average		Single application Actual		Single application Time weighted average	
	1 m	5 m	1 m	5 m	1 m	5 m	1 m	5 m
Initial	1.333	0.2			1.001	0.15		
Short term	0.734	0.11	0.913	0.137	0.973	0.146	0.986	0.148
24 h								
2 d	0.580	0.087	0.780	0.117	0.947	0.142	0.973	0.146
4 d	0.413	0.062	0.634	0.095	0.894	0.134	0.947	0.142
Long term	0.280	0.042	0.507	0.076	0.826	0.124	0.907	0.136
7 d								
14 d	0.147	0.022	0.360	0.054	0.680	0.102	0.826	0.124
21 d					0.560	0.084	0.760	0.114
28 d					0.461	0.069	0.693	0.104
42 d					0.313	0.047	0.593	0.089

PEC (sediment)

Method of calculation	Portion of the active substance in the sediment layer according to the “worst-case” water/sediment study

Application rate	1 x 0.1 kg as/ha corresponding to initial PEC_{SW} (parent) of 0.92 µg/l, 4 % drift, 1 m buffer and 0.6 %, 5 m buffer CL 153815: Consideration of molar mass ratio (376 : 283)

PEC_{SED}	Picolinafen			CL 153815		
	Portion in the sediment (% AR)	PEC_{SED} (µg/kg) 1 m	5 m	Portion in the sediment (% AR)	PEC_{SED} (µg/kg) 1 m	5 m
"Initial" (i.e. within minutes)	68.6	21.08	3.2	0.1	0.023	0.004
maximum level	68.6	21.08	3.2	83.1	19.21	2.9
after 100 d	0	0	0	83.1	19.21	2.9

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	PELMO 2.01 calculations with sandy loam (1.5 % C_{org}), precipitation: 872 mm/year (simulation of 10 years with annual application on 5. November in winter wheat
Application rate	0.1 kg/ha (750 g a.i./kg WG)
$PEC_{(gw)}$	
Maximum concentration	<0.001 µg/l
Average annual concentration	<0.001 µg/l

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

Direct photolysis in air	No data
Quantum yield of direct phototransformation	$2.14 \cdot 10^{-6}$
Photochemical oxidative degradation in air	Calculation according to Atkinson's method (AOPWin 1.89): $t_{1/2}$ = 1.0 d ($C_{OH} = 0.5 \cdot 10^6$ cm^{-3}, 24 h day)
Volatilization	from plant surfaces: ≤ 10 % within 24 h
	from soil: ≤ 5 % within 24 h

PEC (air)

Method of calculation	Not relevant
$PEC_{(a)}$	
Maximum concentration	Not relevant

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	picolinafen CL 153815 in soil and water (shows no biological activity, no toxicological and ecotoxicological relevance)

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

Soil (indicate location and type of study)	Not available

Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

6 Appendix III.6: Chapter 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	LD50 >5000 mg/kg bw (rat)
Long term toxicity to mammals	NOEL 20 mg/kg bw/d (developmental toxicity rabbit)
Acute toxicity to birds	LD50 >2250 mg/kg bw (bobwhite and mallard duck)
Dietary toxicity to birds	LC50 >5314 ppm (bobwhite and mallard duck)
Reproductive toxicity to birds	NOEL 864 ppm (bobwhite and mallard duck)

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
0.1	Cereals	Herbivorous bird	acute	>1400	10
0.1	Cereals	Herbivorous bird	short-term	>850	10
0.1	Cereals	Herbivorous bird	long-term	140	5
0.1	Cereals	Insectivorous bird	acute	>1800	10
0.1	Cereals	Insectivorous bird	short-term	>1800	10
0.1	Cereals	Insectivorous bird	long-term	298	5
0.1	Cereals	Herbivorous mammal	acute	>3100	10
0.1	Cereals	Herbivorous mammal	long-term	12.5	5

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				
O. mykiss	a.s.	acute	mortality	0.68
O. mykiss	a.s.	long-term	mortality, growth, behaviour	0.0064
D. magna	a.s.	acute	mortality	> 0.45
D. magna	a.s.	chronic	mortality, growth, reproduction	0.007
C. riparius	a.s.	long-term	development	0.18
S. capricornutum	a.s.	chronic	biomass	0.00018
L. gibba	a.s.	long-term	fronds	0.057
O. mykiss	CL 153815	acute	mortality	>100
D. magna	CL 153815	acute	mortality	>100
S. capricornutum	CL 153815	chronic	biomass	27
O. mykiss	WG 74.4 %	acute	mortality	>0.376
D. magna	WG 74.4 %	acute	mortality	>0.819
S. capricornutum	WG 74.4 %	chronic	biomass	0.00016

Microcosm or mesocosm tests
A test over 116 d in a glasshouse was conducted. Algae, plants and invertebrates were tested. Conclusions can only be reached for a few species. Effects on algae and plants were observed but recovery occurred up to a concentration of 0.18 µg/L. This concentration is relevant for the risk assessment.

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
0.1	field-crops	microcosm	chronic	1	0.005	10
0.1	field-crops	microcosm	chronic	5	0.14	10
0.1	field-crops	microcosm	chronic	20	6	10

Bioconcentration

Bioconcentration factor (BCF)	580
Annex VI Trigger for the bioconcentration factor	100
Clearance time (CT_{50}) (CT_{90})	
Level of residues (%) in organisms after the 14 day depuration phase	< 5 %

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

Acute oral toxicity	LD 50 > 200 µ/bee
Acute contact toxicity	LD 50 > 200µg/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				
0.5	Cereals	oral	0.25	50
0.5	Cereals	contact	0.25	50

Field or semi-field tests
Not required

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						
T. pyri	Proto-nymphs	750 WG	0.1	Mortality Fertility	0 10	30
A. rhopalosiphi	Adults	750 WG	0.1	Mortality Fertility	0 6	30
P. cupreus	Adults	750 WG	0.1	Mortality Food uptake	0 0	30
Pardosa spp	Adults	750 WG	0.1	Mortality Food uptake	0 +1	30

Field or semi-field tests
not required

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

Acute toxicity	LC_{50} > 1000 mg as/kg
Acute toxicity metabolite CL 153 815	LC_{50} 476.5 mg metabolite/kg
Reproductive toxicity	NOEC 0.5 kg as/ha (0.665 mg as/kg)

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

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
0.1	Cereals	14 d	3759	10
0.1	Cereals	8 w	2.5	5

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

Nitrogen mineralization	Active substance picolinafen:	Tolerable effects up to 502.5 g /ha
	Metabolite CL 153815:	Tolerable effects up to 221 g / ha
Carbon mineralization	Active substance picolinafen:	Tolerable effects up to 502.5 g /ha
	Metabolite CL 153815:	Tolerable effects up to 221 g / ha

Appendix 3

LIST OF STUDIES WHICH WERE SUBMITTED DURING THE EVALUATION PROCESS AND WERE NOT CITED IN THE DRAFT ASSESSMENT REPORT: **PICOLINAFEN**

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIIA-2.7.3	Goldsmith, A. E.	2000	Generation of Chemical and Physical Stability Data on a Batch of Picolinafen 750 g/kg WG – 104 week interim report BASF, RLG 4589 GLP, unpublished PHY2000-777

B.6 Toxicology and metabolism

None

B.7 Residue data

None

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIA-2.10, AIIA-7.2.2	Mangels, G.	2000	Picolinafen (AC 900001): Estimation of the Photochemical Oxidation Rate in the Atmosphere BASF, EXA 00-022 no GLP, unpublished LUF2001-79
AIIA-7.1.1.2.2	Anonym	???	Response for PSD's request for additional information on how an 82 day half-life was calculated for CL 153815 in the UK field dissipation study. BASF BOD2001-457

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIIA-9.2.1	Mangels, G.	2001	Calculation of Predicted Environmental Concentrations of Picolinafen and Its Major Soil Metabolite, CL 153815, in Groundwater Following Applications of Picolinafen (BAS 700H) to Cereals in the United Kingdom BASF REPORT NO. EXA 01-010 no GLP (not relevant), unpublished BASF BOD2001-458

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIA-8.6, AIIIA-10.8	Brandt, A	1997	Greenhouse evaluation of the herbicidal activity of the picolinic acid metabolite of AC 900001, CL 153815, in comparison to the parent AC 900001 BASF, CFS 1997-119 not published PFL2000-5
AIIA-8.6, AIIIA-10.8	Stalmans, H.	1999	Effects on other non-target organisms (Flora) with AC 900,001 (Farmer P. Debois) BASF, BE 99 HS 009 1/2 not published PFL2000-6
AIIA-8.6, AIIIA-10.8	Stalmans, H.	1999	Effects on other non-target organisms (Flora) with AC 900,001 (Farmer L. Baes) BASF, BE99HS009 1/2 not published PFL2000-7
AIIA-8.6, AIIIA-10.8	Brandt, A.	1999	Determination of the ED10 values of AC 900001 technical in non-target crops following foliar application BASF, CFS 1999-094 not published PFL2001-43
AIIIA-10.2.1	Wenzel, A. and Klöppel, H.	2001	Alga, growth inhibition effects of AC 900001 750 WG (SF 09617) on Ankyra judayi BASF, EXT-00-337 GLP, unpublished WAT2001-201

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIIA-10.2.1	Schäfers, C.; Klöppel, H.; Hommen, U. and Barber, C.	2001	Community Level Effects of Picolinafen 750 WG (SF 09617) in an Indoor Semi-Realistic Microcosm study BASF, EXT-00-229 GLP, unpublished WAT2001-202
AIIIA-10.6.1.2	Lührs, U.	2000	Effects of AC900001 in a 750g/kg water dispersible granule formulation (RLF 12357) on reproduction and growth of earthworms Eisenia fetida (Savigny 1826) in artificial soil BASF, 7881022 GLP, unpublished ARW2000-177

