

## Hazardous Substances Consideration Committee

### TOPIC: Consideration of Application for the Modified Reassessment of DuPont Coragen Insecticide

#### Introduction

- 1 DuPont (New Zealand) Limited is seeking the modified reassessment of the substance identified as DuPont Coragen Insecticide. The substance was approved by the Authority on 26 September 2008 via Part 5 of the Hazardous Substances and New Organisms Act 1996 (“the Act”) and has the HSNO Approval Number of HSR007969.
- 2 One of the controls of the approval states that:  
  
*“The maximum application rate for DuPont Coragen Insecticide shall be 0.020 kg ai/ha and 3 times per season (minimum application interval: 7 days).”*
- 3 The applicant intends to market the substance for use as a turf insecticide at an application rate that exceeds the maximum application rate allowed under the existing approval.
- 4 The proposed modification, therefore, relates to an increase in the maximum application rate to allow the substance to be used on turf at the application rate proposed by the applicant.

#### Legislative Criteria for the Application

- 5 Unless otherwise stated, references to section numbers in this report refer to sections of the Act and clauses to clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 (“the Methodology”).
- 6 In its decision dated 27 January 2010 (Application Number: ERMA200233), the Authority determined that the proposed use of the substance at a rate that exceeds the specified maximum application rate is a significant change of use and therefore constitutes grounds for its reassessment (section 62(2)(c)). Consequently, the applicant is able to make an application for the modified reassessment of the substance.
- 7 The application was received on 26 May 2010 in accordance with section 63A on the basis that—
  - (a) a reassessment of the hazardous substance under section 63 is not appropriate because the reassessment will involve only a specific aspect of the approval (i.e. a change in the maximum application rate of the substance); and
  - (b) the amendment is not a minor or technical amendment to which section 67A applies (i.e. a change in use is not considered a minor or technical amendment).
- 8 The Authority may approve or decline an application for reassessment under this section, as it considers appropriate, after taking into account (see section 63A(6)):
  - a) all the effects associated with the reassessment; and

- b) the best international practices and standards for the safe management of hazardous substances.
- 9 When making their decision, the Authority must follow the decision path outlined in Appendix 1.

### **Notification and Consultation**

- 10 The Minister for the Environment was advised of the application<sup>1</sup> and given the opportunity to “call-in” the application<sup>2</sup>. This action was not initiated.
- 11 The Department of Labour (Workplace Group), the New Zealand Food Safety Authority (Agricultural Compounds and Veterinary Medicines (ACVM) Group) and the Department of Conservation were identified as having a specific interest in the application and were provided with a copy of the application (excluding the confidential information, but with the opportunity to access this if necessary).
- 11.1. No comments or submissions were received.
- 12 Other Government departments, Crown agencies and other interested parties, as listed in Appendix 4, were provided with a copy of the application summary and given the opportunity to comment or to make a submission.
- 12.1. No comments or submissions were received.
- 13 The application was publicly notified on the ERMA New Zealand website on 2 June 2010 and advertised in The Dominion Post, the New Zealand Herald, the Christchurch Press and the Otago Daily Times<sup>3</sup>.
- 13.1. One submission was received. The submitter indicated that they objected to this application and that they considered that no products containing toxins of any type should be allowed entry to New Zealand. They considered that allowing an increase in the application rate would result in increased contamination of the environment, further harm to terrestrial insects and more problems in regards to contamination of water courses. Their preference was for “non-toxic” forms of control, they did not, however, provide examples of potential non-toxic alternative forms of control.
- 13.2. The applicant declined to respond to the submission. The Agency considers that the concerns raised by the submitter, including the identified risks, will be addressed by the application of controls on the substance.

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<sup>1</sup> section 53(4)(a)

<sup>2</sup> section 68

<sup>3</sup> section 53

## AGENCY EVALUATION

- 14 To enable the Agency to consider all the effects associated with the proposed reassessment, the Agency has undertaken an assessment of the change in the risks, costs and benefits associated with the proposed modification to the approval of the substance.

### Risk Assessment

- 15 A “cost” is defined in Regulation 2 of the Methodology as “the value of a particular adverse effect expressed in monetary or non-monetary terms”. Thus, these have been assessed in an integrated fashion together with the risks of the adverse effects in the following assessment.
- 16 As the proposed modification relates to a change in use of the substance, the Agency has confined its risk assessment to the use phase of the substance’s lifecycle.
- 17 In accordance with sections 5 and 6 of the Act and clauses 9 and 12 of the methodology, the Agency has assessed the potentially non-negligible risks of the change in use of this substance in terms of risks to the environment, to human health and safety, to the relationship of Māori to the environment, to society and the community, to the market economy, and to New Zealand’s international obligations.

#### *Assessment of the risks to the environment*

- 18 The Agency has classified DuPont Coragen Insecticide as being very toxic to the aquatic environment (9.1A). Thus, organisms in the aquatic environment may be adversely affected if exposed to the substance.
- 19 The Agency has undertaken quantitative modelling of the risks to the environment when used at the proposed application rate and compared this to the risks associated with the use of the substance at the current maximum application rate.
- 20 The results of the risk assessments are summarised in Table 1 and discussed in more detail in Appendix 2.

**Table 1: Risks to the environment from the use of DuPont Coragen Insecticide**

Potential Adverse Effect	Proposed Application Rate	Current Maximum Application Rate	Change in risk
Death or adverse effects to aquatic organisms in the environment.	High acute risk to crustacea and a high chronic risk to crustacea and aquatic insects.	Acute risk to crustacea that can be mitigated through restricted use and a high chronic risk to aquatic insects	Significant increase in risk.
Death or adverse effects to soil organisms, including non-target plants, in the environment.	Risk to springtails via in field exposure.	No risks to soil organisms or non-target plants via either in field or off field exposure	Significant increase in risk.

Death or adverse effects to birds.	High chronic risk for an adverse effect on egg shell thickness and strength	No acute or chronic risks to birds	Significant increase in risk.
Death or adverse effects to bees.	Low risk to bees	Low risk to bees	No significant increase in risk.
Death or adverse effects to non-target invertebrates in the environment.	High risk via either in field or off field exposure	High risk via either in field or off field exposure	No significant increase in risk.
Adverse effects to ground water.	High risk of leaching into ground water	High risk of leaching into ground water	No significant increase in risk.

21 The Agency notes the results of the quantitative modelling and considers that the following existing controls on the substance will reduce the level of risk to the environment at either application rate:

- the approved handler controls (triggered by the 9.1A classification);
- prohibiting the application of the substance into or onto water;
- restricting the method of application of the substance to ground-based methods only;
- when applied by boom sprayer, the boom height should be kept as low as practicable to avoid spray drift;
- The labels for the substance shall state the following:
  - *“The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in the substance leaching into ground-water”*
  - *“Harmful to some beneficial insects – particularly some foliage dwelling predators that may be used in Integrated Pest Management”*
  - *“Due to the persistent nature of chlorantraniliprole in soil, this product is expected to accumulate over successive seasons following repeated use.”*
- DuPont (New Zealand) Limited shall make available to ERMA New Zealand the results of any soil accumulation trials for chlorantraniliprole upon their completion.

22 The Agency notes that the risk assessment indicates that the application frequency of the substance should be restricted to once per year to further reduce the risks to non-target organisms and the environment, so that the level of risk is **negligible**. Therefore, the following revised maximum application rate should be set for the use of the substance on turf:

- The maximum application rate for the substance shall be 0.30 kg ai/ha once per year.

### *Assessment of the risks to human health and safety*

- 23 The Agency has not classified DuPont Coragen Insecticide as being hazardous to human health or safety. Therefore, no assessment of the risks of the substance to human health and safety has been conducted.

### *Relationship of Māori to the Environment*

- 24 The Agency notes that DuPont Coragen insecticide triggers a hazardous property giving rise to the potential for cultural risk including the deterioration of the mauri of taonga flora and fauna species and the environment (i.e. this substance has the potential to leach into ground water, thereby disrupting the mauri of the water).
- 25 In addition, the introduction and use of this substance has the potential to inhibit the ability of iwi/Māori to fulfill their role as kaitiaki, particularly in relation to the guardianship of waterways given the highly ecotoxic nature of the substance to aquatic species.
- 26 On considering the information outlined here and elsewhere in this report, the Agency considers a *minimal* impact from DuPont Coragen insecticide on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga to be *highly improbable*. In addition there is no evidence to suggest that the controlled use of DuPont Coragen insecticide will breach the principles of the Treaty of Waitangi.
- 27 The overall level of risk is therefore considered to be *negligible* assuming that the substance will be handled, stored, transported, used, and disposed of, in accordance with the explicitly stated default and additional controls proposed in this report, and any other controls required by other legislation. It is considered that the increase in the application rate will not affect this assessment.
- 28 However, the Agency notes that should inappropriate use, or accident, result in the contamination of waterways or the environment generally, that users notify the appropriate authorities including the relevant iwi authorities in that region. This action should include advising them of the contamination and the measures taken to contain and remediate.

### *Assessment of the risks to society and the community*

- 29 There are not expected to be any significant adverse impacts on the social environment with the controlled use of the substance as a pesticide, apart from the environmental effects already discussed. Consequently, the Agency considers that this aspect of potential risk need not be considered further.

