Carbendazim									
1.0 mg/kg	65	77	68	72					70.5 ± 5.2
2.0 mg/kg	0	6	18	8					8.0 ± 7.5
5.0 mg/kg	0	0	0	0					0.0 ± 0.0

Table A7.5.2.1-10: Definitive test – EC50 Calculation

Lowest treatment group	5.2 mg a.i./kg
Highest treatment group	100.0 mg a.i./kg
regression slope	75.5
regression constant	-55.9
Coefficient of determination	r^2 = 95 %
EC_{50}	**25.2 mg a.i./kg**
95% confidence limits	10.6 - 59.7

Section 7.5.3.1.2 Short term (dietary) toxicity to birds

Annex Point IIIA XIII 1.2

Avian dietry toxicity test

Official use only

		1 REFERENCE
1.1	**Reference**	Gallagher, S.P., Martin, K.H., Beavers, J.B. (2002); Cypermethrin: A dietary LC50 study with the Northern bobwhite quail ; Wildlife International Ltd., report No. 547-101 (CYP/T324), 31 October 2002 (unpublished). Dates of experimental work: 25 July 2002 – 2 August 2002
1.2	**Data protection**	Yes
1.2.1	Data owner	Chimac Agriphar s.a.
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, US EPA OPPTS number 850.2200, FIFRA subdivision E - section 71-2. OECD Guideline 205.
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 METHOD
3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	2001060167
3.1.2	Specification	As given in section 2
3.1.3	Purity	96.5%w/w
3.1.4	Composition of Product	Not applicable, test carried out on active substance
3.1.5	Further relevant properties	Due to the low water solubility of cypermethrin, the test substance was dissolved in acetone before being mixed into the diet.
3.1.6	Method of analysis in the diet	The method of analysis was developed by Wildlife International Ltd (study report available). Samples were extracted with ethyl acetate and the concentration of cypermethrin in the extracts determined by Gas Chromatography with Electron Capture Detection (GC-ECD). Calibration samples were run alongside each sample set. The LOD was set at 0.10 ng on-column and the LOQ set at 100 ppm a.s. based on the lowest matrix fortification level. Procedural recovery of the analytical method were 106% and 104% for samples taken on days 0 and 5, respectively. The measured concentrations of the dietary samples were not corrected for procedural recovery.
3.2	**Administration of the test substance**	Test substance was administered in the diet. Test diets were prepared by suspending the test article in solvent (acetone) prior to mixing with feed.

Section 7.5.3.1.2 **Short term (dietary) toxicity to birds**
Annex Point IIIA XIII 1.2 **Avian dietry toxicity test**

3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	Not applicable
3.4	**Testing procedure**	
3.4.1	Test organisms	See table A7_5_3_1_1-1
3.4.2	Test system	see table A7_5_3_1_1-2
3.4.3	Diet	All birds were fed a game bird ration formulated to in-house specifications (full diet preparation is provided in the study report). An amount of diet sufficient to last the 5 day exposure period was prepared for each treatment and control group and presented to the birds at test initiation. Test diets were prepared by suspending the test article in solvent (acetone) prior to mixing with feed using a Hobart mixer. Samples of diet were collected at preparation (day 0) to verify the test concentration and to confirm the stability and homogeneity in the diets. Samples were also collected from feed troughs of the control, low and high dose groups on day 5 of the test to assess stability of the test substance under test conditions.
3.4.4	Test conditions	See table A7_5_3_1_1-3
3.4.5	Duration of the test	10 days acclimation + 5 days exposure + 3 days observation
3.4.6	Test parameter	Mortality, signs of toxic effects, food consumption, bodyweight.
3.4.7	Examination / Observation	Twice daily, with the exception of day 8 when birds were observed once before euthanasia.
3.4.8	Statistics	Not required as no mortality occured during the study. Therefore the LC50 was based on the highest test concentration. No statistical analysis was applied to separate mean responses among treatment groups for the endpoints of food consumption and bodyweights.

4 RESULTS

4.1	**Limit Test / Range finding test**	Not performed
4.2	**Results test substance**	
4.2.1	Applied concentrations	Test diets from the 562 and 5620 ppm a.i. test concentrations were used to evaluate homogeneity. Means and standard deviations for the two test concentrations were 599±13.5 ppm a.i. and 5730± 183 ppm a.i., representing 107% and 102% of nominal respectively. The coefficients of variation for these concentrations were 2.25% and 3.19% respectively. Samples collected during the test to verify test substance concentrations for the 1000, 1780 and 3160 ppm a.i. diets had means of 1020, 1900 and 3260 ppm a.i. respectively representing 102%, 107% and 103% of nominal. Stability of the test compound was verified by analysis of diet samples from feeders after being held at ambient for 5 days. Values averaged

Section 7.5.3.1.2 **Short term (dietary) toxicity to birds**
Annex Point IIIA XIII 1.2 **Avian dietry toxicity test**

		104% and 108% of the Day 0 values for the 562 and 5620 ppm a.i. test concentrations respectively.
4.2.2	Effect data (Mortality)	No mortalities occurred during the test in any of the test groups or the controls
4.2.3	Body weight	There was a decrease in mean body weight gain during the treatment period in birds receiving cypermethrin at 3160 and 5620 ppm a.i. test concentrations compared with untreated controls (see table A7_5_3_1_1-4).
4.2.4	Feed consumption	There were no apparent treatment-related effects on feed consumption at any of the test concentrations during the exposure period (see table A7_5_3_1_1-4).
4.2.5	Concentration / response curve	Not applicable
4.2.6	Other effects	There were no clinical signs of toxicity in the control group or in the treatment groups at 562 and 1000 ppm a.i. concentrations. All birds in these groups remained in good health throughout study. In the 1780 ppm a.i. treatment group signs of toxicity were noted on the morning of Day 1. These were wing droop, ruffled appearance and lethargy. These signs of toxicity were observed through to Day 7 for all except two birds which remained normal in appearance and behaviour. One bird continued to display a ruffled appearance until test termination but was nevertheless gaining weight and improving in condition. Lesions from toe picking were also noted in two birds during the course of the test. In the 3160 ppm a.i. treatment group signs of toxicity were first noted on the morning of Day 1. These were hyperexcitability, exhibited by all five birds in the first pen, and wing droop or ruffled appearance exhibited by two birds in the second pen. By the afternoon of Day 7 all birds were normal in appearance and behaviour. In the 5620 ppm a.i. treatment group signs of toxicity were first noted on the morning of Day 1. These were wing droop and ruffled appearance and were exhibited by up to seven birds. These signs of toxicity were observed only up to and through Day 7 for all except two birds which continued to display a ruffled appearance at test termination. These birds were nevertheless gaining weight and improving in condition.
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	None, all control birds remained in good health throughout the study.
4.3.2	Nature of adverse effects	Not applicable
4.4	**Test with reference substance**	Not performed

