EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Acetamiprid

SANCO/1392/2001 – Final.

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

Review report for the active substance **acetamiprid**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 June 2004 in view of the inclusion of acetamiprid in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance acetamiprid, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the Greek authorities received on 22 October 1999 an application from Nisso Chemical Europe GmbH, hereafter referred to as the applicant, for the inclusion of the active substance acetamiprid in Annex I to the Directive. The Greek authorities indicated to the Commission on 1 February 2000 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on acetamiprid was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 22 February 2000, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the

procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 2000/390/EC [1] of 7 June 2000 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that Greece, as rapporteur Member State and France as co-rapporteur Member State, would carry out the detailed examination of the dossier and report the conclusions of the examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

Greece and France submitted to the Commission on 19 March 2001 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of acetamiprid in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Nisso Chemical Europe GmbH being the sole applicant on 4 May 2001.

Further discussion between the Rapporteur Member State and the Co-rapporteur Member State were organised , to review the draft assessment report and the comments received thereon in particular on each of the following disciplines :

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The active substance was evaluated in the Co-rapporteur System. The meetings between the Rapporteur Member State and the Co-rapporteur Member State took place from September 2001 to January 2002.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 10 October 2003.

The dossier, revised draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from July 2003 to June 2004, and was finalised in the meeting of the Standing Committee on 29 June 2004.

The present review report contains the conclusions of this final examination; given the importance of the revised draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the revision of the draft assessment report as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

[1] **OJ No L145, 20.06.2000, p.36.**

The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2004/99/EC[2] concerning the inclusion of acetamiprid in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing acetamiprid they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated possession of regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing acetamiprid will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each acetamiprid containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the sole data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

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[2] **OJ No L309, 06.10.2004, p. 6.**

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of acetamiprid in foodstuffs

The review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) for a 60 kg adult is 0.4 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (1998). This low intake value reflects the current limited use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

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

4.3 Ecotoxicology

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 7 of this report.

5. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of acetamiprid are given in Appendix I.

The active substance shall have a minimum purity of 990 g/kg technical product.

The review has established that for the active substance notified by the applicant (Nisso Chemical Europe GmbH), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the evaluation process are listed in Appendix II.

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

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

In this overall assessment, Member States

- should pay particular attention to worker exposure.
- should pay particular attention to the protection of aquatic organisms.

Risk mitigation measures should be applied where appropriate.

8. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of acetamiprid in Annex I.

Some endpoints however may require the generation or submission of additional studies to be submitted at Member State level in order to support national authorisations for the use under certain vulnerable conditions or to support extensions of the use pattern beyond the uses described under Point 3 above.
This may particular be the case for data on leaching in soil of the metabolite IM-1-5.

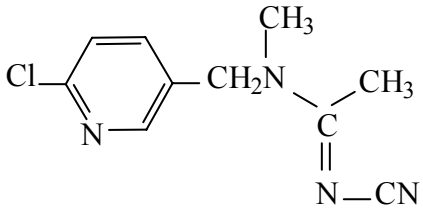
10. Updating of this review report

The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for acetamiprid in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

ACETAMIPRID

Common name (ISO)	Acetamiprid
Development Code (for new actives only)	NI-25
Chemical name (IUPAC)	(E)-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methylacetamidine
Chemical name (CA)	(E)-N-[(6-chloro-3-pyridinyl)methyl]-N'-cyano-N-methylethanimidamide
CIPAC No	Not yet allocated
CAS No	160430-64-8
EEC No	Not yet allocated
FAO SPECIFICATION	Not yet allocated
Minimum purity	990 g/kg
Molecular formula	$C_{10}H_{11}ClN_4$
Molecular mass	222.68
Structural formula	

Melting point	98.9 °C (99.7%)
Boiling point	Not relevant
Appearance	pure a.s. (99.9%): white fine powder, with no characteristic odour technical a.s. (99.9%): very pale yellow fine powder, with no characteristic odour
Relative density	Specific gravity (20 °C/20 °C): 1.330 (99.7%)
Vapour pressure	1.73×10^{-7} Pa at 50 °C (>99%). Expected $<1 \times 10^{-6}$ Pa at 25 °C
Henry's law constant	$<5.3 \times 10^{-8}$ Pa m^3 mol^{-1} at 25 °C
Solubility in water	In distilled water: 4.25 g/l at 25 °C (>99%) pH 5: 3.48 g/l at 25 °C (>99%) pH 7: 2.95 g/l at 25 °C (>99%) pH 9: 3.96 g/l at 25 °C (>99%)
Solubility in organic solvents	At 25 °C: hexane: 6.54 ppm; xylene:4.01 g/100 g; benzene: 2.44 g/100g; dichloromethane:>20 g/100g chloroform: >20 g/100 g; methanol:>20 g/100 g; ethanol: >20 g/100 g; acetone:>20 g/100 g; acetonitrile: >20 g/100g; tetrahydrofuran:>20 g/100g; carbone disulfide:507 ppm (all the above solubilities are expressed as weight of a.s. per weight of solvent) At 20 °C: Ethyl acetate: 37.8 g/l
Partition co-efficient (log P_{ow})	log P_{ow}= 0.80 at 25 °C (>99%) pH: Not determined (neutral conditions)
Hydrolytic stability (DT_{50})	pH 4: Stable at 22 °C, 35 °C and 45 °C pH 5: Stable at 22 °C, 35 °C and 45 °C pH 7: Stable at 22 °C, 35 °C and 45 °C pH 9: at 22 °C, DT_{50}=812 days at 35 °C, DT_{50}=52.9 days at 45 °C, DT_{50}=13.0 days Calculated at 25 °C: DT_{50}=420 days
Dissociation constant	pKa: 0.7 at 25 °C
Quantum yield of direct photo-transformation in water at λ >290 nm	0.10
Flammability	Not highly flammable
Explosive properties	Non-explosive
UV/VIS absorption (max.)	In neutral medium (CH_3OH/H_2O): λ_{max} : 247 nm, 217 nm ε ($M^{-1}xcm^{-1}$): $\varepsilon_{247}= 1.97 \times 10^4$, $\varepsilon_{217}= 1.21 \times 10^4$