### *Assessment of the risks to the market economy*

- 30 Taking into account the level of risk to the environment and to human welfare, no sources of additional risk have been identified that could result in an adverse economic impact on a community.
- 31 The Agency notes that direct economic costs will be borne by the applicant and users of the substance. The HSNO default controls intentionally do not manage direct economic effects. These are for suppliers and users of the substance to address.

### *New Zealand's international obligations*

- 32 The Agency does not anticipate that the use of the substance at the increased application rate will pose any risks to New Zealand's international obligations.

### **Assessment of Beneficial Effects**

- 33 A "benefit" is defined in Regulation 2 of the Methodology as "the value of a particular positive effect expressed in monetary or non-monetary terms". Benefits that may arise from any of the matters set out in clauses 9 and 11 were considered in terms of clause 13.
- 34 The applicant claims that the proposed modification of the approval of the substance will provide the following benefits:
- At present there are a limited number of insecticides currently approved for use on turf. The availability of DuPont Coragen for use on turf, at application rates necessary for effective control of the insect pests in turf, will provide groundsmen with an insecticide option which is virtually harmless to the applicator and those using the amenity area.
  - Increased profits and employment opportunities within DuPont (New Zealand) Limited and those involved in the distribution of the substance within New Zealand.
- 35 The Agency considers the economic and related benefits to be derived from the use of the substance on turf at the increased application rates are potentially significant.

### **Controls**

- 36 As a result of the proposed modification to the approval of this substance, no variations to the existing controls on the substance are necessary, with the exception of the revision of the maximum application rate.
- 37 The Agency has considered the controls imposed by the Authority in approvals given to other pesticides under Part 5 of the Act as well as those transferred to the Act under the *Hazardous Substances (Pesticides) Transfer Notice 2004 (as amended)* and considers that the controls listed in Appendix 3 should apply to the substance.

### **Overall evaluation of risks, costs and benefits**

- 38 The Agency notes that there is a significant increase in the risks to the environment as a result of the increase in the maximum application rate. However, the Agency considers the increased risks of the substance to the environment will be managed by the existing controls on the substance. Therefore, the Agency considers the risks of the substance to the environment and human health, with the existing controls in place, to be negligible.
- 39 The Agency does not consider there to be significant risks to Māori cultural wellbeing, society and the community, the market economy, or to New Zealand's international obligations associated with the modified reassessment.

- 40 The Agency has taken the type and severity of the risks, and the characteristics of such risks into account, and considers that the overall level of risk posed by the substance is negligible.
- 41 The Agency considers that there are benefits associated with the modified reassessment of this substance.
- 42 Thus, the Agency considers that the benefits of the modified reassessment outweigh the costs.

### **Best international practices and standards for the safe management of hazardous substances**

- 43 The requirement to consider best international practices and standards for the safe management of hazardous substances is demonstrated by assessing the proposed modified reassessment against:
- the Globally Harmonised System of Classification and Labelling of Chemicals;
  - international codes of practice and standards;
  - overseas legislative requirements.

#### *Globally Harmonised System*

- 44 The controls applied to the substance as a result of the modified reassessment are based on the HSNO Regulations. These regulations specify a number of controls aimed at managing the risk posed by hazardous substances throughout their lifecycle, such as the requirement for protective clothing and provision of appropriate information, disposal and emergency management requirements. These regulations have previously met the requirements of section 141(1)(b) on best international practices and standards for the safe management of hazardous substances. In particular, the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), published by the United Nations, forms the basis of the HSNO hazard classification system and the requirements for the provision of information on hazards.

#### *International Codes of Practice and Standards*

- 45 The transportation controls on the substance requiring the segregation of incompatible substances are cross-references to the requirements of the Land Transport Rule, the Maritime Rule and the Civil Aviation Rule, which are themselves based on the International UN Transport of Dangerous Goods Model Regulations, the International Maritime Dangerous Goods Code and the International Civil Aviation Organization Regulations.

#### *Overseas Legislative Requirements*

- 46 The Agency notes that the substance is approved for use as a pesticide by a number of overseas regulators. The controls proposed by the Agency are consistent with those imposed by the overseas regulators.

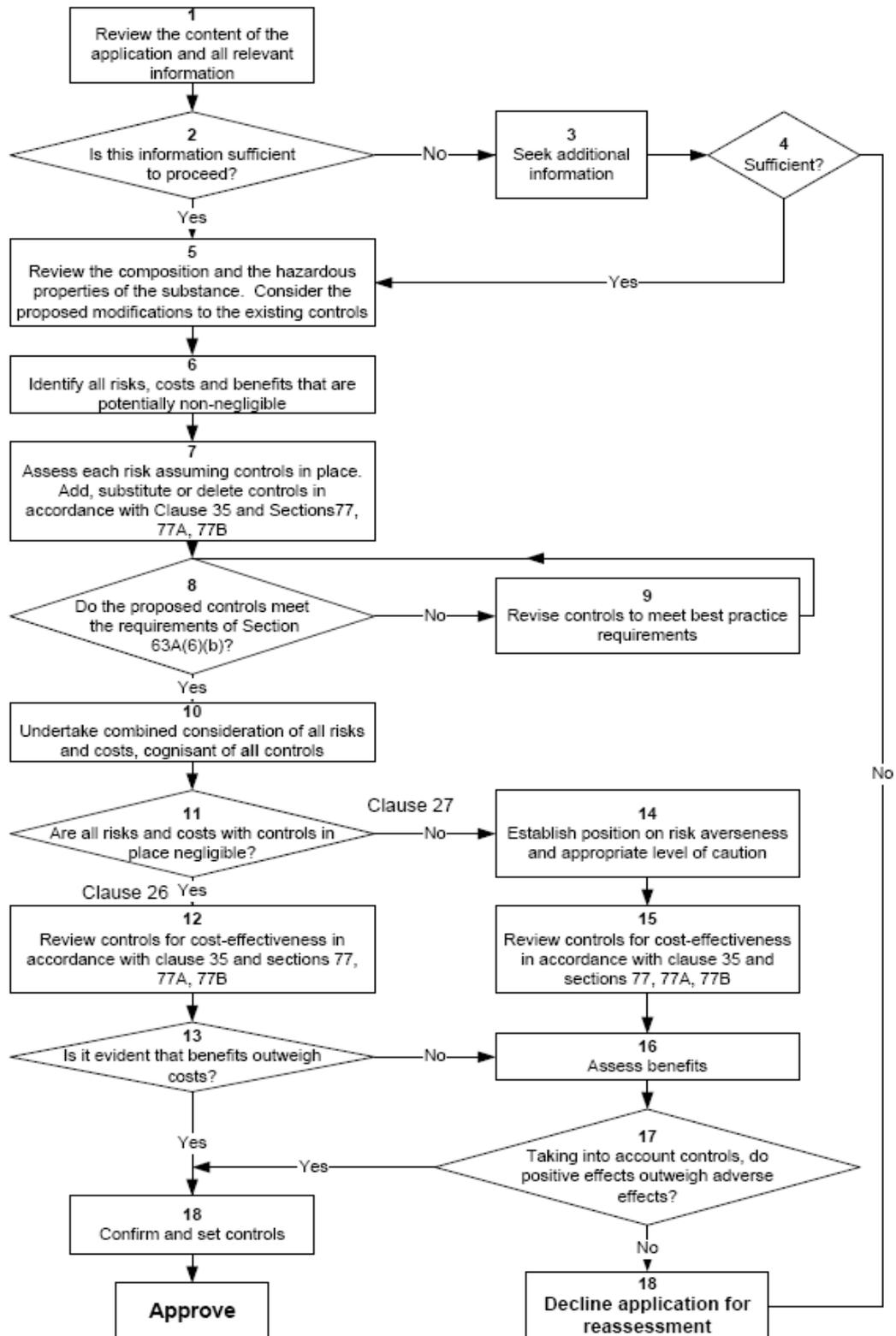
## Conclusions

- 47 DuPont (New Zealand) Limited is seeking the modified reassessment of the substance identified as DuPont Coragen Insecticide to allow its use on turf at application rates that exceed the existing maximum application rate.
- 48 The Agency considers that there are negligible risks to the environment and human health, with the existing controls in place, and benefits associated with the modified reassessment of the substance.
- 49 The Agency considers that the modified reassessment meets the requirements of best international practices and standards for the safe management of hazardous substances.
- 50 The Agency considers that the application for the modified reassessment meets the requirements of section 63A(6) and, therefore, may be approved in accordance with clause 26.
- 51 The Agency considers that the controls listed in Appendix 3 should apply to DuPont Coragen Insecticide.