Section 7.5.3.1.2 **Short term (dietary) toxicity to birds**
Annex Point IIIA XIII 1.2 **Avian dietry toxicity test**

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Cypermethrin technical active substance (purity 96.5%) was administered in the diet to 10-day old northern bobwhite quail (*Colinus virginianus*) at nominal doses of 0, 562, 1000, 1780, 3160 and 5620 ppm a.i. for five days according to OECD guideline 205 (10 birds of undetermined sex/treatment group) . Mortalities, health and clinical observations were recorded twice daily for seven days after the beginning of dosing, and once prior to euthanasia, on Day 8 of the test. Individual body weights were measured at Days 0 (test initiation), 5 and 8. Average food consumption was determined by measuring the change in weight of feed presented to the birds during the exposure period and the post-exposure period.
5.2	**Results and discussion**	No mortality observed in any treatment group. No clinical signs of toxicity nor modification of appearance and behaviour at 562 and 1000 g/kg food. Signs of toxicity (wing droop, ruffled appearance, lethargy, hyper excitability) were observed at 1780, 3160 and 5620 mg/kg food. Treatment-related effect in bodyweight was observed during the exposure period at 3160 and 5620 mg/kg food. Clinical signs/feed consumption: no apparent treatment-related effect during exposure period. LC50 (5d) > 5620 mg a.s./kg feed or > 1376 mg a.s./kg bw/d, based on the mean body weight of 24.5 g and the food consumption of 6 g /day reported in the 5620 mg/kg treatment group. The no observed effect concentration (NOEC) was 1000 ppm a.i. (1000 mg a.s./kg feed) based upon signs of toxicity in birds receiving the 1780 ppm a.i. test concentration.
5.2.1	LD_{50}	> LC_{50} (5 days) = 5620 mg a.s./kg feed based on no mortality at the highest dose level
5.3	**Conclusion**	Validity criteria were fulfilled; no mortality was recorded in any of the three control groups. LC50 (5d) > 5620 mg a.s./kg feed NOEC 1000 mg a.s./kg feed
5.3.1	Reliability	1 Study was evaluated and accepted under directive 91/414/EC
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2008
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version is a dopted.

Section 7.5.3.1.2 Short term (dietary) toxicity to birds

Annex Point IIIA XIII 1.2 **Avian dietry toxicity test**

Conclusion	Applicant's version is a dopted.
Reliability	1
Acceptability	Acceptable
Remarks	

	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_5_3_1_1-1: Test animals

Criteria	**Details**
Species/strain	Northern bobwhite quail (Colinus virginianus)
Source	Wildlife International Ltd., Maryland
Sex	Undetermined as all birds were immature
Initial body weight (bw)	16-25 g at initiation of the test
Breeding population	Birds obtained from production flock. All birds were from the same hatch.
Amount of food	Ad libitum during acclimitisation and during the test. Average feed consumption was determined by measuring the change in weight of feed presented to the birds during the exposure period and the post-exposure period. The accuracy of food consumption could be affected by wastage.
Age at time of first dosing	10 days
Health condition / medication	Birds appeared to be in good health at test initiation and received no form of antibiotic medication during acclimitisation or test period.

Table A7_5_3_1_1-2: Test system

Criteria	Details
Test location	Indoor in thermostatically controlled brooding pens
Holding pens	Each pen had a floor space of approximately 72 x 90 cm and a ceiling height of 23 cm. External walls, ceilings and floors were made of galvanized steel wire and sheeting.
Number of animals	Total number of tested animals = 80
Number of animals per pen [cm²/bird]	5 birds/pen [1.3 cm²/bird]
Number of animals per dose	10 chicks per dose group (5 treatment groups plus 3 untreated control groups).
Pre-treatment / acclimation	All birds were acclimitised to the caging facilities from the day of hatch until initiation of the test. Throughout acclimitisation birds were fed the game bird ration and received a water soluble vitamin mix via their water. Water and feed were supplied *ad libitum*.
Diet during test	All birds were fed a game bird ration formulated to Wildlife International Ltd's specifications. This comprosed a minimum of 27% protein and 2.5% crude fat with a maximum of 5% crude fibre. The diet also contained vitamin and mineral pre-mix.
Dosage levels (of test substance)	Nominal dietary test concentrations were 0, 562, 1000, 1780, 3160, 5620 mg/kg feed. Sufficient quantity of test diet to last the 5 day exposure period were prepared at test initiation and administered at day 0.
Replicate/dosage level	Not applicable, only one preparation/dose.
Feed dosing method	Birds were allowed access to the feed *ad libitum*
Dosing volume per application	Not applicable
Frequency, duration and method of animal monitoring after dosing	Mortalities, health and clinical observations were recorded twice daily for seven days after the beginning of dosing, and once prior to euthanasia, on Day 8 of the test.
Time and intervals of body weight determination	Individual body weights were measured at Days 0 (test initiation), 5 and 8.