Photostability in water (DT_{50})	pH 7: DT_{50}= 34 days under xenon lamp (irradiation: 12 hours/day)

APPENDIX II

END POINTS AND RELATED INFORMATION

ACETAMIPRID

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid and almost complete (> 96% at 24 hrs after single oral administration), C_{max} at approximately 0.5-7 hrs after single low and high oral and i.v. administration
Distribution:	Highest concentration adrenal, thyroid, liver and kidney
Potential for accumulation:	Low potential for body accumulation
Rate and extent of excretion:	Rapid and higher than 90% at 96 hrs, mainly via urine, after single and repeated oral administration, regardless of the dose level
Toxicologically significant compounds:	Parent compound, IC-0, IM-2-1, IM-1-4 (no compound was considered relevant) Metabolite IM-1-5, stable in calcareous soils, is considered relevant
Metabolism in animals:	Approximately > 90% metabolised. Mainly to the nicotinic acid derivative IC-O and demethylated compound IM-2-1 (approx. 50%) and IM-2-1, IS-1-1 and IS-2-1 (approx. 70%) in case of ring labeled and CN labeled, respectively (rats) Metabolite IM-1-5 (4.5%) is detected in rat metabolism only by HPLC analysis

Acute toxicity

Rat LD_{50} oral:	in water: 417 mg/kg b.w. (male) R22 314 mg/kg b.w. (female)
Rat LD_{50} dermal:	> 2000 mg/kg b.w.
Rat LC_{50} inhalation:	> 1.15 mg/l air
Skin irritation:	Not irritant
Eye irritation:	Not irritant
Skin sensitization (test method used and result):	*Not sensitiser (M&K)*

Short term toxicity

Target / critical effect:	Liver
Lowest relevant oral NOAEL / NOEL:	12.4 mg/kg b.w./day (200 ppm), 90 day rat study
Lowest relevant dermal NOAEL / NOEL:	1000 mg/kg b.w./day, 21 day rabbit study
Lowest relevant inhalation NOAEL / NOEL:	No data required

Genotoxicity

Evidence of clastogenic potential *in vitro*. This event was found to be not relevant for the *in vivo* situation with a negative mouse micronucleus assay and metaphase analysis in rat bone marrow

Long term toxicity and carcinogenicity

Target / critical effect:	Liver and kidney
Lowest relevant NOAEL:	7 mg/kg b.w./day (160 ppm), 2 year rat study
Carcinogenicity:	No carcinogenic potential, treatment related mammary glands hyperplasia at 1000ppm

Reproductive toxicity

Target / critical effect - Reproduction:	Reduced postnatal survival and decreased pup weight at parental toxic doses
Lowest relevant reproductive NOAEL / NOEL:	6.5 mg/kg b.w./day (100 ppm) in rats
Target / critical effect - Developmental toxicity:	No teratogenicity or fetotoxicity was observed at the tested doses
Lowest relevant developmental NOAEL / NOEL:	15 mg/kg b.w./day in rabbits

Delayed neurotoxicity

NOEL acute = 10 mg/kg b.w. based on reduced locomotor activity in the rat at high and medium dose

NOEL subchronic = 200 ppm (14.8 and 16.3 mg/kg b.w./day for males and females respectively) based on reduced body weight and food consumptions

Other toxicological studies

The metabolites IM-0, IM-1-3, IM-2-3 and IM-1-4 are considered harmful after single oral administration.

The metabolite IM-1-5 is considered toxic after single oral administration

No evidence of genotoxicity in the Ames bacterial reverse mutation assay for IM-0, IM-1-2, IM-1-3, IM-2-1, IM-2-3, IS-1-1, IS-2-1, IC-0, IM-1-4, IM-1-5, IB-1-1 metabolites

Medical data

Medical surveillance on manufacturing personnel did not reveal any adverse effects related to acetamiprid exposure.

Summary

	Value	Study	Safety factor
ADI:	0.07 mg/kg b.w./day	2 year rat study and 2-generation rat reproductive study	100
AOEL systemic:	0.124 mg/kg b.w./day	13-week rat study	100
	0.07 mg/kg b.w./day	2 year rat study and 2-generation rat reproductive study	100
AOEL inhalation:	Not relevant		
AOEL dermal:	Not relevant		
ARfD (acute reference dose):	0.1 mg/kg b.w./day	Acute neurotoxicity rat study	100
	NESTI for toddlers 4.6% of the ARfD (from peppers).		