Appendix 4

SUGGESTED CLASSIFICATION AND LABELLING: Picolinafen

Hazard symbol	**N**	Dangerous for the environment.
Risk phrase	**R50/53**	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

12611/ECCO/2001
24 September 2001

CONCISE OUTLINE REPORT (Co-Rapporteur System)

Peer Review Programme under Directive 91/414/EEC

Subject: **picolinafen**

Rapporteur Member State: **DE**

Co-Rapporteur Member State: **UK**

The following comments were submitted:

Date	Supplier	File
07.03.2001	BASF	01-picolinafen_com_basf-1.doc
07.03.2001	BASF	02-picolinafen_com_basf-2.doc
07.03.2001	BASF	03-picolinafen_com_basf-3.doc
07.03.2001	BASF	04-picolinafen_com_basf-4.doc
30.03.2001	Greece	05-picolinafen_com_gr.doc
30.03.2001	United Kingdom	06-picolinafen_com_uk.doc
30.03.2001	Denmark	07-picolinafen_com_dk-1.doc
30.03.2001	Finland	08-picolinafen_com_fin.doc
02.04.2001	Denmark	09-picolinafen_com_dk-2.doc

1. Definition of the residues

Residues relevant to the environment:	Picolinafen, CL153815 (soil and water)
Residues relevant to worker safety:	Not relevant
Residues of ecotoxicological relevance:	Picolinafen, (metabolite CL153815 to be confirmed)
Residues relevant to MRLs:	Picolinafen.

2. Data on preparations:

Physical and Chemical properties	One data requirement is still open
Fate and Behaviour	Two data requirements are still open.
Mammalian Toxicology	The data set was considered to be complete.
Ecotoxicology	Two data requirements are still open.
Residues	The data set was considered to be complete.

3. Classification and labelling:

Physical and Chemical properties	No proposal
Fate and Behaviour	No proposal
Mammalian Toxicology	No proposal
Ecotoxicology	R50/53

4. Recommended restrictions/conditions for use:

Physical and Chemical properties	None.
Fate and Behaviour	None.
Mammalian Toxicology	None.
Ecotoxicology	Risk mitigation measures (aquatic) are to be set on MS level.
Residues	None.

Areas of concern: Risk to aquatic organisms

Appendix 1: Reporting table: picolinafen

Appendix 2: List of end points: picolinafen

Appendix 3: List of studies which were submitted during the evaluation process and were not cited in the draft assessment report: picolinafen

Appendix 4: Suggested classification and labelling: picolinafen

Reporting table, Picolinafen (Hb)

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section 1

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(i)	Vol 1, Appendix 3, list of endpoints	NOT*: Notifier's intention is not to support co-formulations with Cyanazine in the EU registration procedure but only for national registration. Thus, Notifier would like to have the table of uses supported by available data revised.	(ii) 30.05.2001 List of intended uses will be revised concerning the Notifier's intention.	--
(ii)	B.1.1.1 Name and address of applicant ...	NOT*: Under Contact person, the telephone and fax number are to be modified as follow: Tel- *32-81-625332 Fax- *32-81-625340 e-mail- catherine.deprez@central-europe.basf.org	(i) 31.05.01 Agree with the rapporteur (ii) 20.04.2001 To be considered in case assessment report (monograph) is revised.	--
(iii)	B.1.1.4 Manufacturer's development code number	NOT*: Further to the acquisition by BASF, a new code has been allocated to the active ingredient, Picolinafen: BAS 700 H	(i) 31.05.01 Agree with the rapporteur. (ii) 20.04.2001 To be considered in case assessment report (monograph) is revised.	--

Comments on typing errors are not included in the reporting table; NOT*: notifier

rapporteur: DE, co-rapporteur UK

section 1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(iv)	B.2.1.1.3 Temperature of decomposition or sublimation	UK: It would appear that there is decomposition occurring at 135 °C, which is before the decomposition point proposed in the monograph.	(i) 31.05.01 UK comment. (ii) 21.05.2001 It seems to be that the decomposition starts at 135 °C (formation of small crystalline particles). On the other hand, according to the DSC only two peaks occur (~ 107 °C phase transition and ~ 325 °C decomposition).	--
(v)	B.2.1.7 Solubility in organic solvents of the as manufactured	UK: There is an unexpected difference in solubility in organic solvents between the pure active substance and the technical material, which can not be explained by the difference in purity. The tests should to be repeated.	(i) 31.05.01 UK comment. (ii) 20.04.2001 The necessity for the requirement cannot be seen, because only the solubility of the technical material is demanded according to Annex II	(i) Data requirement: Repeat tests should be conducted on the technical active substance and purified active substance to confirm the correct solubility in organic solvents. (ii) 30.08.01 No agreement. The necessity for the requirement cannot be seen.

Comments on typing errors are not included in the reporting table; NOT*: notifier

rapporteur: DE, co-rapporteur UK

Reporting table, Picolinafen (Hb)

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section 1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(vi)	Vol. 3, B.3.2.9 Proposed instructions for use	GR: - Please clarify the GAP (Table B.3.3), because the estimated kg as/ha from the column of kg as/hL and the water L/ha are not correct? The actual application rate is x 10.	(i) 31.05.01 The table requires further clarification with regard to rates and water volumes. (ii) 30.05.2001 The details given for the application rates in the list of intended uses are correct for Northern Countries (see also intended uses listed in the endpoints, Vol. 1). However, at MS-level (southern countries) the company will submit a full Annex III dossier on a co-formulation.	--
(vii)	Vol. 3, B.5.1.1.2 Methods for the determination of impurities	UK: - For impurities A19 and A30 in the technical material there is no evidence to demonstrate that they can be accurately quantified using calibration curves for A26 and A 27. Validation data is now available for these impurities.	(i) 31.05.01 UK comment. (ii) 04.05.2001 The study has to be submitted by the notifier	Data requirement: Validation data for the impurities A19 and A30 are necessary. (AIIA 4.1.3)

Comments on typing errors are not included in the reporting table; NOT*: notifier

rapporteur: DE, co-rapporteur UK

Reporting table, Picolinafen (Hb) *CONFIDENTIAL* 11592/ECCO/BBA/01, rev. 2-1 (30.08.01) 4/32

section 1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(viii)	Vol. 3, B.5.5.2 and Vol. 1, 2.2.3	NOT*: -Enforcement method for the air allows a LOQ of 2 µg/l. Based on the reviewed of the AOEL systemic to 0.03 mg/kg bw/day. I would like to have the comment "*based on a proposed AOELsystemic of 0.008 mg/kg bw/d*" removed.	(i) 31.05.01 Inhalation exposure already taken into account in OpEx models and risk assessment. There is no indication from acute studies that picolinafen is more hazardous via the inhalation route than the oral route. There are no grounds for considering this as a separate issue. (ii) 20.04.2001 To be considered in case assessment report (monograph) is revised.	--
		Could you delete the last sentence "Validation data for air down to the toxicological relevant concentration of 2.4 µg/m^3 are missing"?	(i) 31.05.01 Agree with the rapporteur. (ii) 20.04.2001 To be considered in case assessment report (monograph) is revised.	--
		UK: -It is stated that the limit of quantification for air at 2 µg/m^3 is too high as the toxicological relevant concentration is 2.4 µg/m^3. It is not clear why the Limit of Quantification is to high as the toxicological significant level is higher than 2 µg/m^3.	(i) 31.05.01 Typing error should be corrected. (ii) 20.04.2001 Sorry, typing error. To be considered in case assessment report (monograph) is revised.	--

Comments on typing errors are not included in the reporting table; NOT*: notifier

rapporteur: DE, co-rapporteur UK

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section 1

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(ix)	Vol. 3, B.5.5.2	NOT*: - Table B.5.5-2 - The studies referred in this section were used to generate the EU dossier submitted to the RMS and subsequently to MSs for Provisional approval. Therefore, we would like to claim data protection for those studies. Could you have them mention in *B.5.6, references relied on?*	(i) 31.05.01 As these methods are part of the supporting studies they should gain data protection (ii) 20.04.2001 No, because there is no need for this methods. The mentioned GC methods fulfil the requirements.	--
		UK: -The LC-MS-MS methods can now be accepted as the requirements have recently changed.	(i) 31.05.01 UK comment. (ii) 20.04.2001 Yes, but there is no need for this methods. The mentioned GC methods fulfil the requirements.	--

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rapporteur: DE, co-rapporteur UK

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section 2

2. Environmental fate and behaviour

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(i)	Vol 1, 2.5.2 Fate and behaviour in soil	UK: The metabolite CL15815 has an accumulation potential: Field study in UK show a DT_{50} of 107 d, but the „overall decline“ from the peak concentration show that the DT_{90} is > 1 year.	(i) no comment (ii) 09.04.2001 Agreed, but according to its biological activity and the lower toxicity for earthworms and microorganisms the metabolite is considered not to be ecotoxicologically relevant for the soil compartment. In Vol. 1 List of End Points, Definition of the Residue, “shows no biological activity” is added.	--
(ii)	Vol 1, 2.5.4 Fate and behaviour in air	NOT*: A new AOP study with a DT_{50} of 2 days was submitted: “G. Mangels: Picolinafen (AC900001): Estimation of the Photochemical Oxidation Rate in the Atmosphere, 14. August 2000, BASF Report No. EXA 00-022” and should be added.	(i) no comment (ii) 09.04.2001 Agreed. The study was evaluated by RMS and the value is reported in the Addendum and List of End Points.	--
(iii)	Vol 1, Appendix 3, List of End Points, 2.8.3.5	Degradation in soil (route) DK: 1. Non-extractable residues: Presentation of maximum values + day of occurrence and values at the end of the study. 2. Major metabolites: Information about the time, when the maximum values occurred and values at the end of the study.	(i) no comment (ii) 09.04.2001 Agreed. Information is added (incl. updated data on mineralization).	--