# APPENDIX 1 DECISION PATH

*Decision path for modified reassessment for amendments to hazardous substance approvals: application made and determined under section 63A.*

For proper interpretation of the decision path it is important to work through the flowchart conjunction with the explanatory notes



# APPENDIX 2 RISK ASSESSMENT

## Environmental exposure and risk assessment

For Class 9 substances, irrespective of the intrinsic hazard classification, the ecological risk can be assessed for a substance by calculating a risk quotient based on an estimated exposure concentration. Such calculations incorporate toxicity values, exposure scenarios (including spray drift, application rates and frequencies), and the half lives of the component(s) in soil and water. The calculations provide an Estimated Environmental Concentration (EEC) which, when divided by the LC<sub>50</sub> or EC<sub>50</sub>, gives a risk quotient (RQ).

$$\text{Acute RQ} = \frac{\text{EEC}_{\text{short term}}}{\text{LC}_{50} \text{ or } \text{EC}_{50}} \qquad \text{Chronic RQ} = \frac{\text{EEC}_{\text{long term}}}{\text{NOEC}}$$

Levels of concern (LOC) developed by the US EPA (Urban and Cook 1986) and adopted by the Agency, to determine whether a substance poses an environmental risk are provided in Table A2.1.

**Table A2.1: Levels of concern as adopted by the Agency.**

Endpoint	LOC	Presumption
<b>Aquatic (fish, invertebrates)</b>		
Acute RQ ≥	0.5	High acute risk
Acute RQ	0.1-0.5	Risk can be mitigated through restricted use
Acute RQ <	0.1	Low risk
Chronic RQ ≥	1	High chronic risk
<b>Plants (aquatic and terrestrial)</b>		
Acute RQ ≥	1	High acute risk

For terrestrial organisms toxicity-exposure ratios (TER) are used for terrestrial vertebrates and earthworms and hazard quotient (HQ) values for terrestrial invertebrates. This convention results in concern arising if a risk quotient is less than the trigger value for birds and earthworms and more than a trigger value for terrestrial invertebrates. The levels of concerns are shown in Table A2.2.

$$\text{TER} = \text{LD}_{50} / \text{estimated environmental concentration}$$

$$\text{HQ}_{\text{bees}} = \text{application rate} / \text{LD}_{50}$$

$$\text{HQ}_{\text{invertebrates}} = \text{exposure} / \text{LR}_{50}$$

**Table A2.2: Levels of concern in environmental risk assessment for terrestrial organisms**

	Level of Concern (LOC)	Presumption
<b>Bird/ earthworm</b>		
Acute TER	<10	High risk
Chronic TER	<5	High risk

	Level of Concern (LOC)	Presumption
<b>Bees</b>		
HQ	< 50	Low risk
HQ	>50	Higher tier testing required
<b>Terrestrial invertebrates</b>		
HQ	< 2	Low risk
HQ	≥2	Higher tier testing required

If the risk exceeds a predefined level of concern, this suggests that it may be appropriate to refine the assessment or to apply the approved handler (E7) control and/or other controls to ensure that appropriate matters are taken into account to minimize off-site movement of the substance. Conversely, if a worst-case scenario is used, and the level of concern is not exceeded, then in terms of the environment, there is a presumption of low risk which is able to be adequately managed by such things as label statements (warnings, disposal). The E7 control can then be removed on a selective basis.

## AQUATIC RISK

### PROPOSED APPLICATION RATE

#### Assessment of Expected Environmental Concentration

The Agency has used the Generic Estimated Environmental Concentration Model v2 (GENEEC2) surface water exposure model (USEPA 2001) to estimate the EEC of chlorantraniliprole in surface water which may potentially arise as a result of spray drift and surface runoff from the applicant's proposed New Zealand use pattern.

The parameters used in the GENEEC2 modeling are listed in Table A2.3 and represent the recommended use on turf.

**Table A2.3: Input parameters for GENEEC2 analysis.**

	DuPont Coragen Insecticide	Reference
Application rate	0.3 kg ai/ha	applicant
Application frequency	Once or twice a year	
Application interval	7 days	
*K <sub>d</sub>	0.7 Sandy Loam (pH 7.7, OC 1.0%)	Mattson (2006)
** Aerobic soil DT <sub>50</sub>	593.2	McCorquodale & Addison (2005)

		McCorquodale & Mackie (2005) Koch Singles & Berg (2006) Berg & Koch Singles (2006)
Pesticide wetted in?	No	applicant
Methods of application	Low Boom	GENEEC 2
'No spray' zone	0	applicant
Water solubility	1.023 mg/L	Craig & Ramsay (2004)
Aerobic aquatic DT <sub>50</sub>	231 days	Lynn & McCorquodale (2005).
Aqueous photolysis DT <sub>50</sub>	0.6 days	MacDonald et al. 2005

\*The lowest of the K<sub>d</sub> value measured in a non-sand textured soil (i.e. not sand, coarse sand, fine sand, loamy sand) (USEPA, 2001).

\*\*The soil DT<sub>50</sub> value of 593.2 for Chlorantraniliprole follows the GENEEC2 calculation of the upper 90% confidence limit on the mean value (n≥2) of the nine aerobic laboratory values measured at 25°C (USEPA, 2001).

## Output from the GENEEC2 model.

### One application

RUN No. 1 FOR chlorantranilipr ON turf \* INPUT VALUES \*

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-----
RATE (#/AC) No.APPS & SOIL SOLUBIL APPL TYPE NO-SPRAY INCORP
ONE(MULT) INTERVAL Kd (PPM) (%DRIFT) ZONE(FT) (IN)
-----
.267( .267) 1 1 .7 1.0 GRLOFI( 2.9) .0 .0

```

### FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

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-----
METABOLIC DAYS UNTIL HYDROLYSIS PHOTOLYSIS METABOLIC COMBINED
(FIELD) RAIN/RUNOFF (POND) (POND-EFF) (POND) (POND)
-----
593.20 2 N/A .60- 74.40 231.00 56.28

```

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

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PEAK MAX 4 DAY MAX 21 DAY MAX 60 DAY MAX 90 DAY
GEEC AVG GEEC AVG GEEC AVG GEEC AVG GEEC
-----
13.82 13.68 12.89 11.31 10.28

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### Two applications

RUN No. 1 FOR chlorantranilipr ON turf \* INPUT VALUES \*

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RATE (#/AC) No.APPS & SOIL SOLUBIL APPL TYPE NO-SPRAY INCORP
ONE(MULT) INTERVAL Kd (PPM) (%DRIFT) ZONE(FT) (IN)
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.267( .532) 2 7 .7 1.0 GRLOFI( 2.9) .0 .0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC DAYS UNTIL (FIELD)	HYDROLYSIS RAIN/RUNOFF	PHOTOLYSIS (POND)	METABOLIC (POND-EFF)	COMBINED (POND)
593.20	2	N/A	.60- 74.40	231.00 56.28

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
27.51	27.23	25.67	22.52	20.46

The Estimated Environmental Concentration (EEC) for chlorantraniliprole as estimated by GENEEC2 are:

	One application Mg/L	Two applications Mg/L
Peak EEC	0.01382	0.02751
Chronic EEC		
21 days	0.01289	0.02567
60 days	0.01131	0.02252
90 days	0.01028	0.02046

Assessment of acute risk

**Table A2.4: Aquatic Ecotoxicity endpoints for DuPont Coragen Insecticide to be used in risk assessment.**

Acute	Formulation LC <sub>50</sub> or EC <sub>50</sub> (mg /L) (Values given in ai)	Active Ingredient LC <sub>50</sub> or EC <sub>50</sub> (mg ai/L)
Fish	> 1.84	
Crustacea	0.0071	
Algae	> 4	
Chronic		LC50 or EC50 (mg/L)
Fish (90 days)		0.110
Crustacea (21 days)		0.00447
Aquatic Insects (28 days)		0.0025

**Table A2.5: Acute risk quotients derived from the GENEEC2 model and toxicity data.**

	Peak EEC from GENEEC2 (mg/L)	LC <sub>50</sub> or EC <sub>50</sub> (mg/L)	RQ (Acute) EEC/ LC <sub>50</sub> or EC <sub>50</sub>	
			One appl.	Two appl.
Fish	0.02751 (one appl.)	1.84	0.015	0.016
Crustacea	0.01382 (two appl.)	0.0071	3.87	1.95
Algae		4	0.007	0.003

When compared against the relevant acute levels of concern (Table A2.1), the acute RQs derived from the GENEEC2 modeling for chlorantraniliprole indicate the following:

For fish: the acute risk is low  
 For crustacean: the acute risk is high  
 For algae: the acute risk is low

Assessment of chronic risk

**Table A2.6: Chronic risk quotients derived from the GENEEC2 model and chronic aquatic toxicity data.**

	EEC from GENEEC2 (mg/L)	NOEC (mg/L)	RQ (Chronic) EEC/ NOEC
<b>One application</b>			
Fish	0.01028 (90 days)	0.110	0.09
Crustacea	0.01289 (21 days)	0.00447	2.88
Aquatic insects		0.0025	5.16
<b>Two applications</b>			
Fish	0.02046 (90 days)	0.110	0.186
Crustacea	0.02567 (21 days)	0.00447	5.74
Aquatic insects		0.0025	1.03

When compared against the relevant chronic levels of concern (Table A2.1), the chronic RQs derived from the GENEEC2 modeling for chlorantraniliprole indicate the following:

For fish the chronic risk is low  
 For crustacean: the chronic risk is high  
 For aquatic insects the chronic risk is high  
 For algae: the levels of concern to estimate chronic risks to algae are not currently defined

## CURRENT MAXIMUM APPLICATION RATE

The parameters used in the GENEEC2 modeling are listed in Table A2.7 and represent the recommended use on vegetable brassicas (highest rate).