Table A7_5_3_1_1-3: Test conditions (housing)

Criteria	Details
Test temperature	Average temperature in the brooding compartment of the pens was 39±2°C(SD) with the average room temperature for the study being 29.8±1.2°C(SD).
Shielding of the animals	Not specified
Ventilation	The air handling system was designed to vent up to 15 room air volumes per hour and replace them with fresh air.
Relative humidity	Average relative humidity of 56±4°C(SD).
Photoperiod and lighting	16 hours of light per day (maintained by clock), with an average of 173 lux of illumination

Table A7_5_3_1_1-4: Effect Data

Treatment Group ppm a.i.	Mean body weight (g)			Mean food consumption (g/bird/day)	
	Day 0	Day 5	Day 8	During dosing	Post-dosing
0	21	32 (11)	39 (7)	7	8
562	20	31 (11)	39 (7)	6	9
1000	20	32 (12)	40 (7)	6	8
1780	21	31 (10)	38 (7)	6	8
3160	21	31 (9)	38 (8)	7	11
5620	21	28 (7)	36 (8)	6	10

Bracketed figures are the mean change, calculated using individual body weights

Reported figures have been rounded to the nearest whole number

Section 7.5.3.1.3 Effects on reproduction of birds
Annex Point IIIA XIII 1.3

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		1 REFERENCE
1.1	**Reference**	Frey, L. (2003); Cypermethrin: Reproduction study with the northern bobwhite quail; Wildlife International Ltd.; project no. 547-103 (CYP/T329), 22 May 2003 (unpublished). Dates of experimental work: 9 October 2002 – 14 April 2003
1.2	**Data protection**	Yes
1.2.1	Data owner	Chimac-Agriphar s.a.
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, FIFRA guidleline 71-4 OECD guideline 206
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 METHOD
3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	2001060167
3.1.2	Specification	As given in section 2
3.1.3	Purity	96.5% w/w
3.1.4	Composition of Product	Not applicable, study was performed on the technical grade active substance
3.1.5	Further relevant properties	
3.1.6	Method of analysis	The method of analysis was developed by Wildlife International Ltd (study report available). Samples were extracted with ethyl acetate and the concentration of cypermethrin in the extracts determined by Gas Chromatography with Electron Capture Detection (GC-ECD). Calibration samples were run alongside each sample set. The LOD was set at 0.10 ng on-column and the LOQ set at 100 ppm a.s. based on the lowest matrix fortification level. The individual procedural recoveries were in the range 88-107%. The measured concentrations of the dietary samples were not corrected for procedural recovery.
3.2	**Administration of the test substance**	Test substance was administered in the diet. Test diets were prepared by mixing cypermethrin (dissolved in acetone) into a premix which was then used for weekly preparation of the final diet.

Section 7.5.3.1.3 Effects on reproduction of birds
Annex Point IIIA XIII 1.3

3.3	**Testing procedure**	
3.3.1	Test organisms	See table A7_5_3_1_3-1
3.3.2	Test system	See table A7_5_3_1_3-2
3.3.3	Diet	See table A7_5_3_1_3-2
3.3.4	Test conditions	See table A7_5_3_1_3-3
3.3.5	Duration of the test	21 days
3.3.6	Test parameter	Adult bodyweight, adult feed consumption, eggs laid, eggs cracked, viable embryos, live embryos, hatchlings, 14 day old survivors, eggshell thickness and offspring bodyweight.
3.3.7	Examination / Observation	All birds were observed daily. Body weights of the adults were recorded before dosing and at two week intervals up to eight weeks after dosing, and then at the end of the study. Food consumption per pen was recorded weekly. During egg laying, eggshell thickness was measured on one egg from odd numbered pens during odd numbered weeks and from even numbered pens during even numbered weeks, when available. Eggs were examined for embryo viability, on day 11-12 of incubation, and survival, on day 21 of incubation The group body weight (by parental pen) of hatchlings was determined after hatching and after an additional 14 days. Macroscopic examinations were recorded at post-mortem on birds which died during the study and on all surviving birds at the end of the exposure period.
3.3.8	Statistics	Not applicable, the NOEC was determined based on no-effects at the highest dose tested.
		4 RESULTS
4.1	**Limit Test / Range finding test**	Performed (38 day pilot study)
4.1.1	Concentration	Three treatment groups (5 pairs/group) were fed diets containing 160, 400 and 1000 ppm cypermethrin respectively. A non-treated diet was also fed to a fourth control group.
4.1.2	Number/ percentage of animals showing adverse effects	No treatment related mortalities occurred in the control, 400 or 1000 ppm dose groups. One incidental mortality did occur in the 160 ppm group, however following observations at necropsy this single mortality was considered to be unrelated to treatment. Additionally there were no signs of toxicity nor any treatment-related effects on feed consumption, bodyweight or egg production at any of the concentrations tested.
4.1.3	Nature of adverse effects	No treatment-related effects were observed in the pilot study.

Section 7.5.3.1.3 Effects on reproduction of birds
Annex Point IIIA XIII 1.3

4.2 Results test substance

4.2.1 Applied concentrations

Dietary analysis: The absence of test substance or co-eluting substance was confirmed for control samples. Homogeneity testing was carried out for the 160 and 1000 ppm a.i. test concentrations (six samples at each concentration, from top, middle and bottom of left and right sections of the mixing vessel). Means and standard deviations were 178±10.2 and 972±12.9 ppm a.i. respectively, with coefficients of variation of 5.73 and 1.33% respectively.

Measured concentrations of cypermethrin in the freshly prepared then frozen diet ranged from 93 to 104% of the nominal values. Measured concentrations in diet samples collected from feeders after seven days at ambient also ranged from 93 to 104% of the Day 0 values.

4.2.2 Effect data (Mortality and reproductivity)

Mortality: No treatment-related mortalities occurred during the study. Two incidental mortalities occurred, one in the 160 ppm a.i. treatment group and the other in the 400 ppm a.i. treatment group.