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rapporteur: DE, co-rapporteur UK

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
		Rate of degradation in soil UK: The DT_{50} of picolinafen determined in the "route of degradation" study should be considered in the endpoint list (1^{st} order: 44-49 days)	(i) no comment (ii) 09.04.2001 Agreed, but the DT_{50}-values were considered (10 and 14 days), calculated by square root kinetics (best fit). DT_{50} values (1^{st} order) are added as additional information.	--
(iii)	*cont.* Vol 1, Appendix 3, List of End Points, 2.8.3.5	Rate of degradation in field (met. CL153815) UK: The $DT_{50,field}$ value (82 d) of the metabolite CL153815 was calculated with PRZM and do not take into account differences in molecular weights between parent and metabolite. A study was submitted in UK with calculation using Modelmaker (new DT_{50}: 107 days)	(i) no comment (ii) 09.04.2001 The study has to be submitted by the notifier and has to be evaluated by RMS. (ii) 16.07.2001 The study [Anonym, "Response for PSD's requerst for additional information on how an 82 day half-life was calculated for CL 153815 in the UK field dissipation study", BASF] was submitted and evaluated by RMS. The study is reported in the addendum. The new DT_{50}-value of 107 days is reliable and was added in the Endpoint list.	--
		Sorption in soil UK: Inclusion of the lowest K_d/K_{OC}-value of picolinafen (248/15000)	(i) no comment (ii) 09.04.2001 Agreed. Values are added.	--

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rapporteur: DE, co-rapporteur UK

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section 2

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
		PEC_{soil} UK: Addition of the assumptions used for PEC_{soil} calculations.	(i) no comment (ii) 09.04.2001 Agreed. The DT_{50}-value is added and minor changes are made in the values presented.	--
(iii)	*cont.* Vol 1, Appendix 3, List of End Points, 2.8.3.5	UK: New PEC_{soil} calculations for metabolite CL15815 with more realistic assumptions (DT_{50}: 180 days, initial conc. = 54 % of applied a.s.)	(i) no comment (ii) 09.04.2001 Agreed. New PEC_{soil} calculations for metabolite CL15815 has to be submitted by the notifier. (ii) 16.07.2001 The study [Anonym, "Response for PSD's requerst for additional information on how an 82 day half-life was calculated for CL 153815 in the UK field dissipation study", BASF] was submitted and evaluated by RMS (see addendum). The new DT_{50}-value of 107 days is reliable and should be used as worst case assumption for PEC_{soil} calculation.	Data requirement: New PEC_{soil} calculations for metabolite CL153815 with more realistic assumptions (DT_{50}: 107 days, initial conc. = 54 % of applied a.s.)
		Water-sediment study UK: Maximum level of parent in sediment is 68.6 % AR and not 68.8 %	(i) no comment (ii) 09.04.2001 Agreed. The value is corrected.	--

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rapporteur: DE, co-rapporteur UK

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(iii)	*cont.* Vol 1, Appendix 3, List of End Points, 2.8.3.5	PEC_{sw} UK: PEC_{sw} calculations were conducted with a 5 m buffer and not with a 1 m buffer (parent and metabolite CL15815)	(i) no comment (ii) 09.04.2001 Agreed. PEC_{sw} for a 1 m buffer are added (calculated by RMS).	--
		PEC_{sed} UK: Are the PEC_{sed}-calculations in agreement with the ECCO criteria?	(i) no comment (ii) 09.04.2001 The approach used is according to the ECCO-criteria, but a 1 m buffer has to be considered. Assumptions and updated values (calculated by RMS) are reported.	--
		Photochemical oxidative degradation in air NOT*: A new AOP study with a DT_{50} of 2 days was submitted: "G. Mangels: Picolinafen (AC900001): Estimation of the Photochemical Oxidation Rate in the Atmosphere, 14. August 2000, BASF Report No. EXA 00-022" and should be added.	(i) no comment (ii) 09.04.2001 Agreed. The study was evaluated by RMS and the value is reported in the addendum and List of End Points.	--

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rapporteur: DE, co-rapporteur UK

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(iv)	Vol 3, B.8.1.2.2 Field studies, Table B.8.1-13	Rate of degradation in field (met. CL153815) UK: The $DT_{50,field}$ value (82 d) of the metabolite CL153815 was calculated with PRZM and do not take into account differences in molecular weights between parent and metabolite. A study was submitted in UK with calculation using Modelmaker (new DT_{50}: 107 days)	(i) no comment (ii) 09.04.2001 The study has to be submitted by the notifier and has to be evaluated by RMS. (see iii). (ii) 16.07.2001 The study [Anonym, "Response for PSD's requerst for additional information on how an 82 day half-life was calculated for CL 153815 in the UK field dissipation study", BASF] was submitted and evaluated by RMS. The study is reported in the addendum. The new DT_{50}-value of 107 days is reliable and was added in the Endpoint list.	--

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rapporteur: DE, co-rapporteur UK

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(v)	Vol 3, B.8.3 PECs in soil, Table B.8.3-2	UK: New PEC_{soil} calculations for metabolite CL15815 with more realistic assumptions (DT_{50}: 180 days, initial conc. = 54 % of applied a.s.)	(i) no comment (ii) 09.04.2001 Agreed. See (iii). (ii) 16.06.2001 The study [Anonym, "Response for PSD's requerst for additional information on how an 82 day half-life was calculated for CL 153815 in the UK field dissipation study", BASF] was submitted and evaluated by RMS (see addendum). The new DT_{50}-value of 107 days is reliable and should be used as worst case assumption for PEC_{soil} calculation.	Data requirement, see above, (iii)
(vi)	Vol 3, B.8.6.1 PECs in surface water (PEC_{SW}), Table B.8.6-2	UK: PEC_{sw} calculations were conducted with a 5 m buffer and not with a 1 m buffer (parent and metabolite CL15815)	(i) no comment (ii) 09.04.2001 Agreed. See (iii).	--
(vii)	Vol 3, B.8.6.2 PECs in sediment (PEC_{SED}), Table B.8.6-5	UK: Are the PEC_{sed}-calculations in agreement with the ECCO criteria?	(i) no comment (ii) 09.04.2001 See (iii).	--

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rapporteur: DE, co-rapporteur UK

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(viii)	Vol 3, B.8.6.3 PECgw	UK: This section summarises the applicant's groundwater modelling. It is not entirely clear how the RMS has concluded that the metabolite CL 153815 is unlikely to exceed 0.1 µg/l in groundwater given the criticism with certain input parameters. The RMS may wish to note that the applicant has submitted revised modelling with more appropriate input parameters that confirm that contamination above 0.1 µg/l is not expected.	(i) no comment (ii) 27.08.2001 The evaluation of the lately submitted study of Mangels (2001, BASF Report EXA 01-010) indicated some deficiencies of the study, e.g., the calculation does not consider the reduction of the DT50 of metabolite CL153815 with increasing soil depth. Therefore, the notifier is asked to check the simulation.	Data requirement: Revised modelling of potential for groundwater contamination of metabolite CL 153815 with more appropriate input parameters (amendment to study of Mangels, 2001).

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section 3

3. Ecotoxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
(i)	Vol. 1, Appendix 3, List of End Points	DK: - Bioconcentration: Are there any information on the clearance CT_{50} and/or CT_{90} for the active substance and for ^{14}C-compounds?	(i) 04.07.2001 no comment (ii) 24.04.2001 Radioactivity decreased by 95 % during 14 days. Therefore depuration is acceptable.		--
		- Algae: In the risk assessment a TER value of 11 in a distance of 20 meter is presented. This value is a higher tier assessment using a time weighted average concentration (PEC_{twa} of 0.016 µg/L). It would be informative to mention the arguments for using this value, and the tier 1 TER value of 5.5.	(i) 04.07.2001 no comment (ii) 24.04.2001 The crucial toxicity value for the risk assessment was extracted from microcosm test with a static exposure regime. Therefore PECini are relevant for the risk assessment (see Addendum 1 to the Monograph).		--
		- Earthworms: The 8 weeks TER value of 2.5 is lesser than the Annex VI trigger value of 5. Please specify the arguments (NOEC based on increase in body weight) for accepting this value.	(i) 04.07.2001 no comment (ii) 29.05.2001 The NOEC reproduction is based on body weight increase. Experience shows that such an increase may occur but according to these state of scientific knowledge it is an effect which does not appear in field tests.		--

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rapporteur: DE, co-rapporteur UK

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section 3

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
(ii)	B.9.1 Effects on birds	UK: - Picolinafen has the potential to bioaccumulate, therefore some consideration of the risk to fish-eating birds were useful.	(i) 04.07.2001 no comment (ii) 20.04.2001 When monograph will be revised the fish-eating scenario will be included.		--
		- Some comments to confirm that no major metabolites were identified in plants would have shown that this area had been considered.	(i) 04.07.2001 no comment (ii) 30.05.2001 When the monograph will be revised comments will be given to this issue.		--
		UK: - In addition to the potential risk on fish-eating birds, it is from interest to know the RMS's opinion about the risk to earthworm-eating birds.	(i) 04.07.2001 The UK Advisory Committee on Pesticides has now requested that the potential for biomagnification in earthworms and the exposure of earthworm-eating birds is considered as part of the Co-Rapporteur process. The reason for this is that the log p_{ow} trigger of > 3 is clearly exceeded. Given the low toxicity to birds PSD are of the opinion that this route of exposure does not represent a significant risk to birds. We would welcome RMS's views on this. (ii) 23.07.2001 Agreement		--

