Final addendum to the

Additional Report

- public version -

Additional risk assessment provided by the rapporteur Member State Greece for the existing active substance

CADUSAFOS

according to the Accelerated Resubmission Procedure laid down in Commission Regulation (EC) No. 33/2008

April 2009

Table of contents

European Commission

Programme for inclusion of Active Substances in Annex I of Council Directive 91/414/EEC (Articles 5 and 6 of Council Directive 91/414/EEC)

Draft assessment report prepared in the context of the possible inclusion of the following active substance in Annex I of Council Directive 91/414/EEC

CADUSAFOS

Volume 3

Addendum 1 to Additional Report to Annex B

Rapporteur Member State: ***Greece***

January 2009

HELLENIC MINISTRY OF RURAL DEVELOPMENT AND AGRICULTURE
GENERAL DIRECTORATE OF PLANT PRODUCTION
DIRECTORATE OF PLANT PROTECTION
DEPARTMENT OF PESTICIDES
150 Syngrou Ave.,
17671 Athens
Hellas

B.9 ECOTOXICOLOGY

B.9.1 EFFECTS ON BIRDS (Annex IIA 8.1; Annex IIIA 10.1)

B.9.1.7 Risk assessment

Toxicological Endpoints

Table 4. Toxicological Endpoints for Birds

Organisms	Study Type (test material)	Toxicological Endpoints
Bobwhite quail	Acute LD50 (a.s.)	16.1 mg/kg bw/day
Bobwhite quail	Acute LD50 (Rugby 200 CS)	102.6 mg/kg
Bobwhite quail	Dietary LC50 (a.s.)	10.8 mg/kg bw/day (42.5 ppm)
Bobwhite quail	Reproduction NOEL (a.s.)	1.1 mg/kg bw/day

Risk Assessment for Birds

Birds will not be exposed to cadusafos *via* consumption of vegetative material since:

- Rugby 200CS is applied only as drip-irrigation to bananas.
- The active substance cadusafos is not systemic and there will be no risk of residues translocating from the treated soil into the plant material.

However, there is a finite potential for exposure to insectivorous birds from invertebrates that may have been exposed to treated soil. Furthermore, since the log Pow for cadusafos is >3, there is theoretical potential for bioaccumulation in the food-chain. The potential for secondary poisoning risk to earthworm-eating birds was therefore considered.

Insectivorous Birds

Rugby 200 CS is applied by single drip-irrigation at a rate of 4.0 kg a.s./ha. Therefore, the use of default RUD values for insects intended for spray applications as suggested by SANCO/4145/2000 was not considered to represent the current scenario.

Instead, the calculation of the Tier 1 assessment for insectivorous birds as a worst case assumption was calculated using RUD (residue per unit dose) of endogaeic arthropods (living in the soil) to be 5.33 mg/kg (initial PEC_{soil}) (see Table 5).

The Initial PEC_{soil} calculation is as follows:

Initial soil PECs = A x (1- fint) / (100 x depth x bd) Initial soil PECs **=** 5.33

where:

A = application rate (g/ha); 4000 g a.s./ha

fint = fraction intercepted by crop canopy; 0 (irrigation lines below the foliage)

depth = mixing depth (cm); 0.05 m for bananas

bd = dry soil bulk density (g/cm^3); 1.5 g/cm^3

Since the product is applied by drip-irrigation (and in the absence of experimental data) it is worst-case to assume that the concentration on arthropods is equal to the initial PEC in soil.

Table 5: TER values for acute, short-term and long term risk for small insectivorous birds

Scenario	**FIR/bw**	**RUD (mg/kg)**	**ETE**	**Toxicity endpoint**	**TER**
Acute	1.04	5.33	5.54	16.1	**3**
Short-term	1.04	5.33	5.54	10.8	**2**
Long-term	1.04	5.33	5.54	1.1	**0.2**

FIR = food intake rate, FIR/bw = relative daily intake, RUD = residue per unit dose, ETE = estimated theoretical exposure, TER = toxicity-to-exposure ratio

The resulting TER values for acute, short-term and long term exposure are below the trigger value of 10 for acute and short-term toxicity and 5 for long-term toxicity. This indicates theoretical risk for insectivorous birds feeding on diet items exposed to cadusafos.

Refining Tier 1 risk assessment

For Tier 1 an assumption as a worst case assumption was calculated using RUD of endogaeic arthropods (living in the soil) to be equal to the initial PEC_{soil}. A more pragmatic risk assessment is provided below following the current GD for birds and mammals (SANCO/4145/2000) taking into consideration RUD values according to Fletcher et al. (1994) and Fischer and Bowers (1997) (Appendix II, table 10).

Table 6: TER values for acute, short-term and long term risk for small insectivorous birds

Scenario	FIR/bw	RUD (mg/kg)	Appl. Rate "	ETE	Toxicity endpoint	TER
Acute	1.04	1	4	4.16	16.1	**3.87**
Short-term	1.04	0.1	4	0.416	10.8	25.96
Long-term	1.04	0.1	4	0.416	1.1	**2.64**

FIR = food intake rate, FIR/bw = relative daily intake, RUD = residue per unit dose, ETE = estimated theoretical exposure, TER = toxicity-to-exposure ratio

The resulting TER values for acute, short-term and long term exposure are below the trigger value of 10 for acute and 5 for long-term toxicity. This indicates theoretical risk for insectivorous feeding on diet items exposed to cadusafos.

Earthworm-eating Birds

Samples of earthworms were collected during the reproduction study with cadusafos technical (conducted at a dose rate of 5.6 mg a.s./kg soil) and analyzed for residues of cadusafos. The results demonstrated that cadusafos residues are stable in earthworms from day 14 to day 56 with a maximum concentration of 0.53 mg/kg worm.

If these data are recalculated to adjust for difference in the application dose, then the maximum application rate of cadusafos is 4.0 kg a.s./ha corresponding to 5.33 mg a.s./kg soil (assuming an incorporation depth of 0.05 m and a soil density of 1.5 g/cm^3). An extrapolation of the results from the earthworm residue study provides a maximum residue of 0.50 mg/kg worm.

Table 7: TER values for earthworm-eating birds

Scenario	PEC worm	FIR/bw	ETE	Toxicity endpoint	TER
Acute	0.50	1.1	0.55	16.1	29
Short-term	0.50	1.1	0.55	10.8	20
Long-term	0.50	1.1	0.55	1.1	**2**

FIR = food intake rate, FIR/bw = relative daily intake, ETE = estimated theoretical exposure, TER = toxicity-to-exposure ratio

The resulting TER values for acute and short-term exposure exceed the trigger of 10, indicating an acceptable risk to earthworm-eating birds. The long-term TER value is below the chronic trigger of 5, indicating a possible risk to earthworm-eating birds from secondary exposure.

Refined Risk Assessment using Focal Species

From the initial Tier I assessment it was concluded that potential risk to insectivorous birds and chronic risk to earthworm-eating birds is possible. However, there are several mitigating factors that the above assessment does not take into account:

- Drip-irrigation in addition to the routine, intensive irrigation in banana plantations is likely to result in a significant dilution of residues in the surface layer of soil, thus reducing exposure of soil insects.
- Soil insects are unlikely to be the sole food source of birds, especially in the autumn (i.e., when Rugby 200 CS is applied) when berries / fruits and nuts are in abundance.
- Banana plantations are not the sole feeding habitat of birds, therefore birds do not exclusively consume food contaminated with cadusafos.

For this refined risk assessment, the use of Rugby 200 CS in the Canary Islands is discussed as representing the crop scenario. The Islands are a group of seven islands off the Moroccan coast of Africa with Tenerife and Gran Canaria as the most important islands for agricultural output. Therefore, Tenerife (the largest island, 2034 km^2) is considered in greater detail as a representative location. Banana growing in Tenerife is located almost exclusively in the coastal strips on the northern and western sides of the island (Diaz-Diaz *et al.,* 1998).

Guidelines Species of Relevance

In the SANCO/4145/2000 guidelines, the wren *(Troglodytidae)* and the tit *(onomatopoeic)* were chosen as worst case indicator species based on their strictly insectivorous diet and their low body weight corresponding to a high food intake rate (FIR). As mentioned above, due to the application of cadusafos by drip irrigation, only endogaeic (living in the soil) invertebrates (arthropods and earthworms) are potentially contaminated. The wren and the tit do not feed on endogaeic invertebrates, and are therefore not relevant species for this refined risk assessment of cadusafos use in banana plantations. Based on the use pattern of cadusafos (4.0 kg a.i./ha) applied by drip-irrigation in bananas, the Tier I assessment assumes potential risk to birds feeding on endogaeic arthropods (i.e., insectivorous birds) through chronic consumption of earthworms. As residues of cadusafos are associated with the soil matrix, epigaeic invertebrates (invertebrates that live or forage primarily above ground) and crop foliage would not be contaminated with cadusafos. Hence, birds feeding on the latter diet items will not be exposed to residues of cadusafos and are therefore not considered in this risk assessment.

Focal Species - Blackbird *(Turdus merula)*

Appropriate refinement of the potential risk to birds from the use of Rugby 200 CS when applied as a single dose of 4.0 kg a.s./ha in the autumn to bananas through drip-irrigation, requires an analysis of focal bird species that are known to frequent the crop at the time of application. The ubiquitous character of the Blackbird *(Turdus merula)* and the Canary Islands chiffchaff *(Phylloscopus canariensis)* known on the archipelago (Martin & Lorenzo, 2001) to utilize this extraordinary habitat. According to a comprehensive field survey in banana plantations in La Palma (Canary Islands), the blackbird *(Turdus merula)* was found to be the most dominant insect ground-foraging bird species (Giessing, 2005; RifCon, 2005). The blackbird is a ubiquitous species which the literature suggests fills similar niches across Europe; therefore behavior in one place can be considered representative of behavior across its European range. The foraging behavior of the blackbird includes digging in the upper soil layer for endogaeic invertebrates up to a depth of 4 cm (Glutz von Blotzheim, 2001). The blackbird is chosen as a relevant insectivorous focal species (over the Canary Islands chiffchaff) for this refined risk assessment of cadusafos use in banana plantations in Tenerife.

While the Canary Islands are visited annually by migratory birds that fly south from Africa in autumn in search of a warmer climate then return to Europe in the spring, the majority of migratory birds are marine (e.g., *Puffinus puffinus* (Procellariidae) (Martin, 1987) and not a concern in assessing the potential risk of cadusafos.