Dermal absorption

33.7% and 15.9% supported by *in vivo* dermal penetration data in rat for the diluted and the concentrated formulation EXP-80667A, respectively

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralisation after 100 days:	9.6 % 120 d
Non-extractable residues after 100 days:	32.3 % 120 d
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	IM-1-4 : 0.91 – 36.17% (day 0.25 - day 182), 53.9% (maximum, day 14 d)
Calcareous soils Major metabolites above 10 % of applied activ substance: name and/or code % of applied rate (range and maximum)	IM-1-4 : 1.95 – 0.86 % (day 0.25 - day 187), 21.15% (maximum, day 7)- **sandy loam soil** IM-1-5 : 1.41 – 13.43 % (day 1 - day 182), 20.02 % (maximum, day 13) –**siltyclay loam soil** IM-1-5 : 0.83 – 8.29 % (day 0.25 - day 187), 12.89 % (maximum, day 7) –**clay loam soil** IM-1-2 : 11.89 – 0.77 % (day 0.25 – day 28) 36.02 % (maximum, day 1) - **sandy loam soil** IC-0 : 3.49 – 0.71% (day 3 – day 28) 10.23 % (maximum, day 7) - **clay loam soil**

Supplemental studies

Anaerobic:	Mineralisation 0.25 % (max. day 182) Non-extractable residues 12.13 % (max., day 14) Major Metabolite :IM-1-4 46.7 % (max. day 119 d)
Soil photolysis:	Mineralisation < 1 % Non-extractable residues 13 % (max., 30 d) Major Metabolite

IM-1-4 : 46.5 % (max. day 30 d irradiated samples) 65.3 % (max. day 30 (dark control samples)

Remarks: **none**

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	parent : 0.8- 5.4 d (n= 4, r^2 = 0.993- 0.997) mean 2.6 days IM-1-4 : : 4.1-226.5 d (n= 3, r^2 = 0. 872-0.997) Mean 133 days
DT_{90}lab (20 °C, aerobic):	Parent: DT_{90}lab : 2.8 – 67.3 d (n= 4, r^2 = 0.993-0.997) mean 20.9 days IM-1-4: no data
DT_{50}lab (10 °C, aerobic):	: 7.7 d (n= 1, r^2 =0.997)
DT_{50}lab (20 °C, anaerobic):	71 d, total system (water and soil) (n= 1, r^2= 0.99)
Calcareous soils	Parent : mean 1.1 days (n=3, r^2= 0.988-0.989)
DT_{50}lab (20 °C, aerobic):	IM-1-5 : > 365 days (r^2= 0.969-0.986) (realistic worst case DT_{50}'s : 450 days (siltyclay loam soil), 388 days (clay loam soil) (n=2) IM-1-2 : 1.1-1.6 days (n=3, r^2= 0.983-0.986) mean 1.3 days IM-1-4 : 2.7 – 5.6 days (n=3, r^2= 0.970-0.988) mean 3.9 days

Field studies (country or region)

DT_{50f} from soil dissipation studies:	parent DT_{50f}: Italy, cropped: 0.4 d (n= 1, r^2=0.881) UK, cropped : 5.4 d (n= 1, r^2=0.892) France, cropped : 4.1 d (n=1, r^2=0.821) Spain, cropped : 1.6 d (n= 1, r^2=0.851) Mean : 2.9 days DT_{50} (IM-1-4): Italy : 17.1 d (n= 1, r^2=1.0)

	UK : 50.1 d (n= 1, r^2=0.901) France : 42.9 d (n=1, r^2=0.907) Spain : 15.1 d (n= 1, r^2=1.0) Mean : 31.3 days
DT_{90f} from soil dissipation studies:	parent DT_{90f}: Italy : 18.4 d; UK : 19.9 d ; France : 31.2 d; Spain : 11.3 d Mean : 20.2 days DT_{90} (IM-1-4): Italy : 56.7 d; UK : 166.5 d ; France : 142.7 d; Spain : 50.2 d Mean : 104 days
Soil accumulation studies:	. Not required
Soil residue studies:	**Not relevant**

Remarks: e.g. effect of soil pH on degradation rate	**none**

Adsorption/desorption

K_f / K_{oc}:

K_d:

$\underline{K_{oc}}$ (parent): 71.1-138.4 (mean of 5 soils106.5),
$^1/_n$= 0.825-0.907, (mean: 0.86)
$\underline{K_{oc}}$ IM-1-4: 132- 223 (mean of 4 soils: 171), $^1/_n$= , 0.712-0.816 (mean: 0.76)

$\underline{K_{oc}}$ IC-0 : 70-258 (mean of 5 soils: 122), $^1/_n$= 0.894-1.007, (mean : 0.953)

$\underline{K_f}$ (parent) : 0.6-3.13 (mean of 5 soils 1.58), $\underline{K_f}$ IM-1-4: 2.16-5. 79 (mean of 4 soils: 3. 22),
$\underline{K_f}$ IC-0 : 0.569- 1.027 (mean of 5 soils 0. 752),

Calcareous soils

$\underline{K_{oc}}$ IM-1-2 : 19 – 95 (mean of 4 soils: 54),
$^1/_n$= 0.856- 0.944 (mean : 0.903)
$\underline{K_f}$ IM-1-2: 0.16- 3.60 (mean of 4 soils: 1.12)

$\underline{K_{oc}}$ IM-1-5 : 453 –563 (mean of 2 soils : 508)
method of calculation : GH Bolt equation

A new adsorption/desorption study for IM-1-5 is not considered necessary anymore. More information is included in the Evaluation Table.