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
(iii)	B.9.2 Effects on aquatic organisms	NOT*: The results of a microcosm study have shown an EAC for aquatic systems of 7 ppb. Thus a buffer zone of less than 1 meter would be needed.	(i) 04.07.2001 no comment (ii) 24.04.2001 The EAC is 0.18 µg/L (see addendum to the monograph) leading in a distance of 20 m to TERs lower than the relevant trigger (if new drift values are used TERs are acceptable in a large distance).		--
		UK: - It is asked to check the following points Table B.9.2.1: The NOEC and LC_{50} for *L. macrochirus* should be 0.57 and >0.57 mg as/L, respectively.	(i) 04.07.2001 no comment (ii) 24.04.2001 In the table the nominal values were used whereas UK proposes the measured ones. In any case it is not important for the overall conclusion.		--
		Table B.9.2.2: The species tested in Reference 1999-524 was *Selenastrum capriconutum* and not *O. mykiss* as stated.	(i) 04.07.2001 no comment (ii) 24.04.2001 Will be changed.		--
	cont.	- You will be aware that some new studies	(ii) 24.04.2001		Data requirement:

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
(iii)	B.9.2 Effects on aquatic organisms	have been submitted to the UK. These were an acute algal study using *A judayi* (Wenzel 2001) and a microcosm study (Schafers *et al* 2001). Our evaluation of these studies is included in the draft UK. PSD are of the opinion that these data are sufficient to demonstrate that restrictive aquatic buffer zone labelling is not required for the proposed use on cereals.	Additional studies are discussed in the addendum to the monograph. It is the opinion of the RMS that no clear changes of the proposed buffer zone are warranted. (i) 04.07.2001 However, there is clearly a difference in our respective interpretations of the results obtained. *Ankyra judayi* was clearly more sensitive than either *Selenatrum capricornutum* or *Anabaena flos aquae* is first tier tests. *A judayi* was one of the main species present in the microcosm study where it made a major contribution to the overall PRC. Thus, the study was considered to present a good basis for making a regulatory decision for this species. Adverse effects on the numbers of *Ankyra* cells present were detected at concentrations down to 0.0018 mg as/L. However, even at the highest concentration tested (0.007 mg as/L), the density of *Ankyra* after 6 weeks had returned to that found in the control. Thus, we would disagree with the statement in the Addendum that "No recovery was observed for higher concentrations". Given the fact that this was an indoor test system with limited opportunity for recolonisation, this study provides strong evidence that impacts will be transient and that recovery is possible. It adds further support to		The notifier is requested to submit data on the question how representative *Ankyra judayi* for other algae species is. (Annex IIA-8.2, Annex IIIA-10.2) (MS-Level)
(iii)	*cont.* B.9.2 Effects on aquatic				

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rapporteur: DE, co-rapporteur UK

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
	organisms		the evidence from the *Selenastrum* recovery study (Baker *et al* 1999), which could not itself be directly used due to the fact the cells were removed and placed in clean water, hence the true "time-to-effect" could not be established. The EAC from the microcosm study is considered to be 0.007 mg as/L (not 0.00018 mg as/L as stated in the Reporting Table: the value of 0.00018 mg as/L is considered to be the NOEC for this species). Thus the EAC is greater than the spray drift PECsw of 0.0013 mg as/L at 1 metre by a factor of 5. When account is taken of the fact the only a single application per crop is recommended, the EAC is directly relevant for the risk assessment. The UK National Pesticide Committees have therefore concluded that the risk to aquatic life is acceptable without restrictive buffer zone labelling. (Any future use for more frequent application would require a new risk assessment and most probably additional higher tier toxicity studies.) (ii) 20.07.2001 The report on the microcosm study is very difficult to read because data on cell number are only available on a CD which is structured in a unsatisfying way. Furthermore, the cell numbers especially for *Ankyra* are not summarised in one table. Putting together these		
(iii)	*cont.* B.9.2 Effects on aquatic organisms				

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rapporteur: DE, co-rapporteur UK

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
			values the following conclusions can be reached: • The variability in the controls increases considerably especially at day 28 and later; • The variability in the treatments is also considerably, therefore only clear differences are detectable; • From a statistical point of view the highest treatment level cannot be used as NOEC because there is only one replicate available; • For the treatment levels 0.072 and 0.18 µg/L there are clear effects between day 2 and 7 and clear recovery thereafter; • For the treatment levels 0.45, 1.13, and 2.81 clear effects were determined starting with day 2 but no recovery until the end of the study; there is an exception in one replicate on day 42 and 56 with 1.13 µg/L; • For the treatment level 7.03 also clear effects were observed starting with day 2; however, on day 42 high cell numbers were determined The "recovery" in the one replicate of the highest test concentration should not be used as base for setting the NOEC because it is not consistent with the data generated in the 6 replicates for the lower test concentrations.		
(iii)	*cont.* B.9.2 Effects on aquatic organisms				

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
			Therefore, 0.18 µg/L should be used as NOEC. The TER-value in a distance of 20 m is below the relevant trigger value of 10. However, the TER is based on a NOEC value and algae are the most sensitive organisms. According to Annex VI the EC_{50} should be used to assess the risk for algae but it is unlikely that a valid EC_{50} for the most sensitive algae species *Ankyra judayi* can be extracted from the microcosm test results. The data from the standard laboratory test with this species allow for a comparison between NOEC and EC_{50}. The difference between these values for different endpoints and time points was 2 at a minimum. Taking into account this factor the TER of 6 should be regarded as acceptable. The notifier is requested to submit data on the question how representative is *Ankyra judayi* for other algae species. (i) 20.08.2001 After further discussion with RMS, the co-RMS agrees that 0.18 µg/L should be used as NOEC for the microcosm study.		
(iii)	*cont.* B.9.2 Effects on aquatic organisms				

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
(iv)	B.9.4 Effects on bees	GR: - Please clarify the results on Table B.9.4-6. According to article 10.4 (Annex III of Directive 91/414/EEC) and the worst case scenario: Q_{HO}=Dose (g/ha)/LD_{50} oral (µg as/bee)= 100/100 = 1 Q_{HC}=Dose (g/ha)/LD_{50} contact (µg as / bee)= 100/200 = 0.5	(i) 04.07.2001 no comment (ii) 08.05.2001 The calculation of the hazard quotient on the basis of 0.1 kg as/ha will not change the classification “no risk for honey bees” because the quotient is clearly below the trigger-value of 50.		--
(v)	B.9.5 Effects on other arthropod species	GR: - Please justify why there is no study of any foliage dwelling predator	(i) 04.07.2001 no comment (ii) 29.05.2001 Because of the time of application (early spring and autumn) foliage dwelling predators are not likely to be exposed by direct spray, contact on fresh or dry residues. Oral uptake via host organisms is considered of minor importance. Furthermore, three ecological groups of non-target-arthropods are not effected by picolinafen.		--

Comments on typing errors are not included in the reporting table; NOT*: notifier

rapporteur: DE, co-rapporteur UK

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section 3

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)	
(vi)	B.9.6 Summary and risk assessment for earthworms	UK: - There is some evidence to indicate that the major soil metabolite CL 153815 may have a field DT_{90} > 365 days.	(i) 12.05.2001 Only if DT_{90} > 365 days the long-term risk from metabolite will need to be considered further. (ii) 29.05.2001 Notifier is to be requested to submit new calculations of the DT_{90} of the metabolite CL 153815. If DT_{90} > 365 days further studies with earthworms have to be submitted.		Data requirement: a) Notifier is requested to submit a new calculation of the field DT_{90} for the metabolite CL 153815. b) If the metabolite CL 153815 should have a field DT_{90} > 365 days the long term risk will need to be considered further. (Annex IIA-8.4, Annex IIIA-10.6)
(vii)	B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk	GR: - It is good to know these results but according to the fact that there is not any acceptable Guideline for higher plant, how can we interpret further? There must a residue definition in order to estimate the relevance to the environment.	(i) 04.07.2001 no comment (ii) 29.05.2001 As there is no guideline (up to now a draft of EPPO exists) further evaluation should be done on member state level. Remark: An additional assessment is done based on probit-calculations (see Addendum 1 to the Monograph)		--
(viii)	B.9.10 Effects on biological methods of sewage treatment	GR: - Please justify why the effects on biological methods of sewage treatment are “not relevant”. According to the other herbicide, dimethenamid-P, one study was included.	(i) 04.07.2001 no comment (ii) 24.04.2001 A nitrification test in accordance with ISO 9509 is available and a NOEC of 1 mg/L (LOEC 10 mg/L) was determined after 4 hours.		--

Comments on typing errors are not included in the reporting table; NOT*: notifier

rapporteur: DE, co-rapporteur UK

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4. Mammalian toxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(i)	B.6.5.1 2-Year Feeding Study in Rats *cont.*	UK (04.04.2001): Overall, 1.9 mg/kg bw (= 50 ppm from 13 – 24 months) is considered the **NOAEL** for chronic toxicity in this study based on the increased severity of hamosiderin deposition at 2.3 mg/kg bw/day (= 50 ppm from 0 – 12 months).	(i) (06.06.2001) RMS does not accept UK proposal on the basis that the increase in hemosiderin deposition in males and females at 50 ppm at interim sacrifice after 12 months was not considered to be biologically adverse because this effect was transient and not associated with a decrease in red blood cell parameters. The UK accepts the RMS arguments supporting the non-adversity of this finding and does not contest this issue further. (ii) (16.05.2001): The proposal of a NOAEL of 1.9 mg/kg bw is not accepted. The **NOAEL** for chronic toxicity from this study was 50 ppm or approximately 2.4 mg/kg bw/d. The increase in hemosiderin deposition in males and females at 50 ppm at interim sacrifice after 12 months was not considered to be biologically adverse because this effect was transient and not associated with a decrease in red blood cell parameters. Furthermore, spleen weights were not increased at 50 ppm. At terminal sacrifice after 2 years no differences in hemosiderin deposition in the spleen were observed between controls and 50 ppm.	