Refinement of PD (portion of different food types in the diet)

The blackbird is an omnivorous species which depends all year round on animal food items to some extent. The remainder of their diet consists largely of berries and fruits. The most important animal food items are earthworms *(Annelida),* beetles *(Coleoptera),* ants *(Formicidae),* snails *(Gastropoda),* and to a lesser extent *Chilopoda/Diplopoda, Arachnida* and other arthropods and their larvae (Glutz von Blotzheim, 2001). During the breeding season the blackbird relies exclusively on animal feed items (Glutz von Blotzheim, 2001).

Literature data indicate that the qualitative and quantitative composition of the animal diet varies slightly between different habitat types (see Table 8). Since the information concerning the specific extent of utilization of the banana plantations by the blackbird focuses on the breeding season (spring), and not when cadusafos would be applied in the autumn, it is assumed that the use of average feed consumption data most reliably reflect the situation in banana plantations. This also represents a worst-case diet composition for the blackbird in the autumn because it is highly unlikely that the blackbirds diet will consist solely (or a higher percentage) of animal feed items; rather, the majority of its diet is likely to consist of fall berries and fruits from the islands.

Table 8: Diet composition of the blackbird

Location (Reference)	**Epigaeic arthropods and gasteropods (%)**	**Endogaeic arthropods (%)**	**Earthworms** (%)
Oak forest and adjacent orchard (Torok, 1981)	91	1	8
Habitat unknown (Dyrcz, 1969)	44	2	34
Orange grove (Iglesias et al., 1993)	53	4	42
Various habitats (Havlin, 1962)	74	17	5
Mean	**66**	**6**	**22**

Based on this information, the diet composition of the blackbird in banana plantations is assumed to be:

- 66% (PD = 0.66) epigaeic arthropods and gastropods,
- 6% (PD = 0.06) endogaeic arthropods and
- 22 % (PD = 0.22) earthworms

Refinement of PT (portion of diet obtained from treated area)

There is no specific data concerning the proportion of diet obtained from the treated area (PT) are available for blackbirds in banana plantations. Results from a UK radio-tracking study in orchards (Crocker *et al.,* 1998) where 43 blackbirds were monitored are therefore utilized for estimating the PT. Banana plantations could be considered similar to orchards in terms of structure and form (dense crop canopy, within a patchwork environment of other crops that was similar to the landscape study in the UK). Therefore behavior of the ubiquitous blackbird is considered similar in both habitats.

Ninety five percent (95%) of the blackbirds in this study spent less than 82% of potential foraging time among orchard trees (PT = 0.82), non orchard habitat was their preferred location. Hence, for the purpose of an acute and short-term assessment, it is considered valid to incorporate a PT of 0.82 for the blackbird in banana plantations.

For the long-term risk assessment, the use of the 95th percentile severely overestimates exposure when considering a time frame of several days to weeks. More appropriately, an average value for PT should be the used, e.g., the 50th percentile of the available data set, corresponding to a PT = 0.218 (Crocker *et al.,* 1998). Furthermore, when considering the distribution and extent of banana plantations in Tenerife (Diaz-Diaz *et al,* 1998), the area coverage is almost exclusively in the coastal strips on the northern and western sides of the island. As the banana plantations represent only a small percentage of the land mass and are in distinct locations, the proposed refinement to the PT for birds is considered appropriate.

Refinement of FIR (food intake rate)

Central European blackbirds have a body weight of about 113 g and their average daily food intake is estimated as 279.1 kJ/day based on a body weight of 113 g (Crocker *et al,* 2002).

Arthropods on average contain 21.9 kJ/g dry weights and consist of 70.5% water. Therefore, arthropods contain 6.5 kJ/g fresh weight. A blackbird using 279.1 kJ/day must consume 43.2 g arthropods per day. Adjusting this figure for assimilation efficiency (76% for a passerine bird) results in an average daily food intake for a blackbird of 56.5 g arthropods per day, if exclusively feeding on arthropods. Related to the average body weight the FIR of blackbirds feeding on arthropods will be 0.50.

Regarding the earthworm fraction in the diet of blackbirds, a blackbird of 113 g body weight ingests 119.5 g earthworms (Crocker *et al.,* 2002). This results in a FIR/bw of 1.06.

Refined exposure assessment

The exposure assessment for the blackbird theoretically foraging in banana plantations treated with cadusafos at a rate of 4.0 kg a.s./ha is depicted in Table 9 and 10.

Table 9: Exposure assessment for the blackbird in banana plantations

Diet items	Epigaeic arthropods	Endogaeic arthropods	Earthworms
Application rate (kg a.i/ha)	4.0	4.0	4.0
C (mg a.i/kg)	0	5.33	0.50
FIR	0.50	0.50	1.06
AV	1	1	1
PT	0.82*/0.218^	0.82*/0.218^	0.82*/0.218^
PD	0.66	0.06	0.22
ETE	0*/0^	0.13*/0.03^	0.10*/0.03^
ETE total	0.23* / 0.06^		

*Acute and short-term values

^ Long-term values

Table 10: Refined risk assessment

Scenario	ETE	Toxicity Daily dose	TER
Acute	0.23	16.1	70
Short-term	0.23	10.8	47
Long-term	0.06	1.1	18

Alternative refined exposure assessment

A more pragmatic risk assessment is provided below following the current GD for birds and mammals (SANCO/4145/2000) taking into consideration RUD values according to Fletcher et al. (1994) and Fischer and Bowers (1997) (Appendix II, table 10).

Table 11: Exposure assessment for the blackbird in banana plantations

Diet items	Arthropods	Earthworms
Application rate (kg a.i/ha)	4.0	4.0
C (mg a.i/kg)	1*/0.1^#	0.50
FIR	0.50	1.06
AV	1	1
PT	0.82*#/0.218^	0.82*#/0.218^
PD	0.72	0.22
ETE	1.18*/0.11#/0.03^	0.10*#/0.03^
ETE total	1.28*/0.21#/0.06^	

*Acute and

#Short-term values

^ Long-term values

Table 12: Refined risk assessment

Scenario	ETE	Toxicity Daily dose	TER
Acute	1.28	16.1	12.57
Short-term	0.21	10.8	51
Long-term	0.06	1.1	18

Based on the relevant species (European blackbird), the acute and short-term TER values exceed the trigger of 10 for acute and short-term exposure.
For long-term exposure the TER is > 5.

As applications are made to soil the diet is expected to consist predominantly of large surface active soil invertebrates (e.g. beetles, spiders). In reality, residues on insects following drip application are minimal as the vast majority of their population will not be contaminated.
Furthermore, for the autumn application, is at a time when most birds are not exclusively insectivorous or earthworm eating in their feeding requirements, are unlikely to be nesting within the crop, and are not breeding. Only those birds feeding exclusively on the ground will be exposed for a prolonged period, and commonly occurring ground feeding species tend to be small or larger omnivores not small ground-only feeding insectivores. It is likely that the avian diet will consist of a high percentage of fruits, further reducing the potential risk from consumption of animal feed items.

For bird feeding on the ground only a proportion of the banana floor area is treated so birds will not be feeding exclusively on treated insects or earthworms and consequently the risk is considered to be acceptable.

Consequently, it is expected that cadusafos will not pose a risk to birds.

Conclusion

With regard to the use of cadusafos in banana plantations, the blackbird can be regarded as a relevant species for a refined exposure assessment. Based on this focal species for Tenerife banana plantations, the potential risk to insectivorous birds and the potential chronic risk from secondary poisoning from earthworm consumption are considered acceptable.

References

Crocker, D.R., Prosser, P., Tarrant, K.A., Irving, P.V., Watola, G., Chandler-Morris, S.A., Hart, J & A.D.M. Hart (1998). Contract PN0903. Improving the assessment of pesticide risks to birds in orchards. Central Science Laboratory, York, UK. CSL Report No. EH18/02.

Crocker, D.R., A.D.M. Hart, J. Gurney, & C. McCoy (2002). Ptoject PN0908: Methods for estimating daily food intake of wild birds and mammals. Central Science Laboratory, York, UK.

Diaz-Diaz, R., Garcia-Hemandez, J.E., & K. Loague. (1998). Leaching potentials of four pesticides used for bananas in the Canary Islands. J Environ Qual. 27:562-572.

Dyrcz, A. (1969). Comparative studies on the avifauna of wood and park. Acta orn. 7:337-385.

Giessing, B. (2005). Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data. RIFCON GmbH Report RC 05-015.

Glutz von Blotzheim, U. (2001). Handbuch der Voegel Mitteleuropas. CD-ROM version.

Havlin, J. (1962). Age structure and mortality rate in blackbird opulations. Zool, Listy. 11:279-285.

Iglesias, D.J., Gil-Delgado, J.A. & Barba, E. (1993). Diet of blackbird nestlings in orange groves: seasonal and age related variation. Ardeola 40(2): 113-119.

Martin, A. (1987). Atlas de las aves nidificantes en la isla de Tenerife. Instituto de Estudios Canarios. Monografia XXXII.
http://www.worldwildlife.org/wildworld/profiles/terrestrial/pa/pa1203_full.html

Torok, J. (1981). Food consumption ofnestling blackbirds in an oak forest bordering on an orchard. Opuscula zoological Instituti Zoosystematici Universitatis Budapestinensis. 17/18:145-156.

B.9.3 EFFECTS ON OTHER TERRESTRIAL VERTEBRATES (Annex IIA 10.3)

B.9.3.4.2 Risk assessment

Mammals will not be exposed to cadusafos *via* consumption of vegetative material since:

- The product, Rugby 200CS, is applied only as drip-irrigation to the soil around bananas and not to foliage.
- Cadusafos is not systemic and there will be no risk of residues translocating from the treated soil into the plant material.

However, there is a small potential for exposure to insectivorous mammals from invertebrates that may have been exposed to the treated soil. Moreover, since the log Pow for cadusafos is >3, there is theoretical potential for bioaccumulation within the food-chain. Therefore secondary poisoning risk to earthworm-eating mammals, if any, is also considered.

B.9.3.4.1 Toxicity

In the 2006 EFSA Scientific Peer Review conclusion for cadusafos (Rugby 200 CS) it was acknowledged that the notifier has revised its submission and will only support the use of cadusafos as a nematicide to control nematodes and soil insects on bananas.

Therefore, this revised risk assessment is provided to specifically address the risk to mammals from drip-irrigation uses in banana plantations grown in the Canary Islands.

As cadusafos has a logPow>3, and therefore a potential to bioaccumulate, the risk for secondary poisoning was also considered. The risk to earthworm-eating mammals is addressed according to scenarios established in the Guidance Document on Risk Assessment for birds and mammals under Council Directive 91/414/EEC (SANCO/4145/2000). Theoretical exposure to fish is not assessed since the use of cadusafos in banana plantations does not pose any potential exposure to aquatic organisms, nor does it have the potential to bioaccumulate in fish.