No dependence for parent. No dependence for the metabolites

pH dependence:

Mobility

Laboratory studies:

Column leaching: no data provided not required.

Aged residue leaching: Guideline: BBA Test Guideline Teil IV, 4-2
Aged for (d): 2 d

Time period (d): 4 d

Precipitation (mm): 100 mm

Leachate: 0.3-1.3% total radioactivity in leachate

Leachate: 0.06% acetamiprid, 0.84% IM-1-4

88.9- 93.7% total radioactivity retained by the soil (the majority of radioactivity was detected in the four upper soil layers)

Calcareous soils

Two soils : EU sandy loam (pH: 8.4),
US sandy loam (pH: 8.7)

Aged for (d) : 64 d

Leaching period: 20 d

Precipitation (cm) : 50.8 cm (equivalent to 1038 ml)

Major metabolites during aging period:

IC-0 : 33.5% (day 28)

IM-1-2 : 27.3% (day 7)

IM-1-4 : 11.7% (day 14)

IM-1-5 : 8.8% (day 64)

Mean DT_{50} values

Parent : 2.7 days, IM-1-2: 2.4 days

IM-1-4 : 11.9 d, IC-0 : 33.7 d, IM-1-5 : 122 d

Leaching phase

EU soil , Segment 1: 0-6 cm

total 4.5% of A.R.(3.9% associated with IM-1-5)

EU soil , Segment 2 : 6-12 cm

Total 1.7% of A.R.(mostly associated with IM-1-5)

US soil , Segment 1: 0-6 cm

total 5.3% of A.R.(1.9% associated with IM-1-5)

No significant quantities of radioactivity found in subsequent segments.

Leachate

EU soil : total 5% of A.R. (associated with IC-0)

US soil : total 19.3% of A.R. (associated with IC-0)

Field studies:

Lysimeter/Field leaching studies: no data submitted and no data required.

Remarks: **none**

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	parent: stable at pHs 4, 5 and 7 at temperatures 22, 35 and 45°C
	pH9 (25°C) DT_{50} : 420 days (calculated from Arrhenius plot) pH9 (35°C) DT_{50} : 52.9 days pH9 (45°C) DT_{50} : 13 days
Major metabolites:	pH9: 45°C IM-1-4 : 14.8% AR (35 d) IM-1-3 : 60.5% AR (35 d) **IM-1-5** pH4 (20°C) DT_{50} : 67.2 d pH7 (20°C) DT_{50} : 159.2 d pH9 (20°C) DT_{50} : 23.5 d pH11 (20°C) DT_{50} : 19 hr
Photolytic degradation:	parent DT_{50} : 34 days (irratiated samples) no photodegradation in dark samples
Major metabolites:	IB-1-1: 35%AR (30 d) IC-0, DT_{50} : 0.4 days Florida summer sunlight IM-1-4: very low photolytic degradation rate **IM-1-5** DT_{50} : 21.1 – 36.1 d (irradiated samples) Mean : 26.1 d DT_{50} : 36.2 – 152 d (dark control samples) Mean : 82.6 d

Biological degradation

Readily biodegradable:	Not readily biodegradable
Water/sediment study: DT_{50} water: DT_{90} water:	Parent - DT_{50} water : 3.6 – 5.8 days Parent – DT_{90} water: 31.1 – 36.6 days (Biphasic kinetics, r^2= 0.91-0.93, n= 2)

	IM-1-4, DT_{50} water : 27.8 days (1^{st} order kinetics, r^2= 0.89, n= 1) IC-0, DT_{50} water : 84.5 days (1^{st} order kinetics, r^2= 0.97, n= 1) Parent - DT_{50} sediment : 40.1 – 44.4 days Mean:42.3 d (Biphasic kinetics, r^2= 0.90-0.99, n= 2)
DT_{50} whole system: DT_{90} whole system:	not calculated
Distribution in water / sediment systems (active substance)	<u>parent:</u> 29.96% in water, 39% in sediment on day14.(1^{st} system- Manningtree) 19% in water, 36.55% in sediment on day 30 .(2^{nd} system- Ongar) <u>IM-1-4</u>: max. 12.3% in water, 30.7% in sediment on day 30 .(1^{st} system) max. 9.6% in water, 2.5% in sediment on day14 (2^{nd} system) <u>IC-0</u> : max 26.15% in water, 3.32% in sediment on day 62 (2^{nd} system)
Distribution in water / sediment systems (metabolites)	
Accumulation in water and/or sediment:	**Not relevant**

Degradation in the saturated zone	no data provided, not required.
Remarks:	**None**

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	$1.73x10^{-7}$ Pa at 50 °C (>99%). Expected $<1x10^{-6}$ Pa at 25 °C
Henry's law constant:	$<5.3x10^{-8}$ Pa m^3 mol^{-1} at 25 °C