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rapporteur: DE, co-rapporteur UK

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(i)	B.6.5.1 2-Year Feeding Study in Rats			
(ii)	B.6.10 Summary of Mammalian Toxicology and Proposed ADI, AOEL ARfD and Drinking Water Limit (Annex IIa 5.10)	FIN (27.03.2001): With a safety factor of 100, an **ARfD** of 0.05 mg/kg/day may be set for acute hematological effects, based on the NOEL of 5.2 mg/kg/day in dog which seems to be the most sensitive species for these type of effects.	(i) (06.06.2001) Finland proposes **ArfD** based on haematological effects from a dog study, RMS seconds this (but bases it on Rabbit teratology study). UK ACP concurs that an ArfD should be set and considers it to be 0.1 mg/kg/day based on the NOAEL for haemolysis of 11 mg/kg/day in the rat 28 day dietary study with a safety factor of 100. This is considered the more appropriate study to use, given the wide dose spacings in the dog dietary study and the rabbit teratology study. (ii) (16.05.2001): The proposal of an **ARfD** is accepted. The ARfD of 0.05 mg/kg/day set for acute haematological effects should be based on the NOEL of 5.0 mg/kg/day in rabbit oral teratology study with a safety factor of 100.	

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(iii)	B.6.10 Summary of Mammalian Toxicology and Proposed ADI, AOEL ARfD and Drinking Water Limit (Annex IIa 5.10) *cont.*	UK (04.04.2001): A short term systemic **AOEL** of 0.01 mg/kg bw/day is proposed. The AOEL is based on the NOAEL from the 90 day time point in the year dog study. The NOAEL from the 90 day time point in the year dog study is 1.8 mg/kg bw/day and is based on the reduction in body weight, body weight gain and food efficiency in males.	(i) (06.06.2001) The UK proposed a 90 day interim OAEL in the one year dog study of 1.8 mg/kg/day based on reductions in body weight gain and food efficiency in males. The RMS dismissed these effects on grounds of no statistical significanceand set the NOAEL for the same time point at 5.2 mg/kg/day. In the 90 day dog study both the RMS and the UK proposed a similar NOAEL (1.7 mg/kg/day) both basing this on thyroid and parathyroid weights and microscopic changes in the thyroid. It should be considered that such organ weights or microscopic effects were not examined at the 90 day time point in the one year dog study hence it is not possible to set the NOAEL for this time point with certainty at 5.2 mg/kg/day. It can be set at 1.8 mg/kg/day with certainty however as this approximates the NOAEL for the organ weight and microscopic effect in the 90 day study. In addition, too much weight should not be given to statistical significance of the bodyweight and food efficiency changes given the small numbers of animals used per group and sex in the 12 month dog study. Ultimately this will impacts on the AOEL and the UK proposes A short term systemic **AOEL** of 0.01 mg/kg bw/day is proposed. The AOEL is based on the NOAEL from the 90 day time point in the year dog	

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rapporteur: DE, co-rapporteur UK

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(iii)	B.6.10 Summary of Mammalian Toxicology and Proposed ADI, AOEL ARfD and Drinking Water Limit (Annex IIa 5.10)		study. (ii) (16.05.2001): A systemic **AOEL** of 0.03 mg/kg bw/d is proposed. The AOEL is based on the NOAEL of 5.2 mg/kg bw/d. This NOAEL is derived from the 1-year dog study at the 90-day timepoint. Based on the collective results from the 90-day and one-year dog studies, the overall NOAEL for 90 days of treatment with picolinafen in dogs is 150 ppm (approximately 5.2 mg/kg bw/d, calculated from food consumption data). This NOAEL is supported by reductions in mean body weights and cumulative body weight gain for the first 13 weeks of treatment for males and changes in haematology parameters for females, at 1,500 ppm (highest concentration tested). There was no statistical significant decrease in mean body weights or mean cumulative body weight gain at 150 ppm for the first 13 weeks of treatment. No treatment-related changes in organ weights of treatment-related macroscopic or microscopic finding were noted at 150 ppm at study termination in the one-year dog study.	
(iv)	B.6.12 Dermal absorption	UK (04.04.2001): A default **dermal penetration** value of 10%	(i) (06.06.2001) UK ACP proposes 25% dermal absorption as it	(i) Open Point:

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		in man is assumed. No dermal penetration study was submitted. There were no additional toxicological effects observed on dermal administration compared to dietary administration and the large molecular weight of picolinafen (376) would also limit dermal penetration.	considers comparison of 28 day rat dermal and dietary studies indicate a higher figure than 10%. It does not consider it to be as high as 80 or 60% however due to the accuracy of the NOAEL/LOAEL borders in each study. (ii) (16.05.2001): The proposal of a **dermal penetration** value of 10% in man is accepted. Comparison of the NOAELs from the 28 day rat dermal (50 mg/kg bw/d) and 28 day rat dietary study (10.5 mg/kg bw/d), taken into account 60% oral absorption, would indicate a dermal penetration value of approximately 12%.	Final dermal absorption value to be used for assessment in the range 10-25%. (ii) (28.08.2001): The proposed range of 10–25% as estimate for dermal absorp–tion is not supported for practi–cal reasons. For the purpose of exposure assessment a dermal absorption value of 12% is proposed (based on the comparison of the NOAELs from the 28 day rat dermal (50 mg/kg bw/d) and 28 day rat dietary study (10.5 mg/kg bw/d), and taking into account 60% oral absorption)

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(v)	B.6.14 Exposure data	UK (04.04.2001): A default **dermal penetration value of 10%** in man is assumed. This value is used to estimate the exposure data **for the risk assessment.**	(i) (06.06.2001) Where a more precautionary value of 25% for dermal penetration in man is assumed and the highest recommended dose of 'AC90001' is applied (0.1 kg a.s./ha), estimates of exposure using the combination German Model /POEM exposure model exceed the short-term systemic AOEL where PPE are worn. Where the lower application rate (0.05 kg a.s./ha) is used, predicted exposures are within acceptable levels where operators wear PPE. (ii) (16.05.2001): The proposal of a dermal penetration value of 10% in man (instead of 60% used in the monograph) is accepted (see point iv). On this basis the estimated exposures are lower than assumed in the monograph; all uses are acceptable.	
(vi)	Open point: Classification (see 2.1.4 and B.4) *cont.*	DK (26.03.2001): Picolinafen should be classified **R48/22** Danger of serious damage to health by prolonged exposure due to haemolytic anemia.	(ii) (16.05.2001): A classification is not justified. Reductions in haematology parameters as hemoglobin, hematocrit, red blood cell counts were significant in comparison to the correspondent controls, but were in the normal biological range of blood values. The observed haematological changes did not indicate any severe organ dysfunction. There was no decreased bone marrow production of blood cells. Increased erythropoietic activity in the	

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(vi)	Open point: Classification (see 2.1.4 and B.4)		bone marrow was only an adaptive response to haemolytic activity. No clinical signs of an anaemia were noted indicating serious damage.	

Further comment by the Co-RMS:

(i) Estimates of exposure using the combination German Model /POEM exposure model exceed the short-term systemic AOEL for all PPE clothing regimes considered when the highest recommended dose of 133 g 'AC90001' is applied. These estimates of exposure assume dermal absorption of 25% for both the concentrate and the in-use dilution. Dermal absorption may not be as high as 25% when predicting systemic exposure from the mixing and loading operation, as 'AC900001' is formulated as a wettable granule. These may therefore be conservative estimates of exposure, although it is noted that application of the product is the significant source of exposure.

Where the lower application rate of 0.066 kg product per hectare is used, predicted exposures are within acceptable levels where operators wear protective gloves and respiratory protective equipment (RPE) when mixing/loading and protective gloves during application.