**Table A2.7: Input parameters for GENEEC2 analysis.**

	DuPont Coragen insecticide	Reference
Application rate	0.020 kg ai/ha	label
Application frequency	3 per season	label
Application interval	7 days	
*K <sub>d</sub>	0.7 Sandy Loam (pH 7.7, OC 1.0%)	Mattson (2006)
**Aerobic soil DT <sub>50</sub>	593.2	McCorquodale & Addison (2005) McCorquodale & Mackie (2005) Koch Singles & Berg (2006) Berg & Koch Singles (2006)
Pesticide wetted in?	No	
Methods of application	Low Boom Droplet size: a) fine b) medium/coarse	GENEEC 2
'No spray' zone	-	
Water solubility	1.023 mg/L	Craig & Ramsay (2004)
Aerobic aquatic DT <sub>50</sub>	231 days	Lynn & McCorquodale (2005).
Aqueous photolysis DT <sub>50</sub>	0.6 days	MacDonald et al. 2005

\*The lowest of the K<sub>d</sub> value measured in a non-sand textured soil (i.e. not sand, coarse sand, fine sand, loamy sand) (USEPA, 2001).

\*\*The soil DT<sub>50</sub> value of 593.2 for Chlorantraniliprole follows the GENEEC2 calculation of the upper 90% confidence limit on the mean value (n≥2) of the nine aerobic laboratory values measured at 25°C (USEPA, 2001).

\*\*\*Longest value taken in accordance with GENEEC2 guidance document (USEPA, 2001).

### Output from the GENEEC2 model.

#### a) Droplet Size: Fine

RUN No. 1 FOR Chlorantranilipr ON Brassicas \* INPUT VALUES \*

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RATE (#/AC) No.APPS & SOIL SOLUBIL APPL TYPE NO-SPRAY INCORP  
ONE(MULT) INTERVAL Kd (PPM) (%DRIFT) ZONE(FT) (IN)

-----  
.018( .053) 3 7 .7 1.0 GRLOFI( 2.9) .0 .0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

-----  
METABOLIC DAYS UNTIL HYDROLYSIS PHOTOLYSIS METABOLIC COMBINED  
(FIELD) RAIN/RUNOFF (POND) (POND-EFF) (POND) (POND)

-----  
593.20 2 N/A .60- 74.40 231.00 56.28

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

-----  
PEAK MAX 4 DAY MAX 21 DAY MAX 60 DAY MAX 90 DAY  
GEEC AVG GEEC AVG GEEC AVG GEEC AVG GEEC

-----  
2.74 2.71 2.55 2.24 2.04

**b) Droplet Size: Medium/Coarse**

RUN No. 2 FOR Chlorantranilipr ON Brassicas \* INPUT VALUES \*

-----  
RATE (#/AC) No.APPS & SOIL SOLUBIL APPL TYPE NO-SPRAY INCORP  
ONE(MULT) INTERVAL Kd (PPM) (%DRIFT) ZONE(FT) (IN)

-----  
.018( .053) 3 7 .7 1.0 GRLOME( .8) .0 .0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

-----  
METABOLIC DAYS UNTIL HYDROLYSIS PHOTOLYSIS METABOLIC COMBINED  
(FIELD) RAIN/RUNOFF (POND) (POND-EFF) (POND) (POND)

-----  
593.20 2 N/A .60- 74.40 231.00 56.28

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

-----  
PEAK MAX 4 DAY MAX 21 DAY MAX 60 DAY MAX 90 DAY  
GEEC AVG GEEC AVG GEEC AVG GEEC AVG GEEC

-----  
2.68 2.65 2.50 2.19 1.99

The Estimated Environmental Concentration (EEC) for chlorantraniliprole as estimated by GENEEC2 are:

**Vegetable Brassicas Low Boom (fine)**

Peak EEC 2.74 µg/L = 0.00274 mg/L

Chronic EEC (21 days) 2.55 µg/L = 0.00255 mg/L

Chronic EEC (60 days) 2.24 µg/L = 0.00224 mg/L

Chronic EEC (90 days) 2.04 µg/L = 0.00204 mg/L

**Vegetable Brassicas Low Boom (Medium/coarse)**

Peak EEC 2.68 µg/L = 0.00268 mg/L

Chronic EEC (21 days) 2.50 µg/L = 0.00250 mg/L

Chronic EEC (60 days) 2.19 µg/L = 0.00219 mg/L

Chronic EEC (90 days) 1.99 µg/L = 0.00199 mg/L

Assessment of acute risk

**Table A2.8: Aquatic Ecotoxicity endpoints for DuPont Coragen insecticide to be used in risk assessment.**

<b>Acute</b>	<b>Formulation LC<sub>50</sub> or EC<sub>50</sub> (mg/L)</b>	<b>Active Ingredient LC<sub>50</sub> or EC<sub>50</sub> (mg ai/L)</b>
Fish	> 1.84	
Crustacea	0.0071	
Algae	> 4	
<b>Chronic</b>		<b>LC<sub>50</sub> or EC<sub>50</sub> (mg/L)</b>
Fish		0.110
Crustacea		0.00447
Aquatic Insects		0.0025

The Estimated Environmental Concentration (EEC) for chlorantraniliprole as estimated by GENEEC2 are shown in Table 2.9, along with the aquatic data for chlorantraniliprole for the most sensitive species tested.

**Table A2.9: Acute risk quotients derived from the GENEEC2 model and toxicity data.**

<b>Fine Spray</b>	<b>Peak EEC from GENEEC2 (mg/L)</b>	<b>LC<sub>50</sub> or EC<sub>50</sub> (mg/L)</b>	<b>RQ (Acute) EEC/ LC<sub>50</sub> or EC<sub>50</sub></b>
Fish	0.00274	> 1.84	< 0.1
Crustacea		0.0071	0.39
Algae		> 4	< 0.1

<b>Medium/ Coarse Spray</b>	<b>Peak EEC from GENEEC2 (mg/L)</b>	<b>LC<sub>50</sub> or EC<sub>50</sub> (mg/L)</b>	<b>RQ (Acute) EEC/ LC<sub>50</sub> or EC<sub>50</sub></b>
Fish	0.00268	> 1.84	< 0.1
Crustacea		0.0071	0.38
Algae		> 4	< 0.1

When compared against the relevant acute risk quotients (Table A2.1), the acute RQs derived from the GENEEC2 modeling for chlorantraniliprole indicate the following:

- Fish: the acute risk is low
- Crustacea: the acute risk can be mitigated through restricted use (both droplet sizes)

Algae: the acute risk is low

Assessment of chronic risk

**Table A2.10: Chronic risk quotients derived from the GENEEC2 model and chronic aquatic toxicity data.**

<b>Fine Spray</b>	EEC from GENEEC2 (mg/L)	NOEC (mg/L)	RQ (Chronic) EEC/ NOEC
Fish	90 day 0.00204	0.110 (90 day)	< 0.1
Crustacea	21 day 0.00255	0.00447 (21 day)	0.57
Aquatic Insects		0.0025 (28 day)	1.02

<b>Medium/ Coarse Spray</b>	EEC from GENEEC2 (mg/L)	NOEC (mg/L)	RQ (Chronic) EEC/ NOEC
Fish	90 day 0.00199	0.110 (90 day)	< 0.1
Crustacea	21 day 0.00250	0.00447 (21 day)	0.56
Aquatic Insects		0.0025 (28 day)	1.00

When compared against the relevant chronic risk quotients (Table A2.1), the chronic RQs derived from the GENEEC2 modeling for chlorantraniliprole indicate the following:

Fish: the chronic risk is low  
 Crustacean: the chronic risk is low (both droplet sizes)  
 Aquatic Insect: the chronic risk is high (both droplet sizes)  
 For algae: the levels of concern to estimate chronic risks to algae are not currently defined

**Overall Summary of Aquatic Risk Assessment**

The quantitative assessment of the risks to the aquatic environment at the proposed rate shows that the use of the substance at this rate presents a high acute risk to crustacea and a high chronic risk to crustacea and aquatic insects. This compares the results using the current maximum application rate, which identified an acute risk to crustacea that can be mitigated through restricted use and a high chronic risk to aquatic insects. There is, therefore, a significant increase in the acute and chronic risks to crustacea at the proposed application rate.

# SOIL ORGANISMS, EXPOSURE AND RISK ASSESSMENT

## PROPOSED APPLICATION RATE

The soil invertebrate toxicity assessment was performed according to “Guidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC, October 2002”. The risk assessment is based on a TER (toxicity-exposure ratio) approach. If the acute TER = <10 further testing and assessment is required.

The maximum application rate of DuPont Coragen Insecticide is 0.3 kg ai/ha per ha. These values were used to calculate concentrations in soil adjacent to an application area. It was assumed that drift from a 1 ha treated area was evenly distributed over a 1 ha non-target area.

It is assumed that 2.9% by ground boom application low boom will drift outside the target area by (assumption based on GENEEC2 modelling).

For the off field deposition of DuPont Coragen Insecticide see Table A2.11. For the in-field situation the drift percentage is not taken into account.