Photolytic degradation

Direct photolysis in air:	Not studied - no data requested
Photochemical oxidative degradation in air DT_{50}:	DT_{50} of 0.140 days (Atkinson's method)
Volatilisation:	from plant surfaces (BBA guideline): <1 % after 24 hours from soil (BBA guideline): <1% after 24 hours

Remarks:	**None**

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD_{50} 213 mg/kg bw (rats)
Acute toxicity to birds:	LD_{50} 98 mg/kg bw (mallard duck)
Dietary toxicity to birds:	LC_{50} >5000 ppm (>741 mg/kg bw/d) (bobwhite quail)
Reproductive toxicity to birds:	NOEL 250 ppm (25.1 mg/kg bw/d) (mallard duck)
Short term oral toxicity to mammals:	NOEL= 15 mg/kg/d

Aquatic Organisms

	Species	Test substance	Time Scale	Toxicity (mg / l)	Endpoint
Acute toxicity fish:	*Oncorhynchis mykiss*	Acetamiprid	96 h	>100	Mortality, EC_{50}
	Oncorhynchis mykiss	Metabolite IM-1-4	96 h	98.1	Mortality, LC_{50}
Long term toxicity fish:	*Pimephales promelas*	Acetamiprid	35 days	19.2	Growth NOEC
Bioaccumulation fish:	Not relevant				
Acute toxicity invertebrate:	*Daphnia magna*	Acetamiprid	48 h	49.8	Mortality, EC_{50}
	Daphnia magna	Metabolite IM-1-4	48 h	43.9	Mortality, EC_{50}
	Daphnia magna	Metabolite IM-1-2	48 h	99.8	Mortality, EC_{50}
	Daphnia magna	Metabolite IC-0	48 h	>95.1	Mortality, EC_{50}
	Daphnia magna	EXP 60707A (acetamiprid 20 %)	48 h	>159	Mortality, EC_{50}
Chronic toxicity invertebrate:	*Daphnia magna*	Acetamiprid	21 d	5	Reproduction, NOEC
Acute toxicity algae:	*Scenedesmus subspicatus*	Acetamiprid	72 h	>98.3	Biomass, EC_{50}
	Scenedesmus subspicatus	EXP 60707A (acetamiprid 20 %)	72 h	>97.8	Biomass, EC_{50}
Chronic toxicity sediment dwelling organism:	*Chironomus riparius*	Acetamiprid	28 days	0.005	Emergence & developmental rate, NOEC
	Chironomus riparius	Metabolite IM-1-4	48 h	76.0	Mortality, LC_{50}

Acute toxicity aquatic plants:	*Lemna gibba*	Acetamiprid	14 d	1.0	Fronds, EC_{50}

Honeybees

Acute oral toxicity:	LD 50 ~ 14.53 microg./bee (acetamiprid) LD50 8.85 microg. a.s./bee (EXP 60707 A tested formulation) (acetamiprid 20 %)
Acute contact toxicity:	LD50 ~ 8.09 microg./bee (acetamiprid) LD50 9.26 microg. a.s./bee (EXP 60707 A tested formulation) (acetamiprid 20 %)

Other arthropod species

Test species	Application	Status (kg as/ha)	% Effect	Endpoints
Typhlodromus pyri	Protonymphs	0.09-0.18	100 No eggs	Mortality Fertility
Aphidius rhopalosiphi	Adult	*0.2-0.4*	100 No fecundity	Mortality Fertility
Coccinella septempunctata	3 days old larvae	0.09-0.18	100 No fecundity	Mortality Fertility
Poecilus cupreus	Adult	0.2-0.4	$\leq$ 3.3 0.17 (same as the control)	Mortality Feeding rate
Typhlodromus pyri	Protonymphs	0.01, 0.018, 0.032, 0.057, 0.1 (in 200 l/ha water)	51.7 (at 0.018 Kg /ha) No effect on repro. up to 0.032 Kg /ha)	Mortality Fertility
Aphidius rhopalosiphi	Adult	0.001, 0.003, 0.009, 0.027, 0.081 (in 200 l/ha water)	53.1 (at 0.009 Kg /ha) No effect on repro. up to 0.009 Kg /ha)	Mortality Fertility

Typhlodromus pyri	Protonymphs	Off-crop (13 g a.s./ha)	- 1.1 (day 0) 6.2 (day 0)	Corrected Mortality % Sublethal effects (% reduction)
		In-crop (100 g a.s./ha)	39.1 (day 0) to 5.1 (day 14) Not assessed	Corrected Mortality % Sublethal effects (% reduction)
Aphidius rhopalosiphi	Adult	Off-crop (13 g a.s./ha)	90 (day 0) to 0 (day 14) 42.4 (day 7) to 32.5 (day 21)	Corrected Mortality % Sublethal effects (% reduction)
		In-crop (100 g a.s./ha)	70 (day 0) to 0 (day 21) 54.7 (day 7) to 34.6 (day 21)	Corrected Mortality % Sublethal effects (% reduction)
Coccinella septempunctata	3 days old larvae	Off-crop (13 g a.s./ha)	42.9 (day 0) to 4.3 (day 14) -16.4 (day 7)	Corrected Mortality % Sublethal effects (% reduction)
		In-crop (100 g a.s./ha)	95.9 (day 0) to26 (day 28) 14.4 (day 28)	Corrected Mortality % Sublethal effects (% reduction)