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5. Residues

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(i)	Vol. 3, B.7.1	UK: - In the wheat metabolism study interpretation would be helped if it was made clear that it is only the lower part of the straw that is being analysed. A sentence could be added at the start of the straw analysis to make this clear.	(i) 31.05.01 UK comment. (ii) 21.05.2001 Agreed. To be considered in case assessment report (monograph) is revised.	--
(ii)	Vol. 3, B.7.2	UK: - From the available residues data that support the GAP residues in grain were <0.05 mg/kg and in straw did not exceed 0.12 mg/kg (higher levels found after application at later growth stages have been excluded). From these residues it can be calculated that the trigger for animal studies of 0.1 mg/kg diet as received has not been exceeded. It can therefore be concluded that the animal metabolism study was not required and MRL's for products of animal origin should not be set.	(i) 31.05.01 UK comment. (ii) 31.05.2001 Agreed however, the MRL proposal made in the monograph is based on the available LOQ of analysis methods for animal tissues. This proposal is used for the risk assessment (TMDI calculation). However, MRL setting will only be decided by the EU Commission.	--
(iii)	Vol. 3, B.7.2	NOT*: - Table B.7.2-1, should the values for urine + faeces after 2 days be in normal character instead of being in bold?	(i) 31.05.01 I think the notifier is correct. (ii) 21.05.2001 The bold characters were only applied to make it obvious that almost quantitative excretion was reached already after two days.	--

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rapporteur: DE, co-rapporteur UK

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No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
(iv)	Vol. 3, B.7.4	NOT*: - List of intended uses: As monograph will be on internet at some stage of the EU evaluation and since BASF intention is to not support Cyanazine EU re-registration under Commission Regulation 421/2000/EC, we would like to have the table revised – See attachment I BASF is also supporting uses as a co-formulation with other active ingredient such as Pendimethalin and Isoproturon. An Annex III dossier will be submitted at Member State Level.	(i) 31.05.01 There is no need to modify the monograph the notifier requested the use of a cyanazine product. (ii) 21.05.2001 Table B.7.4-1 will be removed from the chapter B.7.4. The "List of uses supported by available data" in Vol.1, 2.8.3 Appendix III: Listing of the end points will be amended according to the intention of the notifier.	--
(v)	Vol. 3, B.7.9	NOT*: - 1st Paragraph, 1st Sentence, Could you write: "A confined rotational crop study (Chiu, 1998, **MET 98-007**) in *carrots, soya bean, lettuce, sugar beet, peas* ***and sunflower***	(i) 31.05.01 The company reference could be included. (ii) 21.05.2001 The notifiers reference number MET 98-007 is not used in the citation within the monograph. Instead, RIP1999-1003 refers to the study which is included together with that notifiers reference in chapter B.7.17. Sunflower is added in the white version of the monograph.	--
(vi)	Vol. 3, B.7.9	NOT*: - Table 7.9-1, column *Radiochemical Purity* – Last row, Could you write **99.45 %** instead of 97.95% (see Page 31 of the study report)	(i) 31.05.01 The correct purity is 99.45 % (ii) 21.05.2001 Agreed. To be considered in case assessment report (monograph) is revised.	--

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rapporteur: DE, co-rapporteur UK

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(vii)	Vol. 3, B.7.12.2	GR: - In order to be consistent with the conclusions of point B.7.8, the fact that feeding studies on domestic animals are not necessary, should also be stated in the first sentence of point B.1.12.2	(i) 31.05.01 The co-rapporteur agrees with the comments of Greece. (ii) 21.05.2001 Agreed. To be considered in case assessment report (monograph) is revised.	--
(viii)	Vol. 3, B.7.12.2	GR: - To our opinion, it is not necessary to set an MRL at the LOQ for products of animal origin, as animal intakes, based on the use according to the critical GAP, are insignificant.	(i) 31.05.01 The co-rapporteur agrees with the comments of Greece. (ii) 31.05.2001 The MRL proposal made in the monograph is based on the available LOQ of analysis methods for animal tissues. This proposal is used for the risk assessment (TMDI calculation). However, MRL setting will only be decided by the EU Commission.	--
(ix)	Vol. 3, B.7.15	NOT: - Table B.7.15-1 – At the present time, the application of picolinafen for Annex I listing concerns the cereal crop. Why does the TMDI calculation cover wine, tea, hops and coffee for the 36-50 Yr old Woman. Could you clarify in the text?	(i) 31.05.01 The co-rapporteur agrees with this comment. (ii) 21.05.2001 Since the risk assessment (TMDI calculation) given in the monograph is a worst case assessment all raw agricultural commodities are included in the intake calculations of both the 4 - 6 years old girl and the 36 - 50 years old woman, despite of the limited use of picolinafen in cereals only.	--

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(x)	Vol. 3, B.7.15	GR: - Products of animal origin should not be listed in the commodities for TMDI calculation	(i) 31.05.01 The co-rapporteur agrees with the comments of Greece. (ii) 31.05.2001 Agreed however, since validated methods of analysis are available an MRL at the LOQ was proposed and consequently this value was used for the worst case risk assessment.	--

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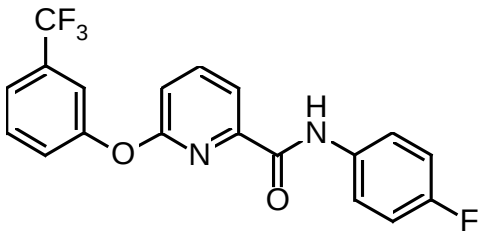
rapporteur: DE, co-rapporteur UK

Chapter 1 (identity, physical and chemical properties, details of uses, further information, classification and labelling)

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

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	4'-Fluoro-6-[(α,α,α-trifluoro-m-tolyl)oxy]picolinanilide
Chemical name (CA)	N-(4-Fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]-2-pyridinecarboxamide
CIPAC No	639
CAS No	137641-05-5
EEC No (EINECS or ELINCS)	not assigned
FAO Specification (including year of publication)	not available
Minimum purity of the active substance as manufactured (g/kg)	> 950 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None.
Molecular formula	$C_{19}H_{12}F_4N_2O_2$
Molecular mass	376.3
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	Melting range: 107.2 - 107.6 °C (PAS 98.7 %)
Boiling point (state purity)	No defined boiling point observable, decomposition at > 230 °C (PAS 98.7 %)
Temperature of decomposition	No defined boiling point observable, decomposition at > 230 °C
Appearance (state purity)	fine crystalline white to chalky solid with musty smell (PAS 98.7 %)
Relative density (state purity)	1.45 g/cm^3 (PAS 98.7 %)
Surface tension	72.3 mN/m
Vapour pressure (in Pa, state temperature)	$1.7 \cdot 10^{-7}$ Pa (20 °C, extrapolated, PAS 99.5 %)
Henry's law constant (Pa m^3 mol^{-1})	$1.6 \cdot 10^{-3}$ Pa m^3 mol^{-1} (20 °C)
Solubility in water (g/l or mg/l, state temperature)	pH 5 buffer: $3.8 \cdot 10^{-5}$ g/l pH 7 buffer: $4.7 \cdot 10^{-5}$ g/l pH 9 buffer: $3.8 \cdot 10^{-5}$ g/l DI water: $3.9 \cdot 10^{-5}$ g/l (at 20 °C:)
Solubility in organic solvents (in g/l or mg/l, state temperature)	<u>TAS (97.8 %), 20 °C</u> acetone: 557 g/l dichloromethane: 764 g/l ethyl acetate: 464 g/l n-hexane: 3.8 g/l methanol: 30.4 g/l toluene: 263 g/l
Partition co-efficient (log P_{OW}) (state pH and temperature)	solvent — log P_{OW} DI water — 5.37 pH 5 buffer — 5.36 pH 7 buffer — 5.43 pH 9 buffer — 5.36
Hydrolytic stability (DT_{50}) (state pH and temperature)	Stable at pH 4, 7 and 9 (5 d, 50 °C)
Dissociation constant	No dissociation between pH 2 – 12
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	202 nm: ε=39500 [l mol^{-1} cm^{-1}] 230 nm: ε=14600 [l mol^{-1} cm^{-1}] (shoulder) 290 nm: ε=13000 [l mol^{-1} cm^{-1}]
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Xe-lamp (λ > 290 nm), continuos irradiation pH 5 buffer: 25 d pH 7 buffer: 31 d pH 9 buffer: 23 d
Quantum yield of direct phototransformation in water at λ > 290 nm	$2.14 \cdot 10^{-6}$
Flammability	not highly flammable
Explosive properties	not explosive

List of uses supported by available data

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	(l)	(m)
Winter Wheat Winter Barley Winter Rye Triticale (autumn only	Northern Country		F	Weeds	WG	750 g/kg	Over plant spray	Post-em (BBCH 11) to BBCH 29	1		0.025-0.05	200-400 (max.400 applied for in DE)	0.05-0.1		
Winter Wheat Winter Barley	Southern Country		F	Weeds			Over plant spray	Post-em to BBCH 29	1			200	0.05		Notifier intends only combinations with other active substances

(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 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
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	none
with regard to toxicological data	none
with regard to fate and behaviour data	none
with regard to ecotoxicological data	R50/53

Appendix III.2: Chapter 2 (methods of analysis)
Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	HPLC-UV; 290 nm; RP18 - column
Impurities in technical as (principle of method)	HPLC-UV; 230 nm; RP18 - column GC-FID; DB5 fused silica column
Plant protection product (principle of method)	HPLC-UV; 290 nm; RP8 - column

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	GC-ECD GC-PND GC-MS	0.01 mg/kg (wheat, barley) 0.05 mg/kg (cereals) 0.05 mg/kg (barley)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	GC-ECD	0.01 mg/kg (milk) 0.02 mg/kg (meat, eggs, fat)
Soil (principle of method and LOQ)	GC-ECD	0.01 mg/kg
Water (principle of method and LOQ)	**drinking** GC-PND GC-ECD **surface** GC-PND/MS	 0.05 µg/l 0.1 µg/l 0.1 µg/l
Air (principle of method and LOQ)	HPLC-UV	2 µg/m³
Body fluids and tissues (principle of method and LOQ)	-	

Appendix III.3: Chapter 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 absorbed (60% based on urinary and biliary excretion within 48 h for males at low dose)
Distribution	Widely distributed
Potential for accumulation	No evidence for accumulation (<0.5% after 7 days: highest residues of the aniline-label in blood and spleen)
Rate and extent of excretion	Rapidly excreted, ca. 88% within 48 h via urine (48/62% for males/females) and feces
Metabolism in animals	Extensively metabolised (>87%) by hydrolytic cleavage (to substituted picolinic acid and *p*-fluoroaniline), oxidation, acteylation, and subsequent glucuronide and

	sulfate conjugations
Toxicologically significant compounds (animals, plants and environment)	Parent compound and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 4000 mg/kg bw
Rat LC_{50} inhalation	> 5.9 mg/L (4 h, dust, nose only)
Skin irritation	Non-irritating
Eye irritation	Non-irritating
Skin sensitization (test method used and result)	Non-sensitizer (M & K)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Red blood cells, spleen, liver (hemolysis); thyroid (hypertrophy, dog)
Lowest relevant oral NOAEL / NOEL	90d overall dog (90 d + 1yr): 150 ppm (5.2 mg/kg bw/d) 1yr dog: 50 ppm (1.4 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL	28d rat: 50 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL	No data - not required