Table 13. Toxicological Endpoints for Mammals (technical material)

Organisms	Study Type	Toxicological Endpoint
Rat	Acute LD50	37.1 (32.2-42.0) mg/kg bw
Rat	Reproduction NOEL	0.045 mg/kg b.w./day

Insectivorous Mammals

Due to the application technique of single drip-irrigation directly to the underlying soil, at a rate of 4.0 kg a.s/ha, the use of the default RUD (residue per unit dose) values for insects from spray applications as suggested by SANCO/4145/2000 was not representative. Therefore as a worst case Tier 1 calculation for assessing the potential risk to insectivorous mammals, a RUD for endogaeic arthropods (living in the soil) was calculated to be 5.33 mg/kg (initial PECsoil) as follows (Table 11).

Initial PEC_{soil} calculation is as follows:

Initial soil PECs = A x (1- fint) / (100 x depth x bd) Initial soil PECs = 5.33

where:

A = application rate (g/ha); 4000 g a.s./ha

fint = fraction intercepted by crop canopy; 0 (irrigation lines below the foliage)

depth = mixing depth (cm); 0.05 m for bananas

bd = dry soil bulk density (g/cm^3); 1.5 g/cm^3

Since Rugby 200 CS is applied by drip-irrigation and in the absence of residue data for insects from the field, a worst-case assumption is that the concentration on arthropods is the same as the initial PEC in soil.

Table 14: TER values for insectivorous mammals

Exposure Scenario	FIR/bw	RUD (mg/kg)	ETE	Toxicity Endpoint (mg/kg bw)	TER
Acute	0.63	5.33	3.36	37.1	11
Long term	0.63	5.33	3.36	0.045	**0.01**

The resulting TER value for potential acute exposure is above the trigger of 10, indicating an acceptable risk to insectivorous mammals. The long-term TER value is below the chronic trigger of 5, which indicates a theoretical risk to insectivorous mammals feeding exclusively on diet items exposed to cadusafos.

Refining Tier 1 risk assessment

For Tier 1 an assumption as a worst case assumption was calculated using RUD of endogaeic arthropods (living in the soil) to be equal to the initial PEC_{soil}. A more pragmatic risk assessment is provided below following the current GD for birds and mammals (SANCO/4145/2000) taking into consideration RUD values according to Fletcher et al. (1994) and Fischer and Bowers (1997) (Appendix II, table 10).

Table 15: TER values for acute and long term risk for small insectivorous mammals

Scenario	FIR/bw	RUD (mg/kg)	Appl. Rate	ETE	Toxicity endpoint	TER
Acute	0.63	1	4	2.52	37.1	14.7
Long-term	0.63	0.1	4	0.252	0.045	**0.17**

FIR = food intake rate, FIR/bw = relative daily intake, RUD = residue per unit dose, ETE = estimated theoretical exposure, TER = toxicity-to-exposure ratio

The resulting TER value for potential acute exposure is above the trigger of 10, indicating an acceptable risk to insectivorous mammals. The long-term TER value is below the chronic trigger of 5, which indicates a theoretical risk to insectivorous mammals feeding exclusively on diet items exposed to cadusafos.

Earthworm-eating Mammals

Samples of earthworms were collected during a reproduction study with cadusafos technical conducted at a dose rate of 5.6 mg a.s/kg soil and analyzed for residues of cadusafos. Cadusafos residues were stable in earthworms from day 14 to day 56 with a maximum concentration of 0.53 mg/kg worm.

If these data are recalculated to adjust for difference in the application dose, then the maximum application rate of cadusafos is 4.0 kg a.s./ha corresponding to 5.33 mg a.s./kg soil (assuming an incorporation depth of 0.05 m and a soil density of 1.5 g/cm^3). An extrapolation of the results from the earthworm residue study provides a maximum residue of 0.50 mg/kg worm.

Table 16: TER values for earthworm-eating mammals

Exposure Scenario	**PEC worm (mg/kg)**	**FIR/bw**	**ETE**	**Toxicity Endpoint (mg/kg bw)**	**TER**
Acute	0.50	1.4	0.70	37.1	53
Long - term	0.50	1.4	0.70	0.045	**0.06**

The resulting TER value for acute exposure is above the trigger of 10, indicating an acceptable risk to earthworm-eating mammals and giving further confidence to the Tier I risk assessment. The long-term TER value is below the chronic trigger of 5 indicating a theoretical risk from secondary exposure to earthworm-eating mammals.

B. 9.3.4.3 Refined Risk Assessment using Focal Species

From the initial Tier I assessment it was concluded that there may be a potential long-term risk to insectivorous and earthworm-eating mammals. However, there are several mitigating factors that the above assessment does not take into account:

- Drip-irrigation in addition to the routine, intensive irrigation in banana plantations is likely to result in a significant dilution of residues in the surface layer of soil, thus reducing potential exposure of soil insects.
- Soil insects from the treated area are unlikely to be the sole food source of mammals, especially in the autumn (i.e., when cadusafos is applied) when alternative food sources, e.g. berries / fruits and nuts are available.

- Banana plantations are not necessarily the sole feeding habitat of mammals; the agricultural practice results in little soil vegetation, which in turn leaves mammals at greater risk of predation, therefore mammals do not exclusively consume from this crop - food contaminated with cadusafos.

For this refined risk assessment, the use of Rugby 200 CS in the Canary Islands is discussed as representing the crop scenario. There are seven islands in the group, located off the Moroccan coast of Africa. Tenerife and Gran Canaria as the most important of the island with respect to agricultural production. Tenerife (the largest island, 2034 km^2) was considered in detail in this risk assessment, as a representative location. Banana growing in Tenerife is located almost exclusively in the coastal strips on the northern and western sides of the island (Diaz-Diaz *et* al., 1998).

Guideline Species of Relevance

In the SANCO/4145/2000 guidance document, the representative insectivorous mammal is the shrew. The Pygmy white-toothed shrew *(Suncus etruscus)* have been spotted in Tenerife banana plantations during an extensive survey conducted by Giessing (2005; Rifcon, 2005). However, the shrew is not very likely to occur in noteworthy numbers in banana plantations due to its habitat preferences.
Other native species to the island that were observed in Tenerife banana plantations are; bats, Algerian hedgehog, rats, rabbit and Western house mouse (Giessing, 2005; RifCon, 2005).

Focal Species - Algerian hedgehog *(Atelerix aligirus)*

In selecting a representative mammalian species to address the potential risk to insectivorous and earthworm-eating mammals, the Algerian hedgehog *(Atelerix aligirus)* was considered the most appropriate based on both diet and occurrence. During the survey by Giessing (2005; RifCon, 2005), the Algerian hedgehog was repeatedly noted to forage on soil invertebrates in the Tenerife banana plantations. This mammal's diet consists mainly of soil insects, isopoda and myriapoda and occasionally small reptiles Based on diet, the numerous bat species that inhabit the islands were not considered as representative as the Algerian hedgehog for assessing the potential risk to insectivorous and earthworm-eating mammals from the use of cadusafos on bananas, since the diet of this organism comprises mainly of flying insects and fruits. Similarly, the diets of other native species (rats, rabbit and mice) contain a lower percentage of soil-dwelling insects compared to the hedgehog, and/or their preferred habitat and key forging grounds were unlikely to be banana plantations that would cause their presence in the crop to be extremely limited, relative to the hedgehog (see report by Giessing, 2005; RifCon, 2005). Therefore, based on the Algerian hedgehog's habitat preferences and its insectivorous diet composition, it was selected as a relevant and representative insectivorous focal species for the following refined risk assessment.

Refinement of PD (portion of different food types in the diet)

The Algerian hedgehog is considered to be an insectivorous species which depends all year round on animal food items. Available information indicates strong similarities to the quantitative diet composition of the Western hedgehog *(Erinaceus europaeus).* To better quantify the diet composition of the Algerian hedgehog, the two species' diets are considered to be identical for the purpose of this assessment.

Literature data indicate that the qualitative and quantitative composition of the Western hedgehog's diet varies slightly between reviews (see Table 17). Since the information concerning the specific extent of utilization of the banana plantations by the Algerian hedgehogs is not recorded for Tenerife, it is assumed that the use of the worst-case/ highest existing values recorded per feed item for the Western hedgehog to be the most reliable and maximum diet composition in reflecting the current situation.

Table 17: Western hedgehog diet composition (as surrogate for Algerian Hedgehog)

Reference	Epigaeic arthropods and gasteropods (%)	Endogaeic arthropods (%)	Earthworms (%)	Others (%)
Yalden 1976 (in % weight)	66	4	13	18
Grosshans 1983 (in % volume)	49	6	5	40
Highest Value	**66**	**6**	**13**	**40**

Based on this information, the diet composition of the Algerian hedgehog in banana plantations is assumed to be as follows for further calculations:

- 66% (PD = 0.66) epigaeic arthropods and gastropods,
- 6% (PD = 0.06) endogaeic arthropods and
- 13% (PD = 0.13) earthworms
- 40% (PD = 0.40) others

Refinement of PT (portion of diet obtained from treated area)

In general, the Algerian hedgehog does prefer shrub-like vegetated areas (Giessing, 2005; RifCon, 2005) and is therefore unlikely to forage exclusively in banana plantations, especially for a repeated long-term risk exposure. Thus, the Algerian hedgehog is expected to obtain a limited portion of its overall diet from the treated area. Therefore, in the long-term, it is assumed that the hedgehog obtains a maximum of 10% (i.e. PT = 0.1%) of its diet from a potentially treated area. A PT= 0.1 based on foraging time is considered conservative for estimating the potential long-term exposure to cadusafos since the single drip-irrigation application is targeted to reach 15 to 20 cm below the surface and the product does not remain in the soil surface where dwelling arthropods are often found, hence limiting the amount of available contaminated feed. Finally, cadusafos has a Henry's Law Constant of 1.32 x 10^{-1} $Pa.m^3.mol^{-1}$ (at 25°C) and can be considered as volatile, therefore the potential for contamination of insects on the soil or plant surface is also negligible.

However, due to the lack of actual data regarding the long-term feeding behavior of the hedgehog in banana plantations, the refined exposure assessment also considers an exaggerate portion of 30% of the Algerian hedgehog's diet could be obtained from a banana plantation in Tenerife and still contain cadusafos residues. Long-term PTs used in the refined risk assessment in section 4.6 are PT= 0.1 and 0.3.

For the acute risk assessment, the default PT of 1 (portion of diet consists solely (100%) from the treated area) is considered appropriate.

Refinement of FIR (food intake rate)

The Algerian hedgehog has a maximum body weight of about 650 g (Niethammer & Krapp, 1990), which results in an average daily food intake of 674.5 kJ/day (Crocker *et al.*, 2002).