**Table A2.11: Deposition DuPont Coragen Insecticide off-field**

Application scenario	Application rate (kg ai/ha)	% of application drifting	Deposition in drift (kg/ha)	Deposition (mg/m <sup>2</sup> )
Ground (low boom)	0.3	2.9	0.0087	0.87

Soil concentrations of the active ingredient are calculated by assuming the deposition would mix into the top 5 cm of soil, and this soil would have a bulk density of 1500 kg/m<sup>3</sup>, ie the deposition expressed in mg/m<sup>2</sup> would mix into 75 kg of soil.

Deposition after 2 applications was calculated according to European guidance (EU, 2000):

$$PEC_{\text{multiple applications}} = PEC_{\text{one application}} \times (1 - e^{-nki}) / (1 - e^{-ki})$$

Where

- PEC = predicted environmental concentration
- n = number of applications
- k= ln 2/ DT<sub>50</sub> (in days)
- i= interval between two consecutive applications in days, 7 days
- DT<sub>50</sub> = half life soil in days = 491 days [mean DT<sub>50</sub> source internal database]
- e = constant= 2.718

The estimated soil concentrations of DuPont Coragen Insecticide are shown in Table A2.12.

**Table A2.12: Soil concentration of DuPont Coragen Insecticide**

Application scenario	Soil concentration off field (mg/kg)		Soil concentration in field (mg/kg)	
	1 application	2 applications	1 application	2 applications
Ground (low boom)	0.012	0.0228	0.4	0.76

The estimated concentrations and the toxicity-exposure ratios are shown in Table A2.13 and A2.14.

**Table A2.13: Soil invertebrates –TER off-field**

Application scenario	EC <sub>50</sub> / LC <sub>50</sub>	Soil concentration off-field (mg/kg)		TER off-field	
		1 application	2 applications	1 application	2 applications
<b>Earthworm acute toxicity 14 day LC<sub>50</sub> (mg/kg)</b>					
Ground (low boom)	>1000	0.012	0.0228	83333	4386
<b>Springtail chronic toxicity 28 day EC<sub>50</sub> (mg/kg)</b>					
Ground (low boom)	0.39	0.012	0.0228	32.5	17.1

**Table A2.14: Soil invertebrates –TER in-field**

Application scenario	EC <sub>50</sub> / LC <sub>50</sub>	Soil concentration in-field (mg/kg)		TER in-field	
		1 application	2 applications	1 application	2 applications
<b>Earthworm acute toxicity 14 day LC<sub>50</sub> (mg/kg)</b>					
Ground (low boom)	>1000	0.4	0.76	2500	1316
<b>Springtail chronic toxicity 28 day EC<sub>50</sub> (mg/kg)</b>					
Ground (low boom)	0.39	0.4	0.76	0.98	0.51

### Non-target plants risk assessment

The risks to non-target plants were assessed in the original application. The conclusion was as follows: based on the results of a multiple rate test for the most sensitive monocot species, ryegrass, the ER<sub>25</sub> and ER<sub>50</sub> were > 300 g ai/ha for all parameters measured.

The applicant seeks an approval for an application rate of 300 g ai/ha. Given the results of the tests as mentioned above, the Agency considers the risk to non-target plants low.

### Conclusion soil organisms

The toxicity-exposure ratios for acute toxicity of earthworm are many fold above the trigger value so the acute risk to earthworm is low. However, for springtail there is a risk for the in-field situation even after one application.

## CURRENT MAXIMUM APPLICATION RATE

### Soil-based exposure

#### **Springtail**

#### *Folsomia candida*

28 day Chronic test (Mortality and Reproduction)

Reproduction NOEC

0.39 mg as/kg dry weight soil

Guideline: ISO 11267 (1999)

GLP

Klimisch score: 1

Reference: Luhrs (2006)

The Australian assessment estimated that for a 444 day half-life, accumulation would reach a plateau with peak residues approximately 2.4 times higher than from a single season after approximately 4 years. From the Australian estimation, the Agency can estimate that the plateau PEC (ppb) for DuPont Altacor insecticide and DuPont Coragen insecticide are as follows:

#### **Worst case PECs in soil derived from Australian assessment for New Zealand use patterns of DuPont Coragen insecticide.**

<b>Product</b>	<b>Maximum seasonal application rate</b>	<b>Seasonal PEC (ppb)</b>	<b>Plateau PEC (ppb)</b>
DuPont Coragen insecticide	60	50	120

#### **In-field**

Application rate (20 g a.i./ha x 3):

Chlorantraniliprole generates a NOEC (reproduction) value of 0.39 mg/kg for collembolans. Consequently, chlorantraniliprole (scenario: airblast spray orchard) results in a risk quotient of  $0.12/0.39 = 0.31$  (EEC/NOEC = RQ).

If it is assumed that 2.9% (spray scenario: low boom fine spray) of the chlorantraniliprole will reach directly outside the target area (an assumption based on GENEEC2 modeling), then the concentration of chlorantraniliprole adjacent to a sprayed field would be  $0.12 \times 0.029 = 0.00348$  mg/kg soil.

Chlorantraniliprole generates an EC<sub>50</sub> value of 0.39 mg/kg. Consequently, chlorantraniliprole (spray scenario: low boom fine spray) results in a risk quotient of  $0.00348/0.39 = 0.00892$ .

**Non-target invertebrates (soil): The risk is low**

#### **Soil Microbes – Nitrogen turnover**

##### **Rate:**

327.9 g DPX-E2Y45 20SC/ha (0.44 mg DPX-E2Y45 35WG /kg soil dry weight)

3279 g DPX-E2Y45 20SC /ha (4.4 mg DPX-E2Y45 35WG /kg soil dry weight).

**Toxicity Endpoint:** *Deviation from controls*

*Nitrogen turnover*

≥ 25% (327.9 g DPX-E2Y45 20SC/ha soil dry weight after 28 days)

**Results**

The difference between test and control nitrogen turnover was ≥ 25% after 28 days but < 25% after 42 days.

**Reference:**

Reis 2006

**In field**

Application rate: 100 g DPX-E2Y45 20SC/ha (20 g ai/ha) x 3  
(14 day minimum interval)

If it is assumed that the DuPont Coragen insecticide is dispersed to a depth of 0.05 m and the density of soil is 1500 kg/m<sup>3</sup>, then the 30\* mg a.i./m<sup>2</sup> DuPont Coragen insecticide will be dispersed within 75 kg of soil/m<sup>2</sup> giving 30/75 = 0.4 mg/kg.

DuPont Coragen insecticide generates an EC<sub>25</sub> value of 0.44 mg/kg for nitrogen turnover. Consequently, DuPont Coragen insecticide (scenario: airblast spray orchard) results in a risk quotient of 0.40/0.44\*\* = 0.91 (EEC/EC<sub>25</sub> = RQ).

\*Given the mean aerobic soil DT<sub>50</sub> of 491.38 (n=8), it is unlikely to be major degradation over the minimum interval, therefore it is relevant to include both applications as the in-field rate.

\*\*Lowest concentration examined.

**Off field**

Application rate: 100 g DPX-E2Y45 20SC /ha (20 g ai/ha) x 3  
(14 day minimum interval)

If it is assumed that the DuPont Coragen insecticide is dispersed to a depth of 0.05 m and the density of soil is 1500 kg/m<sup>3</sup>, then the 30\* mg a.i./m<sup>2</sup> chlorantraniliprole will be dispersed within 75 kg of soil/m<sup>2</sup> giving 30/75 = 0.40 mg/kg.

If it is assumed that 9.7% (scenario: airblast spray orchard) of the chlorantraniliprole will reach directly outside the target area (an assumption based on GENEEC2 modeling), then the concentration of chlorantraniliprole adjacent to a sprayed field would be 0.4 x 0.097 = 0.0388 mg/kg soil.

DuPont Coragen insecticide generates an EC<sub>25</sub> value of 0.44 mg/kg for nitrogen turnover. Consequently, DuPont Coragen insecticide (scenario: airblast spray orchard) results in a risk quotient of 0.0388/0.44 = 0.088 (EEC/EC<sub>25</sub> = RQ).

\*Given the mean aerobic soil DT<sub>50</sub> of 491.38 (n=8), it is unlikely to be major degradation over the minimum interval, therefore it is relevant to include both applications as the in-field rate.



- Higher tier

Progression to the next tier is only made if the threshold for concern is exceeded at the previous tier.

## Exposure

### Principles

The principles underlying the exposure assessment are the same for all assessments other than higher tier assessments in which more specific field exposure data may be used. The dose that a bird receives (the DDD, Daily Dietary Dose) is calculated from the application rate and a so-called ‘Shortcut value’ for the RUD, Residue Unit Dose, reflecting the concentration on the bird’s food and the quantity of food consumed. Quantities consumed are based on a bird’s energy requirements, its energy assimilation, and the energy content of its food (dry weight). Birds’ energy requirements are based on an algorithm based on bodyweight and bird type (e.g. passerine/non-passerine). The parameters used to calculate a bird’s exposure are summarized in Table A2.15.