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential

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

Target / critical effect	Red blood cells, spleen (hemolysis); liver (hypertrophy)
Lowest relevant NOAEL / NOEL	2yr rat: 50 ppm (2.4 mg/kg bw/d)
Carcinogenicity	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	No effects on reproduction
Lowest relevant reproductive NOAEL / NOEL	2gen rat: > 500 ppm (43 mg/kg bw/d)
Developmental target / critical effect	Increased resorption rate; decreased fetal body weights at maternal toxic doses (rabbit)
Lowest relevant developmental NOAEL / NOEL	Rabbit: 5 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

No data - not required

Other toxicological studies (Annex IIA, point 5.8)

No data - not required

Medical data (Annex IIA, point 5.9)

	Limited; new compound

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.014 mg/kg bw	1yr dog	100
AOEL systemic	0.03 mg/kg bw/d	90d + 1y dog, 60% absorption	100
Drinking water limit			
ARfD (acute reference dose)	0.05 mg/kg bw/d	developmental rabbit	100

Dermal absorption (Annex IIIA, point 7.3)

28d dermal and oral rat studies	10 % (based on comparison of oral and dermal toxicity)

Acceptable exposure scenarios (including method of calculation)

Operator	Intended use acceptable (German model; with PPE)
Workers	Intended use acceptable
Bystanders	Intended use acceptable

Appendix III.4: Chapter 4 (residues)

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

Plant groups covered	wheat
Rotational crops	lettuce, peas, carrots, soya bean, sugar beet
Plant residue definition for monitoring	picolinafen
Plant residue definition for risk assessment	picolinafen
Conversion factor (monitoring to risk assessment)	none

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

Animals covered	lactating goat
Animal residue definition for monitoring	picolinafen
Animal residue definition for risk assessment	picolinafen
Conversion factor (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	yes

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

.....	Uptake of residues after 30 days from treated soil or after 11 months replant after wheat treatment reveals no or very low TRR in the succeeding crops. Highest TRR were found at 0.006 mg/kg in carrot (DAT 78) or soya bean straw (DAT 159).

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

.....	Storage stability of residues of picolinafen in is proven over the period of 21 months. The samples collected in the residue trials have been analysed within 14 d and 8 months being covered by the storage stability tests.

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	no study conducted	no study conducted	no study conducted
Liver	no study conducted	no study conducted	no study conducted
Kidney	no study conducted	no study conducted	no study conducted
Fat	no study conducted	no study conducted	no study conducted
Milk	no study conducted	no study conducted	no study conducted
Eggs	no study conducted	no study conducted	no study conducted

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)
winter wheat	N S	12 x <0.05 mg/kg 5 x <0.05 mg/kg		0.05 mg/kg	0.05 mg/kg
winter barley	N S	12 x <0.05 mg/kg 2 x <0.05 mg/kg			

(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

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

ADI	0.014 mg/kg bw/d
TMDI (European Diet) (% ADI)	0.0015 mg/kg bw → 11 %
NEDI (% ADI)	not calculated
Factors included in NEDI	not applicable
ARfD	not assigned
Acute exposure (% ARfD)	not applicable

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
no study conducted			

* 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)

0.05 mg picolinafen/kg cereals grain

Chapter 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	aniline label: 17.4 % (61 d) (n=1) pyridine label: 22.8 - 43.0 % (100 d) (n=4)
Non-extractable residues after 100 days	aniline label: 43.9 % (61 d), max. 65 % (134 d); pyridine label: 21.2 % (100 d), max. 22.7 (60 d) (n=1)
Major metabolites - name and/or code, % of applied (range and maximum)	CL 153815 (range 23.9 (14 d) – 43.6 % (30 d), max. 43.6 %), end of study: 1.4 - 4.9 % (150 d, 122 d), (n=4)

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

Anaerobic degradation	DT_{50}: 6 – 7 days (2^{nd} order) DT_{90}: 58 – 73 days (2^{nd} order) CL 7693 (range 0 - 8 %, max. 8 %, day 120) CL 153815 (range 35 - 88 %, max. 88 %, day 63)
Soil photolysis	stable to photolysis (DT50: 30.2 days)

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

Method of calculation	picolinafen: Bayer program (version 2.0) method of Timme & Frehse (best-fit) CL 153815: linear regression
Laboratory studies (range or median, with n value, with r^2 value)	DT_{50lab} (20°C, aerobic): 1-14 d (n=4), r^2= >0.95 ($\sqrt{1^{st}}$ order), recalculation by 1^{st} order: Speyer 2.2 (aniline-^{14}C): 46 d (r^2= 0.9574) Speyer 2.2 (pyridine-^{14}C): 50 d (r^2= 0.8198) Engelstadt/Benz: 51d (r^2= 0.4937) Ingelheim/Moers: 47 d (r^2= 0.5475) Kloppenheim/Untere Gewann: 46 d (r^2= 0.5656) CL 153815 (20°C, aerobic): 30-77 days (n=4), r^2= >0.96
	DT_{90lab} (20°C, aerobic): 34-149 d (n=4), r^2=>0.95
	DT_{50lab} (8°C, aerobic): pyridine label, 7 d ($\sqrt{1^{st}}$ order), n=1, r^2= >0.95
	DT_{50lab} (20°C, anaerobic): aniline label, 7 d ($\sqrt{1^{st}}$ order), r^2=0.98, n=1, pyridine label, 6 d, r^2=0.99, n=1 (2^{nd} order)
	degradation in the saturated zone: not measured
Field studies (state location, range or median with n value)	DT_{50f}: 9-64 d (n=8), average 30 d (1^{st} order) locations: 4 in Germany, 3 in France, 1 in UK CL 153815: 19-107 ~~82~~ d (N=8)
	DT_{90f}: 56-212 d (n=8) average, 107 d
Soil accumulation and plateau concentration	DT_{50} is < 3 months and DT_{90} is < 1 yr., picolinafen is not expected to accumulate in the soil

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_d /K_{oc}	picolinafen k_d: 248 - 764 l/kg , K_{OC}: 15,000 - 31,800 l/kg (n = 4) CL 153815 k_d: 6.3 - 16.2 l/kg, K_{OC}: 160 - 783, mean 440 kg/l (n = 4)
pH dependence (yes / no) (if yes type of dependence)	Yes. Stronger binding was observed in acidic soils

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

Column leaching	column leaching study with picolinafen 750 g ai/kg WG formulation showed <0.1 % applied radioactivity in leachate (~200 mm percolate).
Aged residues leaching	leachates contained 0 - 0.09 % of applied radioactivity (~200 mm percolate)
Lysimeter/ field leaching studies	not required. Field studies showed no picolinafen in depth below 10 cm

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	actual: $C = Co * e^{-kt}$, twa: Initial PECs * $(1 - e^{-k*t})/(k*t)$
Application rate	0.1 kg as/ha (750 g as/kg WG), DT_{50}: 64 days

$PEC_{(s)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.133	0.133	intended use = single application	intended use = single application
Short term				
24 h	0.132	0.133		
2 d	0.130	0.132		
4 d	0.127	0.130		

PEC$_{(s)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term				
7 d	0.123	0.128		
28 d	0.098	0.115		
50 d	0.077	0.103		
100 d	0.045	0.081		

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)	Stable at pH 4, 7 and 9 (5 d, 50 °C)
Photolytic degradation of active substance and relevant metabolites	Xe-lamp (λ > 290 nm), continuous irradiation, DT_{50}: pH 5 buffer: 25 d pH 7 buffer: 31 d pH 9 buffer: 23 d
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT_{50} water	1.1 – 1.4 d (sqrt 1st order, n = 2)
- DT_{90} water	
- DT_{50} whole system	6.2 d (1st order, n = 2)
- DT_{90} whole system	
Mineralization	2.5 % AR after 100 d
Non-extractable residues	64 – 83 % AR after 100 d
Distribution in water / sediment systems (active substance)	Water: 22.7 – 52.2 % AR (day 0 sample), 0 % AR after 30 d; sediment: max. 39 – 68.6 % AR (day 0 sample), 0 – 1.9 % AR after 100 d
Distribution in water / sediment systems (metabolites)	Metabolite CL 153815 Water: max. 31.5 – 41.4 % AR (day 7), 0 – 9.3 % AR after 100 d; sediment: max. 83.1 % AR (day 100) and 47.9 % AR (day 62)

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

Method of calculation	4 % spray drift at 1 m and 0.6 % at 5 m distance, 30 cm deep static water body (300 l/m²); Active substance: DT_{50} = 1.4 d, sqrt 1st order; Metabolite: 100 % conversion, DT_{50} = 25 d, 1st order CL 153815: Consideration of molar mass ratio (376:283)
Application rate	1 x 0.1 kg as/ha
Main routes of entry	Spray drift

$PEC_{(sw)}$ (µg/l)	Picolinafen				Metabolite CL 153815			
	Single application Actual		Single application Time weighted average		Single application Actual		Single application Time weighted average	
	1 m	5 m	1 m	5 m	1 m	5 m	1 m	5 m
Initial	1.333	0.2			1.001	0.15		
Short term	0.734	0.11	0.913	0.137	0.973	0.146	0.986	0.148
24 h								
2 d	0.580	0.087	0.780	0.117	0.947	0.142	0.973	0.146
4 d	0.413	0.062	0.634	0.095	0.894	0.134	0.947	0.142
Long term	0.280	0.042	0.507	0.076	0.826	0.124	0.907	0.136
7 d								
14 d	0.147	0.022	0.360	0.054	0.680	0.102	0.826	0.124
21 d					0.560	0.084	0.760	0.114
28 d					0.461	0.069	0.693	0.104
42 d					0.313	0.047	0.593	0.089