The mortality in the 160 ppm a.i. treatment group was a female found dead on Day 2 of Week 12. Prior to death, the female was noted to have extensive head and neck lesions and appeared weak. At necropsy the bird was well muscled, with a body weight of 210 g. Yolk remnants were found in the abdominal cavity. The spleen was pale and slightly enlarged, the kidneys were pale, the cecal contents were pasty, and the ovary was developing. At necropsy, the female's pen mate was noted to have a slightly enlarged spleen, but was otherwise unremarkable.

The mortality in the 400 ppm a.i. treatment group was a female that was euthanized on Day 2 of Week 19 due to her debilitated condition. Prior to death the female was noted as thin and exhibited depression, a ruffled appearance, lethargy, foot lesions and associated lameness. At necropsy, the bird was emaciated, with a body weight of 136 g. There was a loss of muscle mass with the keel prominent. The liver and kidneys were pale and the ovary was regressed. At necropsy, the female's pen mate was noted to have areas of hyperemia in the small intestine, but was otherwise unremarkable.

Reproductive effects: There were no treatment-related effects upon reproductive performance at any of the concentrations tested. When compared to the control group, there were no statistically significant differences in any of the reproductive parameters measured in the 160, 400, or 1000 ppm a.i. treatment groups.

The NOEC was determined to be 1000 ppm (1000 mg a.s./kg feed) based on the highest dose level tested.

See Table A7_5_3_1_3-4

Section 7.5.3.1.3 Effects on reproduction of birds
Annex Point IIIA XIII 1.3

4.2.3	Body weight	There was a slight, but statistically significant ($p < 0.05$) increase in the mean body weight of the males in the 400 ppm a.i. treatment group at termination of the adult portion of the study. Since the difference observed was small, not concentration dependant, and represented an increase in body weight, it was not considered to be related to treatment. Thus it was concluded that there were no treatment-related effects on the body weight of adult birds during the study. See Table A7_5_3_1_3-4
4.2.4	Food consumption	There were inconsistent, but statistically significant, increases in food consumption for different dose groups at different times during the study. In all cases the differences from the control were very small and were not considered to be treatment-related. See Table A7_5_3_1_3-4
4.2.5	Results of residue analysis	Not performed
4.2.6	Other effects	Clinical signs: There were no treatment-related effects on behaviour or appearance of adult birds during the study. No overt signs of toxicity were observed at any of the concentrations tested. Incidental clinical observations noted during the test included those normally associated with injuries and penwear. Autopsy: No treatment-related macroscopic abnormalities were observed in any birds examined.
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	No adverse effects shown by any animals in the control group
4.3.2	Nature of adverse effects	None found

Section 7.5.3.1.3 Effects on reproduction of birds
Annex Point IIIA XIII 1.3

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Cypermethrin technical active substance (96.5% purity) was administered in the diet to twenty-nine week old northern bobwhite quail (*Colinus virginianus*) at nominal doses of 0, 160, 400 and 1,000 ppm a.i. for 21 weeks. There were two birds housed in each pen (one male and one female) and 16 pens for each dose level of cypermethrin and the untreated control.

Body weights of the adults were recorded before dosing and at two week intervals up to eight weeks after dosing, and then at the end of the study. Food consumption per pen was recorded weekly.

Any eggs were collected daily and examined for cracking and eggshell thickness measured. Eggs were incubated and examined for embryo viability and survival and allowed to hatch.

Macroscopic examinations were recorded at *post-mortem* on birds which died during the study and on all surviving birds at the end of the exposure period.

5.2 Results and discussion

No treatment-related mortalities occurred during the study. There were no treatment-related effects on behaviour or appearance of adult birds and no overt signs of toxicity were observed at any of the concentrations tested. It was concluded that there were no treatment-related effects on the body weight of adult birds and any small differences in feed consumption were not considered to be treatment-related.

There were no treatment-related effects upon reproductive performance at any of the concentrations tested and no treatment-related macroscopic abnormalities were observed in any birds examined at autopsy.

5.2.1 NOEC

The NOEC (21 weeks) = 1000 mg a.s./kg feed or 92.0 mg a.s./kg bw/d

5.3 Conclusion

Validity criteria can be considered as fulfilled.

See table A7_5_3_1_3-5.

5.3.1 Reliability

1

5.3.2 Deficiencies

No

Study was evaluated and accepted under Directive 91/414/EC

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2008
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's versionis adopted.
Conclusion	Applicant's versionis adopted.
Reliability	1
Acceptability	Acceptable

Section 7.5.3.1.3 Effects on reproduction of birds
Annex Point IIIA XIII 1.3

Remarks	/
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_5_3_1_3-1: Test animals

Criteria	Details
Species/strain	Northern bobwhite quail (Colinus virginianus)
Source	K&L Quail, Oroville, CA
Sex	Males an females (determined by visual examination of plumage)
Initial body weight (bw)	187-249 g at initiation of the test
Breeding population	All birds were from the same hatch, approaching their first breeding season and had not been used in any previous testing.
Amount of food	Ad libitum during acclimitisation and during the test. Average feed consumption was determined per pen per week by weighing the freshly filled feeder on day 0 and recording the amount of additional diet added during the week before re-weighing the feeder on day 7 of each week.
Age at time of first dosing	29 weeks
Health condition / medication	Birds were examined prior to test initiation for physical injuries and appeared to be in good health. Neither the adults nor offspring were given any medication during the study.