Considering feed items, arthropods on the average contain 21.9 kJ/g dry weight and consist of 70.5% water. Therefore, arthropods contain 6.5 kJ/g fresh weight. An Algerian hedgehog using 674.5 kJ/day needs to eat 103.8 g arthropods per day. Adjusting this figure for assimilation efficiency (88% for an insectivorous mammal) this results in an average daily food intake of an Algerian hedgehog of 117.9 g arthropods per day, if exclusively feeding on arthropods. Related to the average body weight the FIR (food intake rate) for the Algerian hedgehog feeding on arthropods is 0.18.

Regarding the earthworm fraction (8.1 kJ/g fresh weight) in the diet, Algerian hedgehogs need to eat 83.3 g earthworms per day. Adjusting this figure for assimilation efficiency (88% for an insectivorous mammal) this results in an average daily food intake of 94.6 g earthworms/day, if exclusively feeding on earthworms. Related to the average body weight the FIR for Algerian hedgehogs feeding on earthworms will be 0.15.

Refined exposure assessment

The exposure assessment for the Algerian hedgehog theoretically foraging in banana plantations treated with cadusafos at a rate of 4.0 kg a.s./ha is depicted in Table 18 and Table 19.

Table 18: Exposure assessment for the Algerian hedgehog foraging in banana plantations

Diet items	Epigaeic arthropods (& Others)	Endogaeic arthropods	Earthworms
Application rate (kg a.i/ha)	4.0	4.0	4.0
C (mg a.i/kg)	0	5.33	0.50
FIR	0.18	0.18	0.15
AV	1	1	1
PT	1*/0.1^	1*/0.1^or0.3^	1*/0.1^or0.3^
PD	0.66	0.06	0.13
ETE	0*/0^	0.06* / 0.006^ or 0.02^	0.01*/ 0.001^ or 0.003
ETE total	0.07* /0.007^ or 0.023		

*Acute and short-term values

^ Long-term values; PT is calculated for both 10% and 30% of diet obtained from treated field

Table 19: Refined risk assessment

Exposure Scenario	ETE	Toxicity Daily dose (mg/kg bw)	TER
Acute	0.07	37.1	530
Long-term	0.007	0.045	6.4
Long-term	0.023	0.045	**2**

Alternative refined exposure assessment

A more pragmatic risk assessment is provided below following the current GD for birds and mammals (SANCO/4145/2000) taking into consideration RUD values according to Fletcher et al. (1994) and Fischer and Bowers (1997) (Appendix II, table 10).

Table 20: Exposure assessment for the blackbird in banana plantations

Diet items	Arthropods	Earthworms
Application rate (kg a.i/ha)	4.0	4.0
C (mg a.i/kg)	1*/0.1^	0.50
FIR	0.18	0.15
AV	1	1
PT	1*/0.1^or0.3^	1*/0.1^or0.3^
PD	0.72	0.13
ETE	0.129* / 0.005^ or 0.0155^	0.01*/ 0.001^ or 0.003
ETE total	0.139* /0.006^ or 0.0185	

*Acute and

^ Long-term values

Table 21: Refined risk assessment

Scenario	ETE	Toxicity Daily dose	TER
Acute	0.139	37.1	267
Long-term	0.006	0.045	7.5
Long-term	0.0185	0.045	**2.43**

Based on the Algerian hedgehog as a representative species, the acute and long-term (PT = 10%) TER values exceed the trigger of 10 and 5 respectively, for potential exposure to insectivorous mammals and secondary poisoning to earthworm-eating mammals. The long-term TER calculated using an exaggerated assumption that 30% of the hedgehogs overall diet contains cadusafos is below the trigger of 5. A TER below 5 for the long-term potential risk to mammals consuming insect feed over a long period of time is not a concern since cadusafos is highly unlikely to remain at the surface for a significant period of time from a single drip-irrigation application.

As applications are made to soil the diet is expected to consist predominantly of large surface active soil invertebrates (e.g. beetles, spiders). In reality, residues on insects following drip application are minimal as the vast majority of their population will not be contaminated.

Furthermore, for the autumn application, is at a time when most mammals are not exclusively insectivorous or earthworm eating in their feeding requirements, and are not breeding. Mammals feeding exclusively on the ground tend to be small or larger omnivores not small ground-only feeding insectivores. It is likely that the mammalian diet will consist of a high percentage of other habitats, further reducing the potential risk from consumption of animal feed items.

For mammals feeding on the ground only a proportion of the banana floor area is treated so mammals will not be feeding exclusively on treated insects or earthworms and consequently the risk is considered to be acceptable.

Consequently, it is expected that cadusafos will not pose a risk to mammals.

Conclusions

With regard to the use of cadusafos in banana plantations, the Algerian hedgehog can be regarded as a relevant species for a refined exposure assessment. Based on this focal species for Tenerife banana plantations, the potential risk to insectivorous mammals and the potential risk from secondary poisoning from earthworm consumption are both considered acceptable.

References

Crocker, D.R., A.D.M. Hart, J. Gurney, & C. McCoy (2002). Project PN0908: Methods for estimating daily food intake of wild birds and mammals. Central Science Laboratory, York, UK.

Diaz-Diaz, R., Garcia-Hernandez, J.E., & K. Loague. (1998). Leaching potentials of four pesticides used for bananas in the Canary Islands. J Environ Qual. 27:562-572.

Giessing, B. (2005). Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data. RIFCON GmbH Report RC 05-015.

Grosshans, W. (1983). Zur Nahrung des Igels *(Ericaceus europapaeus L.)* Untersuchung von magen-darminalten schleswig-holsteinischer Igel. *Zoologischer Anzeiger* Jena 211: 364-384.

Mitchell-Jones, A.J., Amori, G., Bogdanoowicz, W., Krystufek, B.(Reijnders, P.J.H., Spitzenburger, F., Stubbe, M., Thissen, J.B.M., Vohralik, V & J. Zima (1999). The atlas of European mammals. T & AD Poyser.

Niethammer, J. & F., Krapp (1990). Handbuch der Saugetiere Europas, Band 3 Insektenfresser, Herrentiere. Akadem. Verl-Ges., Wiesebaden.

Palomo, L.J. & J. Gisbert (2002). Atlas de los mamiferos terrestres de Espana. Dirreccion General de Conservacion de la Naturaleza-SECEM-SECEMU, Madrid.

Yalden, O.W. (1976). The food of the hedgehog in England. *Ada theriolog.* 21:401-424.

B.9.6 EFFECTS ON EARTHWORMS (ANNEX IIA 8.4; ANNEX IIIA 10.6.1)

B 9.6.1 ADDITIONAL DATA

B 9.6.1.1. Toxicity data for EARTHWORMS in a field study

INTRODUCTION

Rugby 200 CS is a nematicide and insecticide containing the active ingredient cadusafos. This study was initiated in the summer of 2004 and was designed to evaluate the effects upon, and subsequent recovery of naturally existing earthworm populations following a single application of Rugby 200 CS applied at one rate, together with forced irrigation to increase exposure. The study was initiated on bare-earth plots in an arable field in South West England and was designed in accordance with the BBA Guideline (Part VI-2-3, 1994: Effects of Plant Protection Products on Earthworms in the Field), the ISO guidance document (ISO 11268-3, 1999: Soil quality -effects of pollutants on earthworms - Part 3: Guidance on the determination of effects in field situations), the recommendations of the International Workshop on Earthworm Ecotoxicology (Greig-Smith et al., 1992) and the recommendations of the International Workshop on Advances in Earthworm Ecotoxicology (Sheppard *et al,* 1997).

MATERIALS AND METHODS

The experimental site was established on an area of land measuring approximately 51 m x 69 m, comprising approximately one third of a hectare. The preceding crop was maize. The study was of a randomised block design with three treatments and four replicates to give a total of twelve plots. The treatments comprised a water control, the test item, at a single rate of 22.5 L ha^{-1} Rugby 200CS (equivalent to 4.5 kg cadusafos ha^{-1}) and a reference item carbendazim applied at 4000 g ai ha $^{-1}$. Pre-study earthworm sampling was conducted at the field site to determine whether sufficient numbers (20 earthworms m^2 in pre-treatment samples (BBA Guideline, 1994)) and appropriate representative species of earthworms were present. Samples were collected from four locations across the site using both the formalin method (Raw 1959) and hand-digging method within the same areas. Twelve plots, each 15 m x 15 m were established on the site. The distance between plots was 3 m. Each plot was uniquely numbered and had a marked central 12 m x 12 m sampling area. The plots were numbered consecutively from 1 to 12 and were prefixed by the replicate number. Six soil cores (each 25 mm x 300 mm) were collected from each of five positions across the site. Soil cores were pooled to give five samples for analysis.

The test item was Rugby 200 CS, a capsule suspension formulation containing the active ingredient cadusafos (nominal content 200 g l^{-1}). The reference item was Delsene 50 Flo, a suspension concentrate containing 500 g l^{-1} carbendazim. Full details of test and reference items are given in Table 2.

Treatments were applied in a volume equivalent to 200 1 ha^{-1}, at the following rates

- Water (control)
- 22.5 L ha^{-1} Rugby 200CS, equivalent to 4.5 kg cadusafos ha^{-1} (test item)
- 4000 g ai ha^{-1} carbendazim (reference item)

RESULTS

Earthworm abundance and biomass

A sample was collected from four areas of the site before the start of the study to confirm that the site was suitable. These samples showed that there were more than 20 earthworms per square metre and that the site would therefore be suitable. Results of the pre-treatment sample collected from each of the 12 plots confirmed that the site was suitable and met the guideline requirements. Earthworm numbers exceeded a mean of 20 per square metre and representatives of the major earthworm groups, including *Aporrectodea caliginosa* were present. Analysis of variance of the pre-treatment sample data showed there were no significant differences between plots for abundance or biomass of total earthworms, or for any individual taxon. Therefore all statistical analyses of data were conducted using two-way analysis of variance. Any differences between treatments and levels of significance were determined and assigned to treatments using Dunnett's tests. Significant differences are not shown for sampling occasions where total numbers were lower than five individuals per square metre in the control treatment.

Total earthworms

In the control treatment, the highest mean numbers (119.8) were found in the pre-treatment sample and the lowest (38.0) in the final sample collected approximately one year after treatment. Abundance in the test item treatment was significantly lower ($p<0.01$) than control on one occasion only, approximately three months after treatment. There were no significant differences on any other sampling occasion. In the reference item treatment, mean numbers were similar to the control in the pre-treatment sample. In the first post-treatment sample, numbers were approximately 34% lower than control and a significant difference ($p<0.05$) was apparent in the second post-treatment sample when numbers were approximately 53.7% of control. This confirms the validity of the study according the ISO guideline criterion. There were no significant differences between the control and either the test or reference item on any sampling occasion.