Table A2.15 Parameters used for estimating bird Daily Dietary Dose

Application rate <sub>multiple-applications</sub>	Application rate <sub>single-application</sub>		
	Multiple Application Factor (MAF) (90 <sup>th</sup> percentile residue based on DT <sub>50(foliage)</sub> = 10 days)		
Shortcut value for Residue Unit Dose, (RUD)	Food intake rate	Daily energy expenditure	Body weight
			Bird type
		Energy in food	
		Energy assimilation efficiency	
	Moisture content of food		
Concentration in/on fresh diet			

### Screening step exposure

Both screening step assessments (acute and reproduction) select from 6 ‘indicator species’ each applicable to a particular type of crop. They are not real species, but, by virtue of their size and feeding habits, their exposure is considered worst-case for birds in a particular crop type. For example, the representative species for orchards is described as a ‘small insectivorous bird’. It is assumed that the relevant indicator species feeds only on contaminated food and the concentration of pesticide on the food is not affected by the growth stage of the crop. Thus, the exposure assessment is expressed as:

$$DDD_{\text{multiple-applications}} = \text{Application rate} \times \text{MAF} \times \text{shortcut value}$$

Where:

- MAF is chosen from a table based on number of applications and interval between applications. For an acute screening assessment, the MAF<sub>90</sub> is used, for a reproductive assessment the MAF<sub>mean</sub> is used;
- Shortcut value is chosen from a table containing 6 crop types with a shortcut value (90<sup>th</sup> percentile and mean) for each.

## Exposure in Tier I acute and Phase-specific reproduction assessments

In the Tier I acute and Phase-specific reproduction assessments exposure is calculated for generic focal species', applicable to particular crops. Such assessments refine the screening step assessments in that:

- there are more bird 'species' (19) and crop options (21);
- the growth stage of the crop is taken into account, affecting the residues on the feed;
- more than one bird species may be considered for any one crop;
- a bird's diet can be calculated to include more than one food item.

The larger number of bird species, crop types and growth stages of the crops leads to a total of 138 RUD shortcut options, each with a mean and 90<sup>th</sup> percentile value.

The exposure assessment of the Phase-specific reproduction assessment uses time-weighted average (TWA) exposure estimates over 1, 2, 3 or 21 days for different phases of the assessment. To estimate these average concentrations, the initial exposure estimates (DDD) are multiplied by TWA factors of:

<u>Exposure</u>	<u>TWA factor</u>
1 day	1.0
2 days	0.93
3 days	0.9
21 days	0.53

## Higher tier

In higher tier assessments, both acute and reproduction, additional factors affecting exposure may be taken into account. These include the proportion of a bird's diet obtained in treated areas and measured residue levels. These higher tier refinements will be substance specific and are not discussed further here.

## Risk Assessment

### Acute assessments

In both the screening and Tier I assessments, exposure estimates are compared to the LD<sub>50</sub> from an oral toxicity study<sup>4</sup>:

$$\text{TER} = \text{LD}_{50}/\text{DDD}$$

Interpretation of the TER is based on thresholds for concern:

TER ≥ 10	no refinement required
TER < 10	proceed to next tier assessment

---

<sup>4</sup> If data are only available from a dietary study these can be used with appropriate conversion to dose/unit bodyweight.

## Reproduction

In the screening assessment, exposure estimates are compared to the lowest NOAEL from an avian reproduction study. Normally the NOAEL has to be converted from units of ppm (mg/kg diet) to mg/kg bw/d. In the first instance a factor of 0.1 is used for such conversion. If specific information is available from the test reports, this is preferable. The TER is:

$$\text{TER} = \text{NOAEL}/\text{DDD}$$

And the thresholds for concern are:

TER $\geq$ 5	no refinement required
TER < 5	proceed to phase-specific assessment

In the phase-specific assessment, risk estimates are made for all phases of reproduction using the measures of toxicity and exposure shown in Table A2.16 and TER are evaluated as shown in Table A2.17.

Table A2.16 Measures of exposure and toxicity used in the reproduction assessment

Breeding phase	Test endpoint used as surrogate	Short-term exposure	Long-term exposure
Pair formation/ breeding site selection	0.1 x LD <sub>50</sub> <sup>5</sup>	1 day DDD	21 day TWA DDD
Copulation and egg laying (5 days pre-laying through end of laying)	NOAEL for the number of eggs laid per hen	1 day DDD	21 day TWA DDD
	NOAEL for mean eggshell thickness	1 day DDD	21 day TWA DDD
Incubation and hatching	0.1 x LD <sub>50</sub>	1 day DDD	21 day TWA DDD
	NOAEL for proportion of viable eggs/eggs set/hen	1 day DDD	21 day TWA DDD
	NOAEL for proportion of hatchlings/viable eggs/hen	3 day TWA DDD	21 day TWA DDD
Juvenile growth and survival until fledging	0.1 x LD <sub>50</sub> (extrinsic adult)	2 day TWA DDD	21 day TWA DDD
	0.1 x LD <sub>50</sub> (extrinsic juvenile)	1 day DDD based on chick shortcut values of 3.8 and 22.7 <sup>6</sup>	21 day TWA DDD based on chick shortcut value of 3.8 and 22.7 <sup>2</sup>
	NOAEL for proportion of 14 day old juveniles/number of hatchlings/hen	3 day TWA DDD	21 day TWA DDD
Post-fledging survival	0.1 x LD <sub>50</sub>	1 day DDD based on chick shortcut values of 3.8 and 22.7 <sup>2</sup>	21 day TWA DDD based on chick shortcut value of 3.8 and 22.7 <sup>2</sup>
	NOAEL for 14 day old	3 day TWA DDD	21 day TWA DDD

<sup>5</sup> From acute study

<sup>6</sup> The two values are to account for ground and foliar dwelling arthropods with mean residue unit doses of 3.5 and 21 respectively. Assessments are made with both values. If TER are exceeded with either value, then an assessment based on the actual composition of the diet of relevant species.

Breeding phase	Test endpoint used as surrogate	Short-term exposure	Long-term exposure
	juvenile weights/hen		

Table A2.17. Interpretation of TER in reproduction phase-specific assessment

Assessment outcome		Next Steps
Short-term exposure (1-3 day)	Long-term exposure (21 day)	
TER ≥ 5	TER ≥ 5	No refinement required
TER < 5	TER ≥ 5	Further refinement is required. One possibility is to determine if the effects are the result of short-term exposure
TER < 5	TER < 5	Further refinement is required. Refinement should focus on refining exposure and the consequences of effects. Little will be gained from additional effects data.

## DuPont Coragen Insecticide assessment

### Exposure

The exposure of birds to DuPont Coragen Insecticide is shown in Tables A2.18 & A2.19.

Table A2.18 Exposure of birds for acute assessment

Assessment	Crop & BBCH class (where appropriate) <sup>1</sup>	Indicator/generic Species <sup>2</sup>	90 <sup>th</sup> percentile short-cut value <sup>3</sup>	Application rate (kg/ha)	MA F (90 <sup>th</sup> %) <sup>4</sup>	DDD <sub>multiple applications</sub>
screening	Turf/ grassland	Large herbivorous bird	50.3	0.3	1.4	21.13
Tier 1, phased approach	Turf/ grassland	sparrow	20.4	0.3	1.4	8.57
		finch	24.7	0.3	1.4	10.37
		goose	50.3	0.3	1.4	21.23
		wagtail	26.8	0.3	1.4	11.26

<sup>1</sup> Crop type (EFSA, 2008, Table I.1 & I.3)

<sup>2</sup> Indicator species (EFSA, 2008, Table I.1 & I.3)

<sup>3</sup> Short-cut value (EFSA, 2008, Table I.1 & I.3)

<sup>4</sup> Multiple application factor (90<sup>th</sup> percentile) (EFSA, 2008, Table 11)

Table A2.19. Exposure of birds for reproduction assessment

Assessment	Crop + BBCH code where appropriate <sup>1</sup>	Generic focal species <sup>2</sup>	Mean short-cut value <sup>3</sup>	Application rate (kg/ha)	MAF mean <sup>4</sup>	TWA DDD <sub>multiple applications</sub>			
						1 day	2 days	3 days	21 days
Screening	Turf/grassland	Large herbivorous bird	26.7	0.3	1.6	12.82	11.92	11.54	6.79
Tier 1 phased approach	Turf/grassland	sparrow	9.4	0.3	1.6	4.51	4.20	4.06	2.39
		finch	11.4	0.3	1.6	5.47	5.09	4.92	2.90
		wagtail	11.3	0.3	1.6	5.42	5.04	4.88	2.87
		goose	26.7	0.3	1.6	12.82	11.92	11.54	6.79

<sup>1</sup> Crop type (EFSA, 2008, Tables I.1 & I.3)

<sup>2</sup> Generic focal species (EFSA, 2008, Tables I.1 & I.3)

<sup>3</sup> Short-cut value (EFSA, 2008, Tables I.1 & I.3)

<sup>4</sup> Multiple application factor (mean) (EFSA, 2008, Table 14)

## Toxicity

The toxicity values used in the risk assessment of DuPont Coragen Insecticide are shown in Table A2.20.