Table A7_5_3_1_3-2: Test system

Criteria	Details
Test location	Indoors in holding pens
Holding pens	Georgia Quail Farm Manufacturing model no. 0330 with a floor area of 1377 cm^2, measuring approximately 27 x 51 cm. Pens had sloping roves with a ceiling height of 20-25 cm and were constructed of galvanised wire mesh and sheeting.
Number of animals (male/female)	64 pairs (1 male, 1 female per pen, 16 pens per treatment group)
Number of animals per pen [cm^2/bird]	1 male and 1 female per pen [688.5 cm^2/ bird]
Number of animals per dose	16 pens (16 males, 16 females) per treatment group
Pre-treatment / acclimation	All birds were acclimitised to the caging facilities for 16 weeks prior to study initiation and were observed daily during this period. Throughout acclimitisation birds were given water and feed *ad libitum*.
Diet during test	The basal diet was formulated to Wildlife International's specifications by Agway Inc. and contained at least 27% protein, 2.5% fat and no more than 5% fibre. Although the basal diet conatained approximately 1.1% calcium, an additional 5% of limestone (38.5% calciul) was added to the basal diets of adults for the purpose of shell formation. Offspring received basal diet without test substance and without the limestone supplement.
Dosage levels (of test substance)	Untreated control, 160, 400, 1000 mg a.s./kg feed (adjusted for purity of test substance). Dose levels were based on results of a range-finder study. Control diet and each treated diet were prepared weekly and presented to the birds once per week.
Replicate/dosage level	16 pens (1 pair of birds) per dose level
Dosing method	Ad libitum
Dosing volume per application	As required
Frequency, duration and method of animal monitoring after dosing	All birds were observed daily throughout the study for signs of toxicity or abnormal effects. Additionally all offspring were observed daily from hatching until 14 days of age.
Time and intervals of body weight determination	Measured at test initiation, at the end of test weeks 2, 4, 6, 8 and at adult termination. Bodyweights were not measured during egg laying so as to avoid any adverse effects of handling on egg production.

Incubation, storing and hatching	Eggs were collected daily and stored in a cold room until incubation, with all eggs laid in a weekly interval being considered as one lot. Prior to incubation the eggs were weighed and examined for cracking. During egg laying, eggshell thickness was measured on one egg from odd numbered pens during odd numbered weeks and from even numbered pens during even numbered weeks, when available. Eggs were incubated at 37.4°C and examined for embryo viability, on day 11-12 of incubation, and survival, on day 21 of incubation, before allowing them to hatch. The temperature and humidity of the incubator were kept constant by forced air currents and the eggs were rotated through an arc of 90° each hour.
Test period after egg-laying	The egg laying phase of the study lasted approximately 11 weks and was followed by a post-adult termination phase (incubation, hatching and 14 day offspring rearing period) lasting 6 weeks.
Turning of eggs	Yes, the incubator was equipped with an autiomatic egg rotation device
Collection period for eggs	The egg laying phase of the study lasted approximately 11 weks.

Table A7_5_3_1_3-3: Test conditions (housing)

Criteria	**Details**
Test temperature	The study room was maintained at 20.6±1.6°C(SD)
Shielding of the animals	Yes, only birds associated with this study were kept in the study room to avoid excessive disturbance
Ventilation	15 room air volumes every hour were vented and replaced with fresh air
Relative humidity	relative humidity 34 ±13%(SD)
Photoperiod and lighting	8:16 hour light/dark regime for the first seven weeks followed by a 17:7 light/dark regime until termination.
Storing, incubation and hatching conditions for eggs	Eggs were incubated at 37.4°C. The temperature and humidity of the incubator were kept constant by forced air currents and the eggs were rotated through an arc of 90° each hour.
Environmental conditions for young birds	On day 21 of incubation eggs were transferred to a Petersime Hatcher. Wire mesh baskets were used to keep hatchlings separated by parental pen of origin. Eggs were not rotated in the hatcher. The average temperature in the hatching compartment was 37.2 ±0.0°C (SD) and a relative humidity of approximately 77% (recorded daily)

Table A7_5_3_1_3-4: Values of reproduction ability

Reproductive parameter	Test Group (ppm)			
	Control	**160**	**400**	**1000**
No. of Replicates	16	15	15	16
Mean adult food consumption (g/bird/day)	18.57	19.29	18.67	20.05
Mean adult body weight at term, males (g)	216	219	229*	212
Mean adult body weight at term, females (g)	244	236	234	246
No. eggs laid[1]	812	755	613	808
Eggs laid (% of maximum laid[4])	72	72	58	72
Eggs cracked (% of total laid)	2	3	2	1
No. eggs set	715	663	539	723
Viable embryos (% of eggs set)	86	92	96	97
Live three-week embryos (% of viable embryos)	99	100	100	100
Hatchlings (% of live three-week embryos)	96	96	96	95
No. of hatchlings	596	586	502	661
No. of 14 day survivors	574	556	489	622
14-day old survivors (% of hatchlings)	96	94	96	93
Mean body weight of hatchlings ± SD (g)[3]	6 ± 1	6 ± 0	6 ± 1	6 ± 1
Mean body weight of 14-day old survivors ± SD (g)	28 ± 3	26 ± 3	27 ± 2	26 ± 3
Hatchlings (% of eggs set)	82	87	92	91
14 day old survivors (% of eggs set)	79	83	88	85
Mean egg shell thickness ± SD (mm)	0.230 ± 0.013	0.228 ± 0.013	0.228 ±0.017	0.228 ± 0.014
Eggs laid/hen	51	50	41	51
Eggs laid/hen/day[2]	0.51	0.51	0.41	0.51
14 day old survivors/hen	36	37	33	39
Hatchlings (% of maximum set)	57	60	52	64
14 day old survivors (% of maximum set)	55	57	50	60

[1] Represents the total number of eggs laid in each group.

[2] Based on 99 days of egg production.

[3] Hatchlings found dead were not weighed

[4] Maximum laid is defined as the largest number of eggs laid by any one hen

Differences between the control and each treatment groups were not significant ($p > 0.05$) except for *.

% values represent pen means for each experimental group.