Table 22: Summary of statistically significant differences to Water Control for earthworm abundance

	4.5 kg/ha cadusafos					4 kg/ha carbendazim				
SPECIES	21 DBA[A]	42 DAA*	97 DAA	203 DAA	357 DAA	21 DBA	42 DAA	97 DAA	203 DAA	357 DAA
Lumbricus terrestris adult	t	t	t	t	t	t	t	t	t	t
Lumbricus terrestris juvenile	t	t		t	t	t	t	t	t	t
Lumbricus festivus adult	-	t	t	t	-	-	t	t	t	--
Lumbricus castaneus adult	t	t	t	t	t	t	t	t	t	t
Lumbricus rubellus adult	t	t	t	t	t	t	t	t	t	t
Aporrectodea caliginosa adult	-	-	-	*	-	-	-	-	-	-
Aporrectodea rosea adult	-	-	t	t	▬ –	-	-	t	t	-
Aporrectodea longa adult	t	t	t	t	t	t	t	t	t	t
Allolobophora chlorotica adult	t	**	-	-	t	t	-	-	-	t
Allolobophora chlorotica juvenile	-	-	-	t	t	-	-	-	t	t
Octolasion cyaneum adult	t	-	t	t	-	t	-	t	t	-
Octolasion cyaneum juvenile	-	-	t	-	t	-	-	t	-	t
Epilobous juvenile	-	-	*	-	-	-	-	*	-	-
Tanylobous Juvenile	t	t	-	-	-	t	t	-	-	-

Unidentifiable	t	t	t	t	t	t	t	t	t	t
TOTAL EARTHWORMS	-	-	*	-	-	-	-	*	-	-

*	Significant difference p<0.05 (ANOVA & Dunnett's test)
**	Significant difference p<0.01 (ANOVA & Dunnett's test)
t	Numbers <5 in total in control treatment. Statistical analysis not considered appropriate
DBA[A]	Days before application
DAA*	Days after application

Table 23: Summary of statistically significant differences to Water Control for earthworm biomass

	4.5 kg/ha cadusafos					4 kg/ha carbendazim				
SPECIES	21 DBA[A]	42 DAA*	97 DAA	203 DAA	357 DAA	21 DBA	42 DAA	97 DAA	203 DAA	357 DAA
Lumbricus terrestris adult	t	t	t	t	t	t	t	t	t	t
Lumbricus terrestris juvenile	t	t	t	t	t	t	t	t	t	t
Lumbricus festivus adult	-	t	t	t	-	-	t	t	t	■ --
Lumbricus castaneus adult	t	t	t	t	t	t	t	t	t	t
Lumbricus rubellus adult	t	t	t	t	t	t	t	t	t	t
Aporrectodea caliginosa adult	-	-	-	*	-	-	-	-	-	-
Aporrectodea rosea adult	-	-	t	t	-	-	-	t	t	-
Aporrectodea longa adult	t	t	t	t	t	t	t	t	t	t
Allolobophora chlorotica adult	t	**	-	-	t	t	-	-	-	t
Allolobophora chlorotica juven ile	-	-	-	t	t	-	-	-	t	t
Octolasion cyaneum adult	t	-	t	t	-	t	-	t	t	-

Octolasion cyaneum juvenile	-	-	t	-	t	-	-	t	-	t
Epilobous juvenile	-	-	*	-	-	-	-	-	-	-
Tanylobous Juvenile	t	t	-	-	-	t	t	-	-	-
Unidentifiable	t	t	t	t	t	t	t	t	t	t
TOTAL EARTHWORMS	-	-	-	-	-	-	-	-	-	-

* Significant difference $p<0.05$ (ANOVA & Dunnett's test)

** Significant difference $p<0.01$ (ANOVA & Dunnett's test)

t Numbers <5 in total in control treatment. Statistical analysis not considered appropriate

DBA[A] Days before application

DAA* Days after application

Table 24: Mean total number of earthworms per treatment (adults and juveniles) collected on each sampling occasion (earthworms m^{-2})

Date	Control	(Standard deviation)	4.5 kg/ha cadusafos	(Standard deviation)	4 kg/ha carbendazim	(Standard deviation)
30Jun2004	119.8	(40.2)	120.5	(27.8)	129.3	(17.9)
1 Sep 2004	74.3	(42.2)	79.0	(14.4)	49.0	(16.1)
26 Oct 2004	67.8	(6.4)	16.3**	(4.0)	31.3*	(21.4)
9 Feb 2005	45.0	(16.9)	35.0	(14.8)	39.0	(19.7)
13&14Jul2005	38.0	(16.8)	52.5	(23.0)	36.5	(26.7)

Epilobous juveniles

Epilobous juveniles were one of the dominant groups found during the study. Numbers were high relative to total earthworms in the control treatment, on all sampling occasions representing a minimum 30% of total numbers (approximately 7 months after treatment) and a maximum of 74% of total numbers (pre-treatment). Abundance was significantly lower ($p<0.01$) in the test item treatment compared to control on the second post-treatment sampling occasion, approximately three months after treatment only. The reference item treatment was also significantly lower ($p<0.05$) than control on this occasion only. There was a significant difference ($p<0.05$) between the control and the test item only on one sampling occasion approximately three months after application.

Table 25: Mean number of epilobous juveniles per treatment collected on each sampling occasion (earthworms m^{-2})

Date	Control	(Standard deviation)	4.5 kg/ha cadusafos	(Standard deviation)	4 kg/ha carbendazim	(Standard deviation)
30 Jun 2004	88.3	(39.5)	90.8	(19.9)	97.3	(13.0)
1 Sep 2004	33.0	(20.8)	37.3	(7.6)	15.8	(1.7)
26 Oct 2004	42.5	(3.1)	6.5**	(3.4)	16.5*	(11.1)
9 Feb 2005	13.5	(9.0)	15.3	(6.0)	15.3	(11.4)
13&14M2005	21.8	(15.3)	33.0	(23.6)	25.8	(24.1)

Tanylobous spp. juveniles

Tanylobous juveniles were found in low numbers (fewer than 5) in the pre-treatment and first post-treatment samples and data here have not been analysed. There were no significant differences between the control and the test or reference item on the second, third or final post-/treatment sampling occasions. There were no significant differences between the control and the test or reference item on the second, third or final post-treatment sampling occasions.

Table 26: Mean number of tanylobous juveniles per treatment collected on each sampling occasion (earthworms m^{-2})

Date	Control	(Standard deviation)	4.5 kg/ha cadusafos	(Standard deviation)	4 kg/ha carbendazim	(Standard deviation)
30 Jun 2004	0.5	(0.6)	0.5t	(0.6)	1.3t	(0.5)
1 Sep 2004	0.3	(0.5)	0.0t	(0.0)	0.8t	(1.5)
26 Oct 2004	4.3	(4.0)	1.8	(2.4)	2.0	(2.8)
9 Feb 2005	6.3	(3.3)	5.5	(3.1)	3.8	(2.1)
13&14Jul2005	1.8	(0.5)	2.0	(0.8)	1.3	(1.3)

* Significant difference p<0.05 (ANOVA & Dunnett's test)

** Significant difference p<0.01 (ANOVA & Dunnett's test)

t Numbers <5 in total in control treatment. Statistical analysis not considered appropriate

***Aporrectodea caliginosa* Adults**

Adults of the species *Aporrectodea caliginosa* comprised approximately 45% of all other taxonomic groups of earthworms found in the water control treated plots during the study. Highest numbers (mean 26.5) were found on the first post-treatment sampling occasion and lowest (mean 4.5) were found on the pre-treatment sampling occasion. Abundance of *Aporrectodea caliginosa* was significantly lower (p<0.05) in the test item treatment than control on the third post-treatment sampling occasion, approximately 7 months after treatment. No significant differences in abundance were found on any other sampling occasion. Biomass of *A. caliginosa* was significantly lower (p<0.05) in the test item treatment than control on the third post treatment sampling occasion, approximately 7 months after treatment. No significant differences in abundance were found on any other sampling occasions.

Table 27: Mean number of Aporrectodea caliginosa adults per treatment collected on each sampling occasion (earthworms m^{-2})

Date	Control	(Standard deviation)	4.5 kg/ha cadusafos	(Standard deviation)	4 kg/ha carbendazim	(Standard deviation)
30 Jun 2004	4.5	(5.1)	7.8	(4.9)	8.3	(7.8)
1 Sep 2004	26.5	(11.8)	33.0	(11.5)	23.3	(16.3)
26Oct2004	7.8	(5.4)	3.3	(3.2)	7.5	(5.6)
9 Feb 2005	14.0	(5.0)	9.3*	(5.6)	12.8	(5.5)
13&14Jul2005	6.3	(5.3)	10.0	(6.8)	2.3	(1.0)

***Allolobophora chlorotica* adults**

The species *Allolobophora chlorotica* comprised approximately 49% of the remaining earthworms sampled (excluding *A. caliginosa*, and tanylobous and epilobous juveniles), of which approximately 33% were adults. On the first post-treatment sampling occasion, approximately one month after treatment, numbers in the test item treatment were significantly lower ($p<0.01$) than control with a mean of 0.5 per square metre compared to a mean of 2.5 per square metre respectively. On the second and third post-treatment sampling occasions there were no significant differences between test item and control treatments. Numbers were too low (fewer than five per square metre) on the pre-treatment and final sampling occasion and no analysis was carried out. No significant differences were found between the reference item treatment and control on any of the dates where analyses were conducted.

Biomass of *Allolobophora chlorotica* adults was significantly lower ($p<0.01$) in the test item treatment compared to the control on the first post-treatment sampling occasion, approximately one month after treatment. No differences were found on any other sampling occasion where analyses were carried out. No significant differences in biomass were found between the reference item and control.

Table 28: Mean n umber of Allolobophora chlorotica adults per treatment collected on each sampling occasion (earthworms m^{-2})

Date	Control	(Standard deviation)	4.5 kg/ha cadusafos	(Standard deviation)	4 kg/ha carbendazim	(Standard deviation)
30 Jun 2004	0.3	(0.5)	0.3t	(0.5)	0.8t	(1.0)
1 Sep 2004	2.5	(1.3)	0.5**	(0.6)	4.0	(0.8)
26Oct2004	4.3	(2.2)	1.5	(1.0)	1.8	(1.5)
9 Feb 2005	5.0	(2.8)	2.3	(2.6)	3.3	(0.5)
13&14Jul2005	0.0	(0.0)	0.5t	(1.0)	0.3t	(0.5)

Allolobophora chlorotica **juveniles**

The highest number of *Allolobophora chlorotica* juveniles were found on the pre-treatment sampling occasion and the lowest on the fourth post-treatment sampling occasion, with means per square metre of 10.8 and 0.8 respectively. There were no significant differences between the test or reference item treatment and control on the first or second post-treatment sampling occasion. On the third and fourth post-treatment sampling occasions, approximately six and twelve months after treatment numbers were too low (fewer than 5 per square metre) for analysis. There were no significant differences between the test or reference item treatments and control on any of the post-treatment sampling occasions, where analysis were carried out.