Chrysoperla carnea	3 days old larvae	Off-crop (13 g a.s./ha)	2.3 (day 0) to –0.1 (day 14) 7.5 (day 7)	Corrected Mortality % Sublethal effects (% reduction)
		In-crop (100 g a.s./ha)	16.3 (day 0) to 6.5 (day 14) 14.9 (day 7)	Corrected Mortality % Sublethal effects (% reduction)

Earthworms

Acute toxicity:	9 mg/kg (at day 14 - acetamiprid) 18.3 mg/Kg (at day 14 - EXP 60707) > 1000 mg/Kg (at day 14 - metabolites IM-1-4 & IC-0) > 1000 mg/Kg (at day 14 - metabolites IM-1-2) > 1000 mg/Kg (at day 14 - metabolites IM-1-5)
Reproductive toxicity:	NOEC 1.26 mg/Kg (8 weeks - EXP 60707)

Soil micro-organisms

Nitrogen mineralization:	No statistically significant effects > ± 25% compared to control control when acetamiprid is applied at 0.2 Kg a.s./ha
Carbon mineralization:	No statistically significant effects > ± 25% compared to control control when acetamiprid is applied at 0.2 Kg a.s./ha

APPENDIX III

ACETAMIPRID

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

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
IIA 1.11	Morishima Y.	2001	Acetamiprid (code no. NI-25) TGAI Analytical Profile of Five Production Batches Generated by: Production Technology Laboratory, Source: Nippon Soda Report/file: RD-II01056 Study No.: C014653 GLP, not published
IIA 2.7	Higashida, S	2001	Acetamiprid-solubility in ethyl acetate Generated by: Nisso Chemical Analysis Service Co., LTD, Source: Nippon Soda Report/file: RD-II 01206 Doc No C 017159 GLP, not published
IIA 2.15	Smeykal, H	2001	Acetamiprid; substance, technical AE F124370 00 1C99 0001 oxidizing properties Generated by: Siemens Axiva GmbH & Co. KG, DEU Source: Aventis CropScience GmbH,DEU Report No 20010404.01 Doc No C013576 GLP, not published

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
IIIA 2.8.6	Uceda, L & Le Gren, I	2002	EXP 60707 A (AE F124370 00 SP20 A2) Determination of particle size distribution Generated by: Aventis CropScience Source: Aventis CropScience Doc No R&D/CRLD/FORM/0235068 Study No 02-31 Doc No C021071 GLP, not published
IIA 4.1.2	Muro, H.	2002	Analysis of nitrosoamine in acetamiprid Generated by: Inspection Center Production Technology Laboratory Report No.: RD-II02108 Study No: C021424 Source: Nippon Soda Co., Ltd GLP: No Unpublished
IIA 4.2.1 IIIA 5.2.1	Reichert, N.	2001	Independent laboratory validation of an analytical method for the determination of acetamiprid in apple and tomato Generated by: Institut Fresenius Study No.: IF-101/07854-00 Study No.: C017995 Source: Aventis CropScience GLP: Yes Unpublished
IIA 4.2.1 IIIA 5.2.1	Class, T.	2001	Independent laboratory validation (ILV) of an analytical residue method (RPAC Study: #EC-97-388) for the determination of acetamiprid in cotton seed Generated by: PTRL Europe PTRL Europe Report No. B 458 G Study No.: C014468 Source: Aventis CropScience GLP: Yes Unpublished

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
IIA 4.2.2 IIIA 5.2.2	Neal, L, N.	2003	Acetamiprid: Validation of the method of analysis for the determination of residues of the acetamiprid metabolite AE 0653700 (IM-1-5) residues in calcareous soils by LC/MS/MS Generated by: Bayer CropScience USA LP Bayer CropScience Report No. B004279 Study No.: 02Y536660 Source: Bayer CropScience USA LP GLP: Yes Unpublished
IIA 4.2.5	Kenji Miya	2003	Development and Validation of the Analytical Method for the Determination of Acetamiprid in Body Fluids and Tissues Nisso Chemical Analysis Cervice Co., Ltd. Nippon Soda Co., Ltd. Study No.: NCAS 03-235 GLP Unpublished

B.6 Toxicology and metabolism

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
IIA 5.1	Hideyuki Saito	2003	Metabolism study of acetamiprid in rat (Determination of IM-1-5) Metabolism & Chemical Laboratory (NSM), Odawara Research Center Nippon Soda Co., Ltd. Report No.: RD-03028, NSM02-024, C030259 GLP: Yes Not piblished

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
IIA 5.2.1	Yoshinobu Fujii	2002a	Acetamiprid suspended in corn oil: Acute oral toxicity study in rats Toxicological Research Department, Odawara Research Center Nippon Soda Co., Ltd. Report No.: RD-II02425, H221, C028186 GLP: Yes Not published
IIA 5.8.1.11	Yoshinobu Fujii	2002b	IM-1-5: Acute oral toxicity study in rats Toxicological Research Department, Odawara Research Center Nippon Soda Co., Ltd. Report No.: RD-II02424, H220, C028187 GLP: Yes Not published