Table A7_5_3_1_3-5: Validity criteria for bird reproduction test according to OECD 206

	Fulfilled	Not fulfilled
Mortality of control animals <10%	**yes**	
Average number of 14-day-old survivors per hen in controls ≥ 14, 12 and 24 for mallard duck, bobwhite quail and Japanese quail	**yes**	
Average eggshell thickness for the control group ≥ 0.34, 0.19 and 0.19 mm for mallard duck, bobwhite quail and Japanese quail	**yes**	
Concentration of the test substance in the diet ≥ 80 % of the nominal concentration throughout the test period	**yes**	

Section 7.5.4.1
Annex Point IIIA XIII 3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators

Acute toxicity to honeybees

			Official use only
		1 REFERENCE	
1.1	**Reference**	Badmin, J.S., Twydell, T.S. (1976); Evaluation of the insecticide WL 43467 (cypermethrin) against the honeybee *Aphis mellifera*; Woodstock Laboratory, Shell Research Ltd, report no. WK61/S/BE137 (CYP/T7), (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Chimac Agriphar s.a	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Guideline not specified	
2.2	**GLP**	No, GLP was not compulsory at the time the study was performed	
2.3	**Deviations**	No raw data, the report is a summary of laboratory investigations.	
		3 METHOD	
3.1	**Test material**	WL 43467 (cypermethrin)	
3.1.1	Lot/Batch number	Not specified	
3.1.2	Specification	Deviating from the specification given in section 2	
3.1.3	Purity	Not specified, however the report mentions that the study was conducted using technical material and also a 400 g/L EC formulation (FX 3315).	
3.1.4	Composition of Product	Not specified	
3.1.5	Further relevant properties	Due to the low water solubility of the technical material, the test substance was dissolved in acetone.	
3.2	**Administration of the test substance**	Oral test: the formulation and the a.s. (In acetone) were added to the 20% honey suspension. 200µl of honey solution containing the a.s. were offered to each replicate of 10 bees. Contact test: CO_2 immobilized bees were treated by topical applications of 1µl suspension of the ventral side of the thorax.	
3.3	**Reference substance**	Parathion	
3.4	**Testing procedure**		
3.4.1	Test organisms	Honeybees (*Apis mellifera L.*); worker bees	
3.4.2	Collection and Acclimatisation	20 bees (mean weight 138 mg in total) were collected from the upper combs of the hive on the afternoon prior to testing. They were held under laboratory conditions (23°C ±2°C, ambient humidity) in muslin cages prior to testing and were fed a 20% honey solution *ad libitum*.	

Section 7.5.4.1
Annex Point IIIA XIII 3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators

Acute toxicity to honeybees

3.4.3	Test system	Bees were treated with the appropriate test concentration and then transferred to 10 x 3.5 cm metal gauze cylinders placed in the airstream of an electric fan and fed a 20% honey solution *ad libitum*. Bees were examined for mortality after 24 hours.
3.4.4	Test concentrations	Topical applications were made by applying 1 µl of test substance in acetone to the ventral abdomen of CO_{2i} immobilised bees using a micrometer syringe. Oral administration was carried out by dispersing the test substance in a 20% honey solution and presenting 0.2 ml in a glass feeding vial to a group of 10 bees. An 8-fold range of concentrations were used to obtain a dose response curve (raw data not reported) and the test repeated at least twice.
3.4.5	Number of replicates	10 bees x 2 replicates/ concentration.
3.4.6	Test conditions	23 ± 2 °C, ambient humidity
3.4.7	Duration of the test	24 hours
3.4.8	Test parameter	Mortality
3.4.9	Examination / Observation	All bees were examined for mortality after 24 hours
		4 RESULTS
4.1	**Results test substance**	
4.1.1	LD_{50}	LD_{50} (cypermethrin, 24h) contact = 0.020 µg a.s./bee LD_{50} (cypermethrin, 24h) oral = 0.035 µg a.s./bee [LD_{50} (400g/L EC formulation, 24h) oral = 0.031 µg a.s./bee]
4.2	**Test with reference substance**	LD_{50} (parathion, 24h) contact = 0.16 µg a.s./bee LD_{50} (parathion, 24h) oral = 0.14 µg a.s./bee
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	Cypermethrin was administered both topically and orally to groups of 10 worker bees and mortality recorded after 24 hours.
5.2	**Results and discussion**	Individual mortality data is not presented, however the report states that a dose response curve was used to obtain the LD_{50} for cypermethrin.
5.2.1	LD_{50}	LD_{50} (cypermethrin, 24h) contact = 0.020 µg a.s./bee LD_{50} (cypermethrin, 24h) oral = 0.035 µg a.s./bee
5.3	**Conclusion**	Cypermethrin can be considered as very toxic to bees
5.3.1	Reliability	2

Section 7.5.4.1
Annex Point IIIA XIII 3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators

Acute toxicity to honeybees

5.3.2 Deficiencies	No raw data presented and the test concentrations used in the study are not reported. However the results appear to be valid in terms of published LD50 values for cypermethrin. This study was reviewed under Directive 91/414/EC. In addition, higher tier field studies on non-target arthropods are available (see Doc IIIA_7.5.6). Therefore it was considered that further laboratory tests on bees are not required.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2008
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version is adopted.
Conclusion	Applicant's version is adopted.
Reliability	4
Acceptability	non acceptable
	The test only provides indicative information about the toxicity of the active substance cypermethrin. No guideline is refered to and no raw data is provided. It is therefore impossible to check the accuracy of the results. However, the results fit the toxicity value available in the pesticide manual (11th edition CDS Tomlin ISBN 1 901396 11 8)
Remarks	The applicant version o the summary is accepted because it is a good summary of the respective Doc IV. However the quality of the Doc IV is not acceptable.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.5.5 **Annex Point IIA.VII.7.5**	**Bioconcentration, terrestrial**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [√]	**Technically not feasible** [ ] **Scientifically unjustified** [√]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The log Pow for cypermethrin was found to be in the range 3.3-3.6 initially indicating potential bioaccumulation in the food chain. However an experimental bioaccumulation factor of 373+/-45 in fish indicates it has a low bioaccumulation potential at least in the aquatic compartment. In addition, the risk of secondary poisoning through the food chain from the aquatic environment is unlikely to be a problem, as the bioavailability of cypermethrin will be poor due to its rapid dissipation from water and strong adhesion to sediment. The substance has a high Koc value which ranges from 80653 to 574360 (see DocIIIA7.2.3.1) which indicates its non-mobile character. Cypermethrin will therefore adhere strongly to soil/sediment making it very difficult for organisms to uptake and accumulate it. In addition, degradation in soil is rapid with $t_{1/2}$ <52 days and an acute toxicity study in earthworm indicated no effects at the test concentration limit of 100mg/kg soil. It can be concluded therefore that there is no concern for bioaccumulation in the terrestrial compartment due to a very limited bioavailability.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	May 2008	
Evaluation of applicant's justification	Log Pow ranges from 5.3 to 5.6 according to Bates 2002a.	
Conclusion	Applicant's justification is accepted.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section 7.5.5 **Bioconcentration, terrestrial** **Annex Point IIA.VII.7.5**
Remarks