Table A2.20. Toxicity values used in risk assessment

Endpoint	Value (mg ai/kg bw/d)	Study	Reference
LD <sub>50</sub>	>2250	Acute oral	Gallagher S, Beavers J (2004) study no DuPont 14378
NOAEL <sub>lowest</sub>	10.1	Reproduction study	Temple D, Beavers J, Fray L, Jaber M (2006) study no Dupont 14384
NOAEL <sub>number of eggs laid/hen</sub>	100		
NOAEL <sub>mean egg shell thickness</sub>	10.1		
NOAEL <sub>proportion of viable eggs set/hen</sub>	100		
NOAEL <sub>proportion of hatchling per viable eggs/hen</sub>	100		
NOAEL <sub>proportion of 14 day old juveniles per number of hatchlings/hen</sub>	100		
NOAEL <sub>14 day juvenile weights/hen</sub>	100		

## Risk Assessment

The results of the risk assessment are shown in Table A2.21 (acute risk) and Table A2.22 (risks to reproduction).

It is concluded that:

The acute risk to birds is low. For the majority of the chronic endpoints the chronic risks are low. However, the risk for an adverse effect on the egg shell thickness and strength is high.

Table A2.21. Acute risks to birds from exposure to DuPont Coragen Insecticide

<b>Crop<sup>1</sup></b>	<b>Indicator Species<sup>2</sup></b>	<b>Assessment</b>	<b>TER<sup>3</sup></b>		<b>Conclusion</b>
Turf/grassland	Large herbivorous bird	Screening	LD <sub>50</sub> /DDD <sub>ma</sub>	106	The toxicity exposure ratio is above the trigger value. Refinement of the acute risk assessment is not required.

<sup>1</sup> Crop type Table I.1 (Annex 1) and Appendix 10

<sup>2</sup> Species type Table I.1 (Annex 1) and Appendix 10

<sup>3</sup> Toxicity-exposure ratio = LD<sub>50</sub>/ Estimated environmental concentration

Table A2.22 Risks to bird reproduction from exposure to DuPont Coragen Insecticide

<b>Breeding phase</b>	<b>Test endpoint used as surrogate</b>	<b>Generic focal species</b>	<b>TER</b>		<b>Conclusion</b>
			<b>Short-term exposure</b>	<b>Long-term exposure</b>	
Reproduction, screening Large herbivorous bird	Lowest NOAEL from reproduction study	Large herbivorous bird	0.79		Tier 1 Phase-specific assessment triggered
Pair formation/ breeding site selection	0.1 x LD <sub>50</sub> <sup>7</sup>	Sparrow	49.89	94.14	Risk is low
		Finch	41.13	77.59	
		Wagtail	41.51	78.40	
		goose	17.56	33.12	
Copulation and egg laying (5 days pre-laying through end of laying)	NOAEL for the number of eggs laid per hen	Sparrow	22.17	41.84	Risk is low
		Finch	18.28	34.48	
		Wagtail	18.45	34.84	
		goose	7.80	14.73	
	NOAEL for mean eggshell thickness	Sparrow	2.24	4.23	Risk is <b>high</b>
		Finch	1.85	3.48	
		Wagtail	1.86	3.52	
		goose	0.79	1.49	
Incubation and hatching	0.1 x LD <sub>50</sub>	Sparrow	49.89	94.14	Risk is low

<sup>7</sup> From acute study

		Finch	41.13	77.59	Risk is low	
		Wagtail	41.51	78.40		
		goose	17.56	33.12		
		Sparrow	22.17	41.84		
	NOAEL for proportion of viable eggs/eggs set/hen	Finch	18.28	34.48		
		Wagtail	18.45	34.84		
		goose	7.80	14.73		
	NOAEL for proportion of hatchlings/viable eggs/hen	Sparrow	24.63	41.84		Risk is low
		Finch	20.33	34.48		
		Wagtail	20.49	34.84		
		goose	8.67	14.73		
	Juvenile growth and survival until fledging	0.1 x LD <sub>50</sub> (extrinsic adult)	Sparrow	53.57		94.14
Finch			44.20	77.59		
Wagtail			44.64	78.40		
goose			18.88	33.12		
0.1 x LD <sub>50</sub> (extrinsic juvenile)		Sparrow	Ground dwelling insects 123.36 Foliar dwelling insects 20.65	Ground dwelling insects 232.75 Foliar dwelling insects 38.96	Risk is low	
		Finch				
		Wagtail				
		goose				
NOAEL for proportion of 14 day old juveniles/number of hatchlings/hen		Sparrow	24.63	41.84	Risk is low	
		Finch	20.33	34.48		
		Wagtail	20.49	34.84		
		goose	8.67	14.73		
Post-fledging survival	0.1 x LD <sub>50</sub>	Sparrow	Ground dwelling insects 123.36 Foliar dwelling insects 20.65	Ground dwelling insects 232.75 Foliar dwelling insects 38.96	Risk is low	
		Finch				
		Wagtail				
		goose				
	NOAEL for 14 day old juvenile weights/hen	Sparrow	24.63	41.84	Risk is low	
		Finch	20.33	34.48		
		Wagtail	20.49	34.84		
		goose	8.67	14.73		

## CURRENT MAXIMUM APPLICATION RATE

The risk assessment was performed according to the Guidance Document on Risk Assessment for Birds and Mammals; SANCO/4145/2000 for birds. This model assumes birds are exposed to DuPont Coragen Insecticide following crop spray. For tier 1 assessments it is assumed that the contaminated diet is not avoided, the animals satisfy their entire food demand in the treated area, the animals feed on a single food type and the concentration in the diet is comparable to the maximum application rate.

Calculations were made for the range of bird types specified in the guidance document and expressed in terms of bird size and diet.

The estimate of chlorantraniliprole toxicity to exposure ratio is dependent on factors such as bird type and body weight, daily food intake, the concentration of chlorantraniliprole in food and feeding behaviour. These factors are considered in the following equation:

### Equation 1. Estimated Theoretical Exposure

The estimated daily uptake of a compound is calculated according to the following equation:

$$ETE = (DFI / bw) \times C \times AV \times PT \times PD \text{ (mg/kg bw/d)}$$

Where:

ETE = Estimated Theoretical Exposure;

DFI = Daily Food Intake rate of indicator species (gram fresh weight per day);

bw = Body weight (g);

C = Concentration of compound in fresh diet (mg/kg);

AV = Avoidance factor (1 = no avoidance, 0 = complete avoidance);

PT = Fraction of diet obtained in treated area (number between 0 and 1);

PD = Fraction of food type in diet (number between 0 and 1; one type or more types).

### In the first tier it is assumed that:

- the contaminated diet is not avoided;
- animals satisfy their entire food demand in the treated area;
- animals feed on a single food type.

Thus the factors AV, PT and PD become 1 and can be omitted.

### Daily Food Intake (DFI in Equation 1)

The Daily Food Intake (DFI) is derived from the Daily Energy Expenditure (DEE) as calculated in Equation 2:

### Equation 2

#### Estimation of Daily Energy Expenditure (DEE)

$$\text{Log (DEE)} = \text{Log } a + b \times (\text{log bodyweight})$$

Factors “a” and “b” are specific to bird type as stipulated in Crocker et al. (2002).

**Small insectivorous birds (passerine) bodyweight = 10 g**

$$\text{Log (DEE)} = 1.0017 + (0.7034 \times (\log 10)) = 1.7051 \text{ kJ/day}$$

$$\text{DEE} = \text{Anti-log } 1.7051 \text{ kJ/day} = 50.71 \text{ kJ/day}$$

**Medium herbivorous birds (non-passerine) bodyweight = 300 g**

$$\text{Log (DEE)} = 0.6768 + (0.7723 \times (\log 300)) = 2.59 \text{ kJ/day}$$

$$\text{DEE} = \text{Anti-log } 2.59 \text{ kJ/day} = 388.94 \text{ kJ/day}$$

The Daily Food Intake is derived from the Daily Energy Expenditure divided by factors specific to the food source (i.e., small insects) as calculated in Equation 3:

**Equation 3**

**Estimation of Daily Food Intake (DFI)**

Daily Food Intake (wet g) =

$$\frac{\text{Daily Energy Expenditure (kJ)}}{\text{Energy in Food (kJ/g dry)} \times (1 - \text{Moisture in Food}) \times \text{Assimilation Efficiency}}$$

where moisture and assimilation efficiency are proportions between 0 and 1.

**Small insectivorous birds (passerine)**

$$\text{Daily Energy Expenditure} = 50.71$$

$$\text{Energy in Food} = 21.9$$

$$\text{Moisture} = 70.5\% \text{ (proportion} = 0.705)$$

$$\text{Assimilation Efficiency} = 76\% \text{ (proportion} = 0.76)$$

Daily Food Intake =

$$\frac{50.71}{21.9 \times (1 - 0.705) \times 0.76}$$

$$= 10.33 \text{ g/day fresh weight}$$

**Medium herbivorous birds (non-passerine)**

$$\text{Daily Energy Expenditure} = 388.94$$

$$\text{Energy in Food} = 18$$

$$\text{Moisture} = 82.1\% \text{ (proportion} = 0.821)$$

$$\text{Assimilation Efficiency} = 53\% \text{ (proportion} = 0.53)$$

Daily Food Intake =

$$\frac{388.94}{18 \times (1 - 0.821) \times 0.53}$$

$$= 227.76 \text{ g/day fresh weight}$$

**Concentration of Compound in Fresh Diet (C in Equation 1)**

The estimated theoretical exposure is also dependent on the concentration of compound in the fresh diet (mg/kg). This was calculated according to the DuPont Altacor insecticide use pattern as stipulated by Du Pont.