Table 29: Mean number of Allolobophora chlorotica juveniles per treatment collected on each sampling occasion (earthworms m^{-2})

Date	Control	(Standard deviation)	4.5 kg/ha cadusafos	(Standard deviation)	4 kg/ha carbendazim	(Standard deviation)
30 Jun 2004	10.8	(3.2)	10.5	(4.8)	8.8	(4.8)
1 Sep 2004	4.8	(2.6)	2.8	(4.3)	2.5	(3.0)
26Oct2004	6.5	(5.6)	2.2	(1.0)	1.8	(1.0)
9 Feb 2005	1.0	(1.2)	0.5t	(0.6)	0.3t	(0.5)
13&14Jul2005	0.8	(1.0)	1.3*	(1.3)	0.3t	(0.5)

* Significant difference p<0.05 (ANOVA & Dunnett's test)

** Significant difference p<0.01 (ANOVA & Dunnett's test)

t Numbers <5 in total in control treatment. Statistical analysis not considered appropriate

Other species

The remaining species sampled comprised approximately 11% of all earthworms collected throughout the study only. Where statistical analysis was appropriate and carried out, no significant differences in abundance or biomass were found between test or reference item treatments and control for any species on any occasion. The *Lumbricus* spp., *L. terrestris* (adult and juvenile), *L. festivus and L. castaneus* were all found in low numbers (fewer than five per square metre) and analysis was not carried out. *Apporectodea rosea* adults were found at their highest (7.5 per square metre) in the reference item allocated treatment on the pre-treatment sampling occasion. Lowest (0.0 per square metre) were found in the test item treatment on the second and third post-treatment sampling occasion. *Octolasium cyaneum* adults were found in low (fewer than five) numbers on the pre-treatment, second and third post-treatment sampling occasions and juveniles on the second and fourth post-treatment sampling occasions. No significant differences were found between test and reference item treatments and control for either adults or juveniles on any of the remaining sampling occasions. The highest number of *Octolasium cyaneum* adults found was a mean of 2.5 per square metre in the control treatment on the fourth post-treatment sampling occasion. No adults were found on 5 occasions across treatments. The highest number of juveniles found was a mean of 7.5 per square metre in the control on the pre-treatment sampling occasion. No juveniles were found on two occasions in the test item treatment on the second and third post-treatment sampling occasion.

Findings and conclusions

Numbers of earthworms and levels of activity can vary considerably between seasons, some species having periods of obligatory diapause, in addition to periods of quiescence induced by adverse weather conditions. In the UK, this is most likely to-be a response to prolonged dry and warm conditions in summer (Edwards and Lofty, 1972, and Sims and Gerard, 1999). In this study it is likely that there were weather-related reductions in the sampled control population during the February 2005 (approximately six months after application) and in the final sample in July 2005 (approximately one year after application).

Two methods of earthworm sampling were used during the study. Hand digging and sorting was used for the pre-treatment sample, and for the first and final post-treatment sample when the formalin method was inefficient. The second and third post-treatment samples were collected using the formalin method. Numbers of earthworms collected from the control plots were in excess of 20 per square metre on all sampling occasions.

Six species of earthworm were collected during this study. Most, (adults and juveniles) belonged to the epilobous morphological group. Juveniles were more abundant than adults in all species collected and identified, and in both morphological groups. The dominant group of earthworms for both abundance and biomass was epilobous juveniles. The tanylobous group of earthworms that includes the *Lumbricus* genus was poorly represented at this site and individuals of species in the genus were found in low numbers (fewer than 5) on most sampling occasions. The most abundant species, present on all sampling occasions, was *Aporrectodea caliginosa.* The range of species collected is believed to be typical for an arable field in the Southwest of England.

During the one year sample period after test and reference item application, the highest number of earthworms collected from control plots was 119.8 per square metre in June 2004 (pre-treatment) and the lowest was 38.0 per square metre, in July 2005 (approximately one year after treatment).

At the first post-treatment sampling occasion (September, 2004) the total number of worms collected from control plots was 38% lower than the number collected on the pre-treatment sampling occasion. This reduction is likely to be an effect of site cultivation; harrowing before treatment application and incorporation of treatments after application. There was a small reduction of 9% in total control abundance between the first and second post-treatment samples (September - end of October 2004). At the time of the second post-treatment sampling occasion in February 2005, numbers in the control treatment were approximately 33% lower than the previous sampling occasion. It is possible that this was a result of the cold weather conditions because soil temperatures remained below 10°C and air temperatures were 12°C or below from December 2004 to February 2005. The final sampling occasion, in July 2005, approximately one year after application, coincided with the highest soil temperature recorded during the study and may have been a cause of the 16% reduction in numbers between the third post-treatment and the final sampling occasions.

The total numbers of worms collected in the reference item treatment were 35% and 53.7% lower than numbers collected from the control samples on the first and second post-treatment sampling occasions. On the second post-treatment sampling occasion, numbers were significantly lower than the control and thus fulfilled the guideline recommendation of 40% to 60% reduction in reference item treated plots. There were no significant differences in the reference item treatment compared with the control in any subsequent samples.

On the first post-treatment sampling occasion, approximately one month after application, there were significant differences in abundance and biomass in adults of one species only, *Allolobophora chlorotica,* in the test item treatment compared to the control. There were no significant differences in abundance and biomass of juveniles of this species compared to control. There were no significant differences on any subsequent sampling occasion for this species.

On the second post-treatment sampling occasion, approximately three months after application, the abundance of total earthworms was lower than the control in the test item treatment. Abundance and biomass were lower in the test item treatment compared to the control for the dominant group, epilobous juveniles, on this sampling occasion. It is likely that the effect on total earthworm numbers reflected the reduction in numbers of the epilobous juveniles since these comprised between 30% and 74% of total earthworm numbers during the study. On subsequent sampling occasions there were no significant differences between total earthworm or epilobous juvenile abundance and biomass. This confirms that the population of these two groups had recovered by the six month sampling occasion in February 2005.

On the six month post-treatment sampling occasion, numbers and biomass for adults of the species *Aporrectodea caliginosa,* were significantly lower in the test item treatment compared with the control. It was not possible to identify juveniles of this species so no data for juvenile *A. caliginosa* is available. On the final sampling occasion, no significant differences were detected for this species, indicating recovery within one year of treatment.

On the final sampling occasion, approximately one year after application, there were no significant differences in abundance or biomass from any group or species of earthworm collected during the study.

In summary, total earthworm abundance in the test item treatment was significantly lower than controls on one occasion only, three months after treatment. Biomass of total earthworms was not affected on any sampling occasion. Abundance and biomass of epilobous juveniles were affected on one occasion only, approximately three months after application, but not on any subsequent sampling date. Populations of both *A. chlorotica* and *A. caliginosa,* the only two species affected in the test item treatment, had recovered within one year of test item application. No effects were observed in any taxon on the final sampling occasion, one year after treatment.

In conclusion, under the conditions of this study, a single application of cadusafos at a rate of 4.5 kg ha^{-1} had no effect on earthworm abundance or biomass in an arable field by the end of the study, approximately one year after application.

REFERENCES

BBA Guideline (1994). Guidelines for the testing of Plant Protection Products Within Registration, Part VI No. 2-3; Effects of Plant Protection Products on Earthworms in the Field. Federal Biological Research Centre for Agriculture and Forestry. (BBA), F.R.G.

Edwards, C.A. and Lofty, J.R. (1972). Biology of Earthworms. Chapman and Hall, London, U.K.

The Good Laboratory Practice Regulations 1999, S.I. no. 3106. United Kingdom Department of Health, London, U.K.

The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004, S.I. no. 994. United Kingdom Department of Health, London, U.K.

Greig-Smith, P.W., Becker, H., Edwards, P.J. and Heimbach, F. (Eds.) (1992) Ecotoxicology of Earthworms. Intercept, Andover, U.K.

International Organisation for Standardisation. ISO 11268-3, (1999). Soil quality - effects of pollutants on earthworms - Part 3: Guidance on the determination of effects in field situations.

Mead, R. and Curnow, R.N. (1990) Statistical methods in Agriculture and Experimental Biology. Chapman and Hall, London, U.K.

The OECD Principles of Good Laboratory Practice as revised in 1997 (1998). Series on Principles of GLP and Compliance Monitoring No.I EMV/MC/CHEM(98)17. Organisation for Economic Co-operation and Development, Paris, France.

Raw, F. (1959) Estimating earthworm population by using formalin. *Nature* (London) 184, 1661-1662

Sheppard, S., Bembridge, J., Holmstrup, M. and Posthuma, L. (Eds.) (1997) Advances in Earthworm Ecotoxicology. SETAC Press.

Sims, R.W. and Gerard, B.M (1999) Earthworms. Synopses of the British Fauna (New Series) Eds. Barnes, R.S.K and Crothers, J.H. No. 31 (revised). Field Studies Council, Shrewsbury, U.K.

Sokal, R.R and Rohlf, F.J (1981) Biometry (2nd edition), Freeman and Co. USA

Zar, J. H. (1999) fourth ed. Biostatistical analysis. Prentice Hall, New Jersey.