Section A8	Measures necessary to protect man, animals and the environment	
Subsection (Annex Point)		**Official use only**
8.1	**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**	
8.1.0 Methods and precautions concerning placing on the market	All formulated cypermethrin products are subject to regulations such as the Plant Protection Products Regulations as well as the Biocidal Products Regulation. Therefore all uses must be approved by the competent authorities before the product can be placed on the market. Each type of product carries an approved label detailing the specific conditions of use and associated hazards. Cypermethrin has been approved for use in agriculture for over 20 years and is listed in Annex I of Directive 91/414/EC. Cypermethrin is very toxic to aquatic organisms and should therefore not enter the drainage system or watercourses.	
8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations	Appropriate engineering controls should be employed during the formulation process, including local exhaust ventilation and the use of personal protective equipment (overalls, gloves and respirator). All workers must be fully trained to handle hazardous substances on the plant. Provide local exhaust or general room ventilation when handling the active substance. Handle in accordance with good industrial hygiene practises. Do not eat, drink or smoke. Wash hands and exposed skin after work and particularly before meals. If splashes do occur, remove any contaminated clothing immediately and wash skin with mild soap and water. Wash splashes to eyes with copious amounts of water immediately. Wear suitable respiratory equipment, chemical-resistant gloves, overalls and chemical goggles/faceshield with safety glasses.	
8.1.2 Methods and precautions concerning storage of the active substance and its formulations	Store only in the original container in a cool, well ventilated place away from all possible sources of ignition and away from food, drink and animal feedingstuffs. Keep out of the reach of children.	
8.1.3 Methods and precautions concerning transport of the active substance and its formulations	When transporting by road, ensure the driver is aware of the potential hazards and is trained in the actions to be taken in case of an accident or emergency. UN 3352 PYRETHROID PESTICIDE, LIQUID, TOXIC (Cypermethrin), Class 6.1, packing group III H.I. no. 60 (ADR) Marine Pollutant (IMDG)	

Section A8	Measures necessary to protect man, animals and the environment	
Subsection (Annex Point)		**Official use only**
8.1.4 Methods and precautions concerning fire of the active substance and its formulations	For small fires, use carbon dioxide or dry chemical to extinguish flames. Use fluxing salts or dry sand to surround and smother the fire. For large fires use water fog or spray or alcohol foam. Do not use water jet or heavy water stream. Cool exposed containers with water spray or fog. Wear full protective equipment when dealing with fire, including breathing apparatus. Ensure area is cleared of all personnel. Do not empty fire control water into drains.	
8.2	**In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)** When heated to decomposition, the evolution of carbon monoxide, carbon dioxide, nitrogen oxides, hydrochloric acid and hydrogen cyanide must be anticipated (information derived from chemical structure).	
8.3	**Emergency measures in case of an accident (IIA8.3)**	
8.3.1 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available	Inhalation: Move casualty to fresh air and allow to rest. If breathing is difficult administer oxygen. If breathing has stopped, apply artificial respiration. Seek medical advice. Skin contact: Remove contaminated clothing immediately and wash exposed skin thoroughly with mild soap and water. If symptoms are severe, seek medical advice. Eye contact: Rinse immediately with copious amounts of clean water for 10-15 minutes. Obtain immediate medical advice. Ingestion: Do not induce vomiting. If conscious, rinse mouth with water ensuring the casualty does not swallow. If swallowed seek medical advice immediately and show the container or label. No specific antidote is known, treatment should be symptomatic.	
8.3.2 Emergency measures to protect the environment	Spillages should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Ensure the area is cleared of all other persons. Soak up spillage onto suitable inert material (e.g. clay or diatomaceous earth) as soon as possible. Collect spillage and place in an appropriate container, tightly closed and properly labelled. Prevent spillage from entering the drainage system or watercourses. If contamination of drains or public waters occurs, notify the appropriate authorities immediately.	