B.7 Residue data

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
IIA 7.0/01	Maestracci, M.	1998	Acetamiprid/Storage Stability Study Generated by: ADME-Bioanalyses Report/title: RPA/NI-25/97051 Study N RPA 97-75 Source: Nippon Soda GLP, GEP : Yes Date: January 8, 1998 Not published
IIA 7.6/88	Sonder K-H	2001	Acetamiprid (AEF124370 Water Soluble Powder (SP) 20% w/w) - Decline of residues in Sweet Pepper European Union (indoor) 2000 Generated by: Aventis CropScience Report/file: DR 00EUI 606 Study DR 00EUI 606 Source: Aventis CropScience GLP, GEP : yes Date: 8 November 2001 Not published

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
IIA 7.6/89	Sonder K-H	2002	Acetamiprid (AEF124370 Water Soluble Powder (SP) 20% w/w) – Residue behaviour in Sweet Pepper (indoor) European Union (Southern zone) 2001 Generated by: Aventis CropScience Report/file: 01 RI 612 Study 01 RI 612 Source: Aventis CropScience GLP, GEP : yes Date: 9 July 2002 Not published

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
AII 7.1.3	Simmonds M.	2003	[^{14}C]-Acetamiprid: Aged Residue Column Leaching Study in Two Calcareous Soils BayerCropScience SA, report C029849 GLP not published
AII 7.1.3	Hardy I.A.J.	2003	Acetamiprid: Kinetic Modelling Analysis of Data from a Laboratory Aged Residue Column Leaching Study BayerCropScience SA, report C029734 No GLP not published
AII 7.2.1.1	Kazuhide Takashima	2002	Hydrolysis of IM-1-5 Nippon Soda CO., LTD, report C028667 GLP not published
AII 7.2.1.2	H. Shiotani	2003	Photodegradation of IM-1-5 in Water Nippon Soda CO., LTD, report C030709 GLP not published
AIII 9.1.3	Hardy I.A.J.	2003	Predicted Environmental Concentrations in Soil (PECsoil) of the Acetamiprid Metabolite IM-1-5 following application to calcareous soils BayerCropScience SA, report C029214 No GLP not published
AIII 9.1.3	Hardy I.A.J.	2003	Predicted Environmental Concentrations in Soil (PECsoil) of the Acetamiprid Metabolite IM-1-2 following application to calcareous soils BayerCropScience SA, report C030239 No GLP not published

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
AIII 9.2.1	Hardy I.A.J.	2003	Predicted Environmental Concentrations in Groundwater (PECgw) of the Acetamiprid Metabolite IM-1-5 following application to calcareous soils using the FOCUS Groundwater Scenarios BayerCropScience SA, report C030675 No GLP not published
AIII 9.2.1	Hardy I.A.J.	2003	Predicted Environmental Concentrations in Groundwater (PECgw) of the Acetamiprid Metabolite IM-1-2 following application to calcareous soils using the FOCUS Groundwater Scenarios BayerCropScience SA, report C029211 No GLP not published
AIII 9.2.1	Hardy I.A.J.	2003	Predicted Environmental Concentrations in Groundwater (PECgw) of the Acetamiprid Metabolite IC-0 following application to calcareous soils using the FOCUS Groundwater Scenarios BayerCropScience SA, report C030238 No GLP not published

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
IIA, 8.2.7	Putt, A.E.	2001	IM-1-4 Acute toxicity to midge *Chironomus riparius* under static conditions. Source: Aventis CropScience Report N B003536 GLP or GEP: yes Published: no
IIA, 8.2.4/01	Shigeru Saito	2002 a	IM-1-5 (N1-((6-chloro-3-pyridyl)methyl)-N1-methylacetamidine): Acute toxicity to *Daphnia magna*. Source : Aventis CropScience Report N° C028602 GLP or GEP: yes Published: no
IIA, 8.2.4/02	Putt A.	2003 a	IM-1-5 - Acute Toxicity to Midge (*Chironomus riparius*) Under Static Conditions. Source : Aventis CropScience Report N°: B004212 GLP or GEP: yes Published: no

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
IIA, 8.2.5.1	Putt A.	2003 b	IM-1-5 - Full life-cycle toxicity test with water fleas, *Daphnia magna*, under static-renewal conditions. Source : Aventis CropScience Report N°: B004214 GLP or GEP: yes Published: no
IIA, 8.3.2/01	Klein S., Rosenkranz B.	2003 a	Effects of IM-1-5 on reproduction of the collembola *Folsomia candida* in artificial soil. Source : Aventis CropScience Report N°: C029622 GLP or GEP: yes Published: no
IIA, 8.3.2/02	S.Schmitzer	2003 b	Effects of IM 1-5 on the Reproduction of Rove beetles *Aleochara bilineata* in the laboratory. Source : Aventis CropScience Report N°: C029798 GLP or GEP: yes Published: no
IIA, 8.4.1/01	Rodgers M.	2002 a	IM-1-5 - Acute toxicity (LC50) to the earthworm. Source : Aventis CropScience Report N°: C028891 GLP or GEP: yes Published: no
IIA, 8.4.1/02	Luhrs U.	2002 a	Acute toxicity (14 days) of IM-1-2 to the earthworm *Eisenia fetida* in artificial soil. Source : Aventis CropScience Report N°: B004154 GLP or GEP: yes Published: no
IIA, 8.4.2	Luehrs U.	2003 a	Effects of IM-1-5 on reproduction and growth of earthworms *Eisenia fetida* in artificial soil. Source : Aventis CropScience Report N°: C029229 GLP or GEP: yes Published: no
IIIA, 10.4.1	Kling, A.	2001	Assessment of side effects of EXP 60707A to the honey-bee *Apis mellifera* L. in the laboratory. Source: Aventis CropScience Report N: B003288 GLP or GEP: yes Published: no