European Commission

Programme for inclusion of Active Substances in Annex I of Council Directive 91/414/EEC (Articles 5 and 6 of Council Directive 91/414/EEC)

Draft assessment report prepared in the context of the possible inclusion of the following active substance in Annex I of Council Directive 91/414/EEC

CADUSAFOS

Second Addendum to Annex C

Confidential Information

Rapporteur Member State: ***Greece***

January 2009

HELLENIC MINISTRY OF RURAL DEVELOPMENT AND AGRICULTURE
GENERAL DIRECTORATE OF PLANT PRODUCTION
DIRECTORATE OF PLANT PROTECTION
DEPARTMENT OF PESTICIDES
150 Syngrou Ave.,
17671 Athens
Hellas

This document has not been peer reviewed and does not represent the opinion of the other Member States not the European Commission

CONFIDENTIAL INFORMATION AVAILABLE WITH RMS

European Commission

Programme for inclusion of Active Substances in Annex I of Council Directive 91/414/EEC (Articles 5 and 6 of Council Directive 91/414/EEC)

Draft assessment report prepared in the context of the possible inclusion of the following active substance in Annex I of Council Directive 91/414/EEC

CADUSAFOS
Volume 3
Addendum 2 to Additional Report to Annex B

Rapporteur Member State: ***Greece***

March 2009

HELLENIC MINISTRY OF RURAL DEVELOPMENT AND AGRICULTURE
GENERAL DIRECTORATE OF PLANT PRODUCTION
DIRECTORATE OF PLANT PROTECTION
DEPARTMENT OF PESTICIDES
150 Syngrou Ave.,
17671 Athens
Hellas

B.9 ECOTOXICOLOGY

B.9.1 EFFECTS ON BIRDS (Annex IIA 8.1; Annex IIIA 10.1)

B.9.1.7 Risk assessment

Toxicological Endpoints

Table 1: Toxicological Endpoints for Birds

Organisms	Study Type (test material)	Toxicological Endpoints
Bobwhite quail	Acute LD50 (a.s.)	16.1 mg/kg bw/day
Bobwhite quail	Acute LD50 (Rugby 200 CS)	102.6 mg/kg
Bobwhite quail	Dietary LC50 (a.s.)	10.8 mg/kg bw/day (42.5 ppm)
Bobwhite quail	Reproduction NOEL (a.s.)	1.1 mg/kg bw/day

Risk Assessment for Birds

Birds will not be exposed to cadusafos *via* consumption of vegetative material since:

- Rugby 200CS is applied only as drip-irrigation to bananas.
- The active substance cadusafos is not systemic and there will be no risk of residues translocating from the treated soil into the plant material.

However, there is a finite potential for exposure to insectivorous birds from invertebrates that may have been exposed to treated soil. Furthermore, since the log Pow for cadusafos is >3, there is theoretical potential for bioaccumulation in the food-chain. The potential for secondary poisoning risk to earthworm-eating birds was therefore considered.

Insectivorous Birds

Rugby 200 CS is applied by single drip-irrigation at a rate of 4.0 kg a.s./ha. Therefore, the use of default RUD values for insects intended for spray applications as suggested by SANCO/4145/2000 was not considered to represent the current scenario. Instead, the calculation of the Tier 1 assessment for insectivorous birds as a worst case assumption was calculated using RUD (residue per unit dose) of endogaeic arthropods (living in the soil) to be 5.33 x 6 =31.98 mg/kg (initial PEC_{soil}). It was noted in the fate meeting that the PECsoil is about 6 times higher than the PECsoil currently used which assumed a uniform distribution of the a.s. over the whole growing area (standard PECsoil for 5cm soil depth). The high PECsoil values will occur only locally (at the irrigation points, about 16% of the total surface). A rough estimate of the PECsoil can be done by multiplying the current PECsoil by 6 according to the fate discussion.

Since the product is applied by drip-irrigation (and in the absence of experimental data) it is worst-case to assume that the concentration on arthropods is equal to the initial PEC in soil.

Table 2: TER values for acute, short-term and long term risk for small insectivorous birds

Scenario	FIR/bw	RUD (mg/kg)	ETE	Toxicity endpoint	TER
Acute	1.04	31.98	33.25	16.1	**0.48**
Short-term	1.04	31.98	33.25	10.8	**0.32**
Long-term	1.04	31.98	33.25	1.1	**0.03**

FIR = food intake rate, FIR/bw = relative daily intake, RUD = residue per unit dose, ETE = estimated theoretical exposure, TER = toxicity-to-exposure ratio

The resulting TER values for acute, short-term and long term exposure are below the trigger value of 10 for acute and short-term toxicity and 5 for long-term toxicity. This indicates theoretical risk for insectivorous birds feeding on diet items exposed to cadusafos.

Food chain from earthworms to earthworms-eating birds

Taking into consideration the standard approach as it is provided by the Guidance document on birds and mammals

- PECsoil = 31.98 mg/kg (PECs initial x 6-worst case)
- The BCF for worms is estimated as BCF = $(0.84 + 0.01\ K_{ow})\ /\ f_{oc}\ K_{oc}$ with K_{ow} = 7080, K_{oc} = 227, and f_{oc} = 0.02 (default value) the resulting BCF is 15.78.
- The estimated concentration in worm (PEC_{worm}) is PEC_{soil} * BCF, i.e. 31.98 * 15.78= 504.6.
- The daily dose for earthworm-eating birds is ETE= 504.6 * 1.1 = 555 mg/kg bw/d
- The long-term TER-values is 1.1/555 =0.002<5 (trigger value) for birds, and therefore the risk is not acceptable.

The long-term TER value is below the chronic trigger of 5, indicating a possible risk to earthworm-eating birds from secondary exposure. It was agreed that the concentration in earthworms should be based on the PECsoil in 5cm depth in the treated area (16% of the total area). This leaves a large area untreated where earthworms would not be contaminated (negligible concentrations of cadusafos according to the fate discussion). This could be taken into account in a “weight of evidence” approach in the risk assessment.

Refined Risk Assessment using Focal Species

From the initial Tier I assessment it was concluded that potential risk to insectivorous birds and chronic risk to earthworm-eating birds is possible. However, there are several mitigating factors that the above assessment does not take into account:

- Drip-irrigation in addition to the routine, intensive irrigation in banana plantations is likely to result in a significant dilution of residues in the surface layer of soil, thus reducing exposure of soil insects.
- Soil insects are unlikely to be the sole food source of birds, especially in the autumn (i.e., when Rugby 200 CS is applied) when berries / fruits and nuts are in abundance.
- Banana plantations are not the sole feeding habitat of birds, therefore birds do not exclusively consume food contaminated with cadusafos.

For this refined risk assessment, the use of Rugby 200 CS in the Canary Islands is discussed as representing the crop scenario. The Islands are a group of seven islands off the Moroccan coast of Africa with Tenerife and Gran Canaria as the most important islands for agricultural output. Therefore, Tenerife (the largest island, 2034 km^2) is considered in greater detail as a representative location. Banana growing in Tenerife is located almost exclusively in the coastal strips on the northern and western sides of the island (Diaz-Diaz *et al.,* 1998).

Guidelines Species of Relevance

In the SANCO/4145/2000 guidelines, the wren *(Troglodytidae)* and the tit *(onomatopoeic)* were chosen as worst case indicator species based on their strictly insectivorous diet and their low body weight corresponding to a high food intake rate (FIR). As mentioned above, due to the application of cadusafos by drip irrigation, only endogaeic (living in the soil) invertebrates (arthropods and earthworms) are potentially contaminated. The wren and the tit do not feed on endogaeic invertebrates, and are therefore not relevant species for this refined risk assessment of cadusafos use in banana plantations. Based on the use pattern of cadusafos (4.0 kg a.i./ha) applied by drip-irrigation in bananas, the Tier I assessment assumes potential risk to birds feeding on endogaeic arthropods (i.e., insectivorous birds) through chronic consumption of earthworms. As residues of cadusafos are associated with the soil matrix, epigaeic invertebrates (invertebrates that live or forage primarily above ground) and crop foliage would not be contaminated with cadusafos. Hence, birds feeding on the latter diet items will not be exposed to residues of cadusafos and are therefore not considered in this risk assessment.

Focal Species - Blackbird *(Turdus merula)*

Appropriate refinement of the potential risk to birds from the use of Rugby 200 CS when applied as a single dose of 4.0 kg a.s./ha in the autumn to bananas through drip-irrigation, requires an analysis of focal bird species that are known to frequent the crop at the time of application. The ubiquitous character of the Blackbird *(Turdus merula)* and the Canary Islands chiffchaff *(Phylloscopus canariensis)* known on the archipelago (Martin & Lorenzo, 2001) to utilize this extraordinary habitat. According to a comprehensive field survey in banana plantations in La Palma (Canary Islands), the blackbird *(Turdus merula)* was found to be the most dominant insect ground-foraging bird species (Giessing, 2005; RifCon, 2005). The blackbird is a ubiquitous species which the literature suggests fills similar niches across Europe; therefore behavior in one place can be considered representative of behavior across its European range. The foraging behavior of the blackbird includes digging in the upper soil layer for endogaeic invertebrates up to a depth of 4 cm (Glutz von Blotzheim, 2001). The blackbird is chosen as a relevant insectivorous focal species (over the Canary Islands chiffchaff) for this refined risk assessment of cadusafos use in banana plantations in Tenerife.

While the Canary Islands are visited annually by migratory birds that fly south from Africa in autumn in search of a warmer climate then return to Europe in the spring, the majority of migratory birds are marine (e.g., *Puffinus puffinus* (Procellariidae) (Martin, 1987) and not a concern in assessing the potential risk of cadusafos.

The experts agreed to use blackbird as a focal species representing vermivorous/omnivorous birds but the risk to smaller insectivorous birds also needs to be addressed (e.g. grey wagtail).

Refinement of PT (portion of diet obtained from treated area)

There is no specific data concerning the proportion of diet obtained from the treated area (PT) are available for blackbirds in banana plantations. Results from a UK radio-tracking study in orchards (Crocker *et al.,* 1998) where 43 blackbirds were monitored are therefore utilized for estimating the PT. Banana plantations could be considered similar to orchards in terms of structure and form (dense crop canopy, within a patchwork environment of other crops that was similar to the landscape study in the UK). Therefore behavior of the ubiquitous blackbird is considered similar in both habitats.

Ninety five percent (95%) of the blackbirds in this study spent less than 82% of potential foraging time among orchard trees (PT = 0.82), non orchard habitat was their preferred location. Hence, for the purpose of an acute and short-term assessment, it is considered valid to incorporate a PT of 0.82 for the blackbird in banana plantations.

For the long-term risk assessment, the use of the 95^{th} percentile severely overestimates exposure when considering a time frame of several days to weeks. More appropriately, an average value for PT should be the used, e.g., the 50th percentile of the available data set, corresponding to a PT = 0.218 (Crocker *et al.,* 1998). Furthermore, when considering the distribution and extent of banana plantations in Tenerife (Diaz-Diaz *et al,* 1998), the area coverage is almost exclusively in the coastal strips on the northern and western sides of the island. As the banana plantations represent only a small percentage of the land mass and are in distinct locations, the proposed refinement to the PT for birds is considered appropriate.

The PT values were from orchards in UK. There is a high uncertainty if the values can be extrapolated to banana plantations. The experts agreed to use the 95th percentile PT for the long-term risk assessment instead of the 50th percentile to account for the uncertainty with regard to the extrapolation to banana plantations. For the acute risk assessment no PT refinement should be applied.