Section A8	Measures necessary to protect man, animals and the environment	
Subsection (Annex Point)		**Official use only**
8.4	**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)**	
8.4.1 Possibility of destruction or decontamination following release in the air	Cypermethrin is non-volatile, therefore there should be no potential hazard to the atmosphere.	
8.4.2 Possibility of destruction or decontamination following release in water, including drinking water	Cypermethrin is a viscous liquid/semi-solid with low water solubility. Therefore it is likely that any material entering water will form an immobile mass which can be removed by mechanical means. Activated carbon can be used on any material that has dissolved and the precipitate removed by mechanical means.	
8.4.3 Possibility of destruction or decontamination following release in or on soil	Cypermethrin adsorbs strongly to soil, therefore any material accidentally released to soil should be relatively localised. Contaminated soil should be removed and placed in appropriate containers for safe disposal or incineration.	
8.5	**Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5)**	
8.5.1 Possibility of re-use or recycling	Empty containers should not be re-used for any purpose. Dispose of in accordance with local regulations. Destroy or puncture empty containers to prevent re-use.	
8.5.2 Possibility of neutralisation of effects	In the event of accidental spillage, chemical absorbents and collected spilled material should be disposed of in accordance with local regulations and by a suitable waste contractor. The preferred method of disposal is incineration, however if this is not possible cypermethrin can be decomposed by hydrolysis at pH 12 or above. For emulsifiable material, 5% sodium hydroxide solution or saturated (7-10%) sodium carbonate can be used. For non-emuslifiable material, a 1:1 v/v mixture of either of these solutions and a water/oil soluble solvent (e.g. denatured alcohol, monoethylene glycol, hexylene glycol or isopropanol) can be used. The material should be covered with hydrolysing agent and left to stand for 7 days. The material should be analysed to ensure the active ingredient has been degraded to a safe level before being disposed of.	
8.5.3 Conditions for controlled discharge including leachate qualities on disposal	Cypermethrin is toxic to fish and other aquatic organisms and should not be discharged into surface waters under any circumstances. Disposal by controlled incineration is preferred.	

Section A8	Measures necessary to protect man, animals and the environment	
Subsection (Annex Point)		**Official use only**
8.5.4 Conditions for controlled incineration	Cypermethrin can be destroyed by controlled high temperature incineration (>1000°C) with effluent scrubbing.	X
8.6	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)** Cypermethrin is highly toxic to aquatic organisms (fish, daphnia) with the exception of green algae. Cypermethrin is a broad spectrum insecticide and will kill beneficial insects, honeybees and other non-target arthropods. Cypermethrin has a low toxicity to earthworms. Comprehensive field studies on the effects of agricultural spray operations on non-target beneficial insects have been carried out and are detailed in DocIIIA_7.5.6. Cypermethrin has low mammalian toxicity and should therefore not pose a risk to roosting bats. It also has a low toxicity to birds, again a full study on the toxicity to birds is provided in DocIIIA_7.5.3.	
8.7	**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7)** Cypermethrin is a list I substance according to Directive 80/68/EEC (organohalogen) and should not be indirectly discharged to groundwater.	

	Evaluation by Competent Authorities
	CONDITIONS FOR CONTROLLED INCINERATION (8.5.4)
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*July 2007*
Materials and methods	*Destruction of cypermethrin by controlled incineration*
Results and discussion	*The criteria as given by the applicant (" halogen content of cypermethrin < 60°C, therefore no specific information about the pyrolytic behaviour is required") are not in relation to the proposed criteria in the TGD. The TGD states that if the waste disposal method suggested is incineration, the compounds generated by burning (e.g. whether polychlorinated dioxins and furans or other halogen compounds can be formed), the recommended burning conditions (temperature, reaction time and oxygen content) and other information needed for the safe incineration of the waste must be given.*
Conclusion	*The applicant must complete this part (8.5.4) with the required data, conform with TGD*
Acceptability	*Not acceptable*

Section A8	**Measures necessary to protect man, animals and the environment**

Subsection (Annex Point)		**Official use only**
Remarks	*None*	
	EVALUATION BY INDUSTRY	
Date	End of 2008	
Results and discussion	Has been completed	
Conclusion		
Acceptability		
Remarks		
	Evaluation by Rapporteur Member State	
Final conclusion	Agreed	

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	March, 2008.	
Materials and methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability	Human Health Part: Acceptable	
Remarks		

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	July, 2009.	
Materials and methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability	Environment Part: Acceptable	
Remarks		

Section A9 (IX)	**Classification and Labelling**	
Section A9 **Annex Point IIA.IX**	**Proposal and justification for the classification and labelling of the active substance according to Directive 67/548/EEC**	**Official use only**
Hazard Symbols	Xn, N	
Indication of danger	Harmful, Dangerous for the Environment	
Risk phrases	R20/22 – Harmful by inhalation and if swallowed R37 – Irritating to respiratory system R50/53 – Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment	
Safety phrases	S2 - Keep out of the reach of children S24 – Avoid contact with skin S36/37/39 – Wear suitable protective clothing, gloves and eye/face protection S60 – This material and its container must be disposed of as hazardous waste S61 – Avoid release to the environment. Refer to special instructions/Safety data sheets	
Justification for proposed classification	The classification of Cypermethrin was agreed at the 29th ATP and appears in Annex I of Directive 67/548/EEC containing the list of harmonised classifications and labelling for substances which are legally binding within the EU	

Section A9 (IX)	**Classification and Labelling**	
Section A9 **Annex Point IIA.IX**	**Proposal and justification for the classification and labelling of the active substance according to Directive 67/548/EEC**	**Official use only**
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	**March, 2008;** **July 2009**	
Materials and methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability	**Human Health: Acceptable.** **Environment part acceptable**	
Remarks		
Date June 2011		
Results and discussion	TM II 2011 Conclusions: Conclusions 29th ATP: Xn; R20/R22 Xi; R37 N; R50/53 According to CLP regulation 1272/2008: Acute Tox. 4, H332 Acute Tox. 4, H301 STOT SE3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 the guidance values in the CLP regulation are changed for specific target organ toxicity – repeated exposure. Guidance values for oral, 90d, rat, cat. 2: 10 mg/kg bw/d < C ≤ 100 mg/kg bw/d. Taking the new criteria into consideration: STOT RE2, H373 Should be added	

Section A9 (IX)	**Classification and Labelling**	
Section A9 **Annex Point IIA.IX**	**Proposal and justification for the classification and labelling of the active substance according to Directive 67/548/EEC**	**Official use only**
Conclusion	BE will get into contact with ECHA and discuss how to proceed as change in dose/concentration guidance values may lead to revision of classification The classification according to CLP 1272/2008 2nd ATP should be: Acute Tox. 4, H332 Acute Tox. 4, H301 STOT SE3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 STOT RE2, H373	
Reliability		
Acceptability		
Remarks		