IIIA, 10.5.1	Schuld, M.	2001	EXP 60707 A: Toxicity to the aphid parasitoid *Aphidius rhopalosiphi* DeStefani-Perez (Hymenoptera : Braconidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Source: Aventis CropScience Report N: C 017048 GLP or GEP: yes Published: no
IIIA, 10.5.1	Adelberger, I.	2001	EXP 60707 A: Toxicity to the predatory mite *Typhlodroms pyri* SCHEUTEN (Acari, Phytoseiidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Source: Aventis CropScience Report N: B003547 GLP or GEP: yes Published: no
IIIA, 10.5.1	Hirth, N.	2001	EXP 60707 A: Toxicity to the green lacewing *Chrysoperla carnea* Steph. (Neuroptera, Chrysopidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Source: Aventis CropScience Report N: C017675 GLP or GEP: yes Published: no
IIIA, 10.5.1	Hirth, N.	2002	EXP 60707 A: Toxicity to the ladybird *Coccinella septempunctata* L. (Coleoptera, Coccinellidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Source: Aventis CropScience Report N: B003697 GLP or GEP: yes Published: no

APPENDIX IV

List of uses supported by available data

ACETAMIPRID

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI days (l)	Remarks: (m)
					Type (d-f)	Conc. 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		
Citrus fruit															
Oranges (not producing trees)	SP, IT, GR	EXP60707A	F	aphids and citrus leaf miner	SP	200	foliar spraying	spring and summer	1-2	30-45 days	0.0075-0.016	600-1000	0.045-0.1	NR	No PHI needed as applications cover uses on citrus in nurseries and young citrus before production starts
Mandarins (not producing trees)	SP, IT, GR	EXP60707A	F	aphids and citrus leaf miner	SP	200	foliar spraying	spring and summer	1-2	30-45 days	0.0075-0.016	600-1000	0.045-0.1	NR	>>
Lemons (not producing trees)	SP, IT, GR	EXP60707A	F	aphids and citrus leaf miner	SP	200	foliar spraying	spring and summer	1-2	30-45 days	0.0075-0.016	600-1000	0.045-0.1	NR	>>
Pome fruit															
Apples-pears	UK, NL, FR, SP, IT, GR	EXP60707A	F	aphids	SP	200	foliar spraying	BBCH 81-87	1-2	20-30 days	0.005-0.0075	500-1500	0.025-0.075	14	North and South Europe
Stone fruit															
Peaches-nectarines	FR, IT, SP, GR	EXP60707A	F	aphids	SP	200	foliar spraying	BBCH 81-87	1-2	20-30 days	0.005-0.0075	500-1500	0.025-0.075	14	South Europe, France South
Cherries	FR, IT, SP	EXP60707A	F	aphids	SP	200	foliar	BBCH	1	NA	0.005-	500-	0.025-	14	South Europe,

							spraying	81-87			0.0075	1500	0.075		France North and South
Plums	FR, IT, SP	EXP60707A	F	aphids	SP	200	foliar spraying	BBCH 81-87	1-2	20-30 days	0.005-0.0075	600-1000	0.035-0.050	14	South Europe, France North and South
Fruiting vegetables															
Tomato	FR, NL,IT, SP, GR	EXP60707A	F	aphids and white fly	SP	200	foliar spraying	BBCH 81-89	1-2	20-30 days	0.005-0.015	600-1200	0.03-0.09	7	outdoors S, France North and South
			G								0.005-0.009	1000-2000	0.05-0.09	3	indoors
Pepper	FR, SP, IT, GR	EXP60707A	F	aphids and white fly	SP	200	foliar spraying	BBCH 81-89	1-2	20-30 days	0.005-0.0015	600-1200	0.03-0.09	7	outdoors S, France South
			G								0.005-0.009	1000-2000	0.05-0.09	3	Indoors
Aubergines	FR, NL,IT, SP, GR	EXP60707A	F	aphids and white fly	SP	200	foliar spraying	BBCH 81-89	1-2	20-30 days	0.005-0.015	600-1200	0.03-0.09	7	outdoors S, France South
			G								0.005-0.009	1000-2000	0.05-0.09	3	Indoors
Oil seeds															
Cotton	IT, SP, GR	EXP60707A	F	Aphids and white fly	SP	200	foliar spraying	When 60-80% squares are open	1-2	20-30 days	0.0075-0.01	500-700	0.035-0.055	14	-
Tobacco	IT, SP, GR	EXP60707A	F	Aphids and white fly	SP	200	foliar spraying	12-14 leaves stage	1-2	20-30 days	0.0075-0.01	600-1000	0.050-0.075	14	-

Remarks:

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