Refinement of FIR (food intake rate)

Central European blackbirds have a body weight of about 113 g and their average daily food intake is estimated as 279.1 kJ/day based on a body weight of 113 g (Crocker *et al,* 2002). Arthropods on average contain 21.9 kJ/g dry weights and consist of 70.5% water. Therefore, arthropods contain 6.5 kJ/g fresh weight. A blackbird using 279.1 kJ/day must consume 43.2 g arthropods per day. Adjusting this figure for assimilation efficiency (76% for a passerine bird) results in an average daily food intake for a blackbird of 56.5 g arthropods per day, if exclusively feeding on arthropods. Related to the average body weight the FIR of blackbirds feeding on arthropods will be 0.50.

Regarding the earthworm fraction in the diet of blackbirds, a blackbird of 113 g body weight ingests 119.5 g earthworms (Crocker *et al.,* 2002). This results in a FIR/bw of 1.06.

Refined exposure assessment

The exposure assessment for the blackbird theoretically foraging in banana plantations treated with cadusafos at a rate of 4.0 kg a.s./ha is depicted in Table 3.

Table 3: TER values for acute, short-term and long term risk for small insectivorous birds

Scenario	FIR/bw	RUD (mg/kg	PT	ETE	Toxicity endpoint	TER
Acute	1.06	31.98	1	33.89	16.1	**0.47**
Short-term	1.06	31.98	1	33.89	10.8	**0.32**
Long-term	1.06	31.98	0.82	27.78	1.1	**0.04**

FIR = food intake rate, FIR/bw = relative daily intake, RUD = residue per unit dose, ETE = estimated theoretical exposure, TER = toxicity-to-exposure ratio

Conclusion

With regard to the use of cadusafos in banana plantations, the blackbird can be regarded as a relevant species for a refined exposure assessment. Based on this focal species for Tenerife banana plantations, the potential risk to insectivorous birds and the potential chronic risk from secondary poisoning from earthworm consumption are not considered acceptable and there is a need for refinement. However it should be taken into account that only 16% of the in-field area is treated due to the drip irrigation which would leave the majority of feed items uncontaminated. This information can be used in a weight of evidence approach (qualitative assessment).

The risk to smaller insectivorous birds also needs to be addressed (e.g. grey wagtail).

References

Crocker, D.R., Prosser, P., Tarrant, K.A., Irving, P.V., Watola, G., Chandler-Morris, S.A., Hart, J & A.D.M. Hart (1998). Contract PN0903. Improving the assessment of pesticide risks to birds in orchards. Central Science Laboratory, York, UK. CSL Report No. EH18/02.

Crocker, D.R., A.D.M. Hart, J. Gurney, & C. McCoy (2002). Ptoject PN0908: Methods for estimating daily food intake of wild birds and mammals. Central Science Laboratory, York, UK.

Diaz-Diaz, R., Garcia-Hemandez, J.E., & K. Loague. (1998). Leaching potentials of four pesticides used for bananas in the Canary Islands. J Environ Qual. 27:562-572.

Giessing, B. (2005). Birds and mammals inhabiting banana plantations on the Canary Islands - Literature survey and re-analysis of monitoring data. RIFCON GmbH Report RC 05-015.

Glutz von Blotzheim, U. (2001). Handbuch der Voegel Mitteleuropas. CD-ROM version.

Martin, A. (1987). Atlas de las aves nidificantes en la isla de Tenerife. Instituto de Estudios Canarios. Monografia XXXII.
http://www.worldwildlife.org/wildworld/profiles/terrestrial/pa/pa1203_full.html

B.9.3 EFFECTS ON OTHER TERRESTRIAL VERTEBRATES (Annex IIA 10.3)

B.9.3.4.2 Risk assessment

Mammals will not be exposed to cadusafos *via* consumption of vegetative material since:

- The product, Rugby 200CS, is applied only as drip-irrigation to the soil around bananas and not to foliage.
- Cadusafos is not systemic and there will be no risk of residues translocating from the treated soil into the plant material.

However, there is a small potential for exposure to insectivorous mammals from invertebrates that may have been exposed to the treated soil. Moreover, since the log Pow for cadusafos is >3, there is theoretical potential for bioaccumulation within the food-chain. Therefore secondary poisoning risk to earthworm-eating mammals, if any, is also considered.

B.9.3.4.1 Toxicity

In the 2006 EFSA Scientific Peer Review conclusion for cadusafos (Rugby 200 CS) it was acknowledged that the notifier has revised its submission and will only support the use of cadusafos as a nematicide to control nematodes and soil insects on bananas. Therefore, this revised risk assessment is provided to specifically address the risk to mammals from drip-irrigation uses in banana plantations grown in the Canary Islands.
As cadusafos has a logPow>3, and therefore a potential to bioaccumulate, the risk for secondary poisoning was also considered. The risk to earthworm-eating mammals is addressed according to scenarios established in the Guidance Document on Risk Assessment for birds and mammals under Council Directive 91/414/EEC (SANCO/4145/2000). Theoretical exposure to fish is not assessed since the use of cadusafos in banana plantations does not pose any potential exposure to aquatic organisms, nor does it have the potential to bioaccumulate in fish.

Table 4. Toxicological Endpoints for Mammals (technical material)

Organisms	Study Type	Toxicological Endpoint
Rat	Acute LD50	37.1 (32.2-42.0) mg/kg bw
Rat	Reproduction NOEL	0.045 mg/kg b.w./day

Insectivorous Mammals

Due to the application technique of single drip-irrigation directly to the underlying soil, at a rate of 4.0 kg a.s/ha, the use of the default RUD (residue per unit dose) values for insects from spray applications as suggested by SANCO/4145/2000 was not representative. Therefore as a worst case Tier 1 calculation for assessing the potential risk to insectivorous mammals, a RUD for endogaeic arthropods (living in the soil) was calculated to be 5.33 x 6 =31.98 mg/kg (initial PEC_{soil}). It was noted in the fate meeting that the PECsoil is about 6 times higher than the PECsoil currently used which assumed a uniform distribution of the a.s. over the whole growing area (standard PECsoil for 5cm soil depth). The high PECsoil values will occur only locally (at the irrigation points, about 16% of the total surface). A rough estimate of the PECsoil can be done by multiplying the current PECsoil by 6 according to the fate discussion.

Since Rugby 200 CS is applied by drip-irrigation and in the absence of residue data for insects from the field, a worst-case assumption is that the concentration on arthropods is the same as the initial PEC in soil.

Table 5: TER values for insectivorous mammals

Exposure Scenario	**FIR/bw**	**RUD (mg/kg)**	**ETE**	**Toxicity Endpoint (mg/kg bw)**	**TER**
Acute	0.63	31.98	20.14	37.1	**1.84**
Long term	0.63	31.98	20.14	0.045	**0.002**

The resulting TER value for potential acute exposure and the long-term TER value are below the chronic trigger of 5, which indicates a theoretical risk to insectivorous mammals feeding exclusively on diet items exposed to cadusafos.

Earthworm-eating Mammals

Taking into consideration the standard approach as it is provided by the Guidance document on birds and mammals

- PECsoil = 31.98 mg/kg (PECs initial x 6-worst case)
- The BCF for worms is estimated as BCF = (0.84 + 0.01 K_{ow}) / f_{oc} K_{oc} with K_{ow} = 7080, K_{oc} = 227, and f_{oc} = 0.02 (default value) the resulting BCF is 15.78.
- The estimated concentration in worm (PEC_{worm}) is PEC_{soil} * BCF, i.e. 31.98 * 15.78= 504.6.
- The daily dose for earthworm-eating mammal is ETE= 504.6 * 1.4 = 706.5 mg/kg bw/d
- The long-term TER-values is 0.045/706.5 =0.00006<5 (trigger value) for mammals, and therefore the risk is not acceptable.

The long-term TER value is below the chronic trigger of 5 indicating a theoretical risk from secondary exposure to earthworm-eating mammals. It was agreed that the concentration in earthworms should be based on the PECsoil in 5cm depth in the treated area (16% of the total area). This leaves a large area untreated where earthworms would not be contaminated (negligible concentrations of cadusafos according to the fate discussion). This could be taken into account in a "weight of evidence" approach in the risk assessment.

Refined Risk Assessment using Focal Species

From the initial Tier I assessment it was concluded that there may be a potential long-term risk to insectivorous and earthworm-eating mammals. However, there are several mitigating factors that the above assessment does not take into account:

- Drip-irrigation in addition to the routine, intensive irrigation in banana plantations is likely to result in a significant dilution of residues in the surface layer of soil, thus reducing potential exposure of soil insects.
- Soil insects from the treated area are unlikely to be the sole food source of mammals, especially in the autumn (i.e., when cadusafos is applied) when alternative food sources, e.g. berries / fruits and nuts are available.
- Banana plantations are not necessarily the sole feeding habitat of mammals; the agricultural practice results in little soil vegetation, which in turn leaves mammals at greater risk of predation, therefore mammals do not exclusively consume from this crop - food contaminated with cadusafos.

For this refined risk assessment, the use of Rugby 200 CS in the Canary Islands is discussed as representing the crop scenario. There are seven islands in the group, located off the Moroccan coast of Africa. Tenerife and Gran Canaria as the most important of the island with respect to agricultural production. Tenerife (the largest island, 2034 km^2) was considered in detail in this risk assessment, as a representative location. Banana growing in Tenerife is located almost exclusively in the coastal strips on the northern and western sides of the island (Diaz-Diaz *et* al., 1998).

It should be taken into account that only 16% of the in-field area is treated due to the drip irrigation which would leave the majority of feed items uncontaminated. This information can be used in a weight of evidence approach (qualitative assessment).

References

Diaz-Diaz, R., Garcia-Hernandez, J.E., & K. Loague. (1998). Leaching potentials of four pesticides used for bananas in the Canary Islands. J Environ Qual. 27:562-572.

European Commission

Programme for inclusion of Active Substances in Annex I of Council Directive 91/414/EEC (Articles 5 and 6 of Council Directive 91/414/EEC)

Draft assessment report prepared in the context of the possible inclusion of the following active substance in Annex I of Council Directive 91/414/EEC

CADUSAFOS

Corrigendum to Second Addendum to Annex C

Confidential Information

Rapporteur Member State: ***Greece***

March 2009

HELLENIC MINISTRY OF RURAL DEVELOPMENT AND AGRICULTURE
GENERAL DIRECTORATE OF PLANT PRODUCTION
DIRECTORATE OF PLANT PROTECTION
DEPARTMENT OF PESTICIDES
150 Syngrou Ave.,
17671 Athens
Hellas

CONFIDENTIAL INFORMATION AVAILABLE WITH RMS