PEC (sediment)

Method of calculation	Portion of the active substance in the sediment layer according to the "worst-case" water/sediment study
Application rate	1 x 0.1 kg as/ha corresponding to initial PEC_{SW} (parent) of 0.92 µg/l, 4 % drift, 1 m buffer and 0.6 %, 5 m buffer CL 153815: Consideration of molar mass ratio (376 : 283)

PEC_{SED}	Picolinafen			CL 153815		
	Portion in the sediment (% AR)	PEC_{SED} (µg/kg) 1 m	5 m	Portion in the sediment (% AR)	PEC_{SED} (µg/kg) 1 m	5 m
"Initial" (i.e. within minutes)	68.6	21.08	3.2	0.1	0.023	0.004
maximum level	68.6	21.08	3.2	83.1	19.21	2.9
after 100 d	0	0	0	83.1	19.21	2.9

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	PELMO 2.01 calculations with sandy loam (1.5 % C_{org}), precipitation: 872 mm/year (simulation of 10 years with annual application on 5. November in winter wheat
Application rate	0.1 kg/ha (750 g a.i./kg WG)

$PEC_{(gw)}$

Maximum concentration	<0.001 µg/l
Average annual concentration	<0.001 µg/l

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

Direct photolysis in air	No data
Quantum yield of direct phototransformation	$2.14 \cdot 10^{-6}$
Photochemical oxidative degradation in air	Calculation according to Atkinson's method (AOPWin 1.89): $t_{1/2}$ = 1.0 d ($C_{OH} = 0.5 \cdot 10^6$ cm^{-3}, 24 h day)
Volatilization	from plant surfaces: ≤ 10 % within 24 h
	from soil: ≤ 5 % within 24 h

PEC (air)

Method of calculation	Not relevant

$PEC_{(a)}$

Maximum concentration	Not relevant

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	picolinafen CL 153815 in soil and water (shows no biological activity, no toxicological and ecotoxicological relevance)

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

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available

Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Chapter 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	LD50 >5000 mg/kg bw (rat)
Long term toxicity to mammals	NOEL 20 mg/kg bw/d (developmental toxicity rabbit)
Acute toxicity to birds	LD50 >2250 mg/kg bw (bobwhite and mallard duck)
Dietary toxicity to birds	LC50 >5314 ppm (bobwhite and mallard duck)
Reproductive toxicity to birds	NOEL 864 ppm (bobwhite and mallard duck)

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
0.1	Cereals	Herbivorous bird	acute	>1400	10
0.1	Cereals	Herbivorous bird	short-term	>850	10
0.1	Cereals	Herbivorous bird	long-term	140	5
0.1	Cereals	Insectivorous bird	acute	>1800	10
0.1	Cereals	Insectivorous bird	short-term	>1800	10
0.1	Cereals	Insectivorous bird	long-term	298	5
0.1	Cereals	Herbivorous mammal	acute	>3100	10
0.1	Cereals	Herbivorous mammal	long-term	12.5	5

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				
O. mykiss	a.s.	acute	mortality	0.68
O. mykiss	a.s.	long-term	mortality, growth, behaviour	0.0064
D. magna	a.s.	acute	mortality	> 0.45
D. magna	a.s.	chronic	mortality, growth, reproduction	0.007
C. riparius	a.s.	long-term	development	0.18
S. capricornutum	a.s.	chronic	biomass	0.00018
L. gibba	a.s.	long-term	fronds	0.057
O. mykiss	CL 153815	acute	mortality	>100
Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
D. magna	CL 153815	acute	mortality	>100

S. capricornutum	CL 153815	chronic	biomass	27
O. mykiss	WG 74.4 %	acute	mortality	>0.376
D. magna	WG 74.4 %	acute	mortality	>0.819
S. capricornutum	WG 74.4 %	chronic	biomass	0.00016

Microcosm or mesocosm tests

A test over 116 d in a glasshouse was conducted. Algae, plants and invertebrates were tested. Conclusions can only be reached for a few species. Effects on algae and plants were observed but recovery occurred up to a concentration of 0.18 µg/L. This concentration is relevant for the risk assessment.

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
0.1	field-crops	microcosm	chronic	1	0.005	10
0.1	field-crops	microcosm	chronic	5	0.14	10
0.1	field-crops	microcosm	chronic	20	6	10

Bioconcentration

Bioconcentration factor (BCF)	580
Annex VI Trigger for the bioconcentration factor	100
Clearance time (CT_{50}) (CT_{90})	
Level of residues (%) in organisms after the 14 day depuration phase	< 5 %

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

Acute oral toxicity	LD 50 > 200 µ/bee
Acute contact toxicity	LD 50 > 200µg/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				
0.5	Cereals	oral	0.25	50
0.5	Cereals	contact	0.25	50

Field or semi-field tests
Not required

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						
T. pyri	Proto-nymphs	750 WG	0.1	Mortality Fertility	0 10	30
A. rhopalosiphi	Adults	750 WG	0.1	Mortality Fertility	0 6	30
P. cupreus	Adults	750 WG	0.1	Mortality Food uptake	0 0	30
Pardosa spp	Adults	750 WG	0.1	Mortality Food uptake	0 +1	30

Field or semi-field tests
not required

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

Acute toxicity	LC_{50} > 1000 mg as/kg
Acute toxicity metabolite CL 153 815	LC_{50} 476.5 mg metabolite/kg
Reproductive toxicity	NOEC 0.5 kg as/ha (0.665 mg as/kg)

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

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
0.1	Cereals	14 d	3759	10
0.1	Cereals	8 w	2.5	5

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

Nitrogen mineralization	Active substance picolinafen:	Tolerable effects up to 502.5 g /ha
	Metabolite CL 153815:	Tolerable effects up to 221 g / ha
Carbon mineralization	Active substance picolinafen:	Tolerable effects up to 502.5 g /ha
	Metabolite CL 153815:	Tolerable effects up to 221 g / ha

Appendix 3

LIST OF STUDIES WHICH WERE SUBMITTED DURING THE EVALUATION PROCESS AND WERE NOT CITED IN THE DRAFT ASSESSMENT REPORT: **PICOLINAFEN**

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIIA-2.7.3	Goldsmith, A. E.	2000	Generation of Chemical and Physical Stability Data on a Batch of Picolinafen 750 g/kg WG – 104 week interim report BASF, RLG 4589 GLP, unpublished PHY2000-777

B.6 Toxicology and metabolism

None

B.7 Residue data

None

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIA-2.10, AIIA-7.2.2	Mangels, G.	2000	Picolinafen (AC 900001): Estimation of the Photochemical Oxidation Rate in the Atmosphere BASF, EXA 00-022 no GLP, unpublished LUF2001-79
AIIA-7.1.1.2.2	Anonym	???	Response for PSD's request for additional information on how an 82 day half-life was calculated for CL 153815 in the UK field dissipation study. BASF BOD2001-457

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIIA-9.2.1	Mangels, G.	2001	Calculation of Predicted Environmental Concentrations of Picolinafen and Its Major Soil Metabolite, CL 153815, in Groundwater Following Applications of Picolinafen (BAS 700H) to Cereals in the United Kingdom BASF REPORT NO. EXA 01-010 no GLP (not relevant), unpublished BASF BOD2001-458

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIA-8.6, AIIIA-10.8	Brandt, A	1997	Greenhouse evaluation of the herbicidal activity of the picolinic acid metabolite of AC 900001, CL 153815, in comparison to the parent AC 900001 BASF, CFS 1997-119 not published PFL2000-5
AIIA-8.6, AIIIA-10.8	Stalmans, H.	1999	Effects on other non-target organisms (Flora) with AC 900,001 (Farmer P. Debois) BASF, BE 99 HS 009 1/2 not published PFL2000-6
AIIA-8.6, AIIIA-10.8	Stalmans, H.	1999	Effects on other non-target organisms (Flora) with AC 900,001 (Farmer L. Baes) BASF, BE99HS009 1/2 not published PFL2000-7
AIIA-8.6, AIIIA-10.8	Brandt, A.	1999	Determination of the ED10 values of AC 900001 technical in non-target crops following foliar application BASF, CFS 1999-094 not published PFL2001-43
AIIIA-10.2.1	Wenzel, A. and Klöppel, H.	2001	Alga, growth inhibition effects of AC 900001 750 WG (SF 09617) on Ankyra judayi BASF, EXT-00-337 GLP, unpublished WAT2001-201

Annex point/ reference number	Author(s)	Year	Title source (where different from company) company, report no. GLP or GEP status (where relevant), published or not BBA registration number
AIIIA-10.2.1	Schäfers, C.; Klöppel, H.; Hommen, U. and Barber, C.	2001	Community Level Effects of Picolinafen 750 WG (SF 09617) in an Indoor Semi-Realistic Microcosm study BASF, EXT-00-229 GLP, unpublished WAT2001-202
AIIIA-10.6.1.2	Lührs, U.	2000	Effects of AC900001 in a 750g/kg water dispersible granule formulation (RLF 12357) on reproduction and growth of earthworms Eisenia fetida (Savigny 1826) in artificial soil BASF, 7881022 GLP, unpublished ARW2000-177

SUGGESTED CLASSIFICATION AND LABELLING: Picolinafen

Hazard symbol	**N**	Dangerous for the environment.
Risk phrase	**R50/53**	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.