Vegetable Brassicas: 20 g ai/ha x 3 applications (7 day minimum interval)

From these values, the Estimated Theoretical Exposure (Equation 1) can be calculated as below.

### Calculation of Estimated Theoretical Exposure Small insectivorous birds (passerine)

$$\text{ETE} = (\text{DFI} / \text{bw}) \times \text{C} \times \text{AV} \times \text{PT} \times \text{PD} \text{ (mg/kg bw/d)}$$

Where (from the example):

$$\text{DFI} = 10.33 \text{ g/day fresh weight (Equation 3)}$$

$$\text{bw} = 10 \text{ g}$$

C = Concentration

Concentration is dependent on factors such as the “Application Rate”, “Residue Unit dose (RUD)” and “Multiple Application Factor (MAF)”.

$$\text{Application Rate} = 0.02 \text{ kg ai/ha}$$

RUD = (residue per unit dose) – converted to 1 kg ai/ha

- For Acute Assessment (90<sup>th</sup> percentile RUD) = 52
- For Short-term and Long-term Assessments (Mean RUD) = 29

MAF = Multiple application factor (concentration immediately after the last application compared to a single application)

*It is expected that repeated applications do not cause appreciable accumulation of residues at least in foliage dwellers because in addition to other factors replacement of individuals due to migration and reproduction will contribute to the residue decline in the population. Therefore no MAF is applied for residues in insects.*

Spray application: Multiply relative daily intake by RUD and application rate (kg/ha) (when applicable multiply also by MAF and  $F_{\text{twa}}$ ).

$F_{\text{twa}}$  = Time Weighted Average

With regard to residues on vegetation a simple  $f_{\text{twa}}$  factor is used in the first tier which is based on the following default values:

- time window (averaging time) = 3 weeks
- $DT_{50}$  = 10 days

With these assumptions  $f_{\text{twa}}$  is 0.53; it means that over a period of 3 weeks the average concentration is about half the initial concentration.

*In the case of insects no default  $f_{\text{twa}}$ -factor is employed in the first tier as the time course of residue level is unknown.*

AV, PT and PD = 1 (Tier 1 assessment)

$$\text{ETE}_{\text{acute}} = (10.33/10) \times 0.020 \times 52$$

$$\text{ETE}_{\text{acute}} = 1.07432 \text{ mg/kg bw/d}$$

$$\text{ETE}_{\text{short-term}} = (10.33/10) \times 0.020 \times 29$$

$$ETE_{\text{short-term}} = 0.599 \text{ mg/kg bw/d}$$

$$ETE_{\text{long-term}} = (10.33/10) \times 0.020 \times 29$$

$$ETE_{\text{long-term}} = 0.599 \text{ mg/kg bw/d}$$

### **Calculation of Estimated Theoretical Exposure Medium herbivorous birds (non-passerine)**

$$ETE = (\text{DFI} / \text{bw}) \times C \times \text{AV} \times \text{PT} \times \text{PD} \text{ (mg/kg bw/d)}$$

Where (from the example):

$$\text{DFI} = 227.76 \text{ g/day fresh weight (Equation 3)}$$

$$\text{bw} = 300 \text{ g}$$

$$C =$$

$$\text{Application Rate} = 0.020 \text{ kg ai/ha}$$

$$\text{RUD} = (\text{residue per unit dose}) - \text{converted to 1 kg ai/ha}$$

- For Acute Assessment (90<sup>th</sup> percentile RUD) = 87
- For Short-term and Long-term Assessments (Mean RUD) = 40

MAF = Multiple application factor (concentration immediately after the last application compared to a single application)

Spray application: Multiply relative daily intake by RUD and application rate (kg/ha) (when applicable multiply also by MAF and  $F_{\text{twa}}$ ).

$$F_{\text{twa}} = \text{Time Weighted Average (long term assessment only)}$$

With regard to residues on vegetation a simple  $f_{\text{twa}}$  factor is used in the first tier which is based on the following default values:

- time window (averaging time) = 3 weeks
- $DT_{50} = 10$  days

With these assumptions  $f_{\text{twa}}$  is 0.53; it means that over a period of 3 weeks the average concentration is about half the initial concentration.

$$\text{AV, PT and PD} = 1 \text{ (Tier 1 assessment)}$$

$$ETE_{\text{acute}} = (227.76/300) \times 0.02 \times 1.7 \times 87$$

$$ETE_{\text{acute}} = 2.25 \text{ mg/kg bw/d (acute)}$$

$$ETE_{\text{short-term}} = (227.76/300) \times 0.02 \times 2 \times 40$$

$$ETE_{\text{short-term}} = 1.216 \text{ mg/kg bw/d (acute)}$$

$$ETE_{\text{long-term}} = (227.76/300) \times 0.02 \times 2 \times 40 \times 0.53$$

$$ETE_{\text{long-term}} = 0.6444 \text{ mg/kg bw/d (acute)}$$

## **Toxicity**

Toxicity data for Chlorantraniliprole show:

Acute LD50 = > 2250 mg ai/kg bw;

5 day dietary study LD50 = > 1729 mg ai/kg bw;

Bird reproduction NOEC = 10.1 mg ai/kg bw.

## **Toxicity Exposure Ratio**

The toxicity exposure ratio is calculated by comparing the ETE to toxicity as follows:

### **Equation 4. Toxicity Exposure Ratio = Toxicity / ETE**

#### **Acute Toxicity Exposure Ratio**

$$TER_a = LD_{50} / ETE$$

##### *Small insectivorous bird*

$TER_a = > 2094$ , the risk does not exceed the acute TER limit of concern (i.e. is > 10).

(RQ = 0.0005, RQ is < 0.5 for acute exposure)

##### *Medium herbivorous bird*

$TER_a = > 1001$ , the risk does not exceed the acute TER limit of concern (i.e. is > 10).

(RQ = 0.001, RQ is < 0.5 for acute exposure)

#### **Short-term Toxicity Exposure Ratio**

$$TER_{st} = LD_{50} / ETE$$

##### *Small insectivorous bird*

$TER_{st} = 2886$ , the risk does not exceed the short-term TER limit of concern (i.e. is > 10).

(RQ = 0.0003, RQ is < 0.5 for acute exposure)

##### *Medium herbivorous bird*

$TER_{st} = 1422$ , the risk does not exceed the short-term TER limit of concern (i.e. is > 10).

(RQ = 0.0007, RQ is < 0.5 for acute exposure)

#### **Long-term Toxicity Exposure Ratio**

$$TER_{lt} = NOEL_{lt} / ETE$$

##### *Small insectivorous bird*

$TER_{lt} = 16.86$ , the risk does not exceed the long term TER limit of concern (i.e. is > 5).

(RQ = 0.05, RQ is < 1 for chronic exposure)

##### *Medium herbivorous bird*

$TER_{lt} = 15.67$ , the risk does not exceed the long term TER limit of concern (i.e. is > 5).

(RQ = 0.06, RQ is < 1 for chronic exposure)

### **Summary of the Tier 1 Risk Assessment for Birds (DuPont Coragen insecticide – Current maximum application rate)**

The unrefined tier 1 risk assessment showed that vegetable brassicas treated with DuPont Coragen insecticide according to the label instructions poses a low risk to small insectivorous and medium herbivorous birds with regard to acute, short-term and long-term toxicity.

## **Overall Summary of Avian Risk Assessments**

The quantitative assessment of the risks to birds at the proposed rate shows that the use of the substance at this rate presents a high chronic risk for an adverse effect on egg shell thickness and strength. This compares the results using the current maximum application rate, which identified there were no acute or chronic risks to birds. Overall, therefore, there is a significant increase in the chronic risks to birds at the proposed application rate.

## **TERRESTRIAL INVERTEBRATES (BEES) RISK ASSESSMENT**

### **PROPOSED APPLICATION RATE**

The terrestrial invertebrate risk assessment for agricultural pesticides determines whether or not the proposed application poses an unacceptable risk to terrestrial invertebrates (bees).

The following European model has been adopted by ERMA New Zealand to assess the risk to bees [Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC, SANCO/ 10329/2002 rev. 2 final, 17 October 2002].

Hazard Quotient (HQ) = Application Rate / LD<sub>50</sub>

Application rate: the maximum single application rate (g active ingredient/ha).

LD<sub>50</sub>: µg active ingredient/bee.

The maximum application rate of DuPont Coragen Insecticide is 300 g ai/ha.

The contact toxicity value LD<sub>50</sub> > 100 µg ai/bee is the most relevant parameter for the risk assessment.

HQ= 300/ 100 = 3

The critical HQ is 50 which was validated against incidents (EPPO 2002).

### **Conclusion bees**

Given those HQ's the Agency considers there is a low risk for bees when DuPont Coragen Insecticide is applied according to the label and good agricultural practice.

### **CURRENT MAXIMUM APPLICATION RATE**

The terrestrial invertebrate risk assessment for agricultural pesticides determines whether or not the proposed application poses an unacceptable risk to terrestrial invertebrates (bees).

The following European model has been adopted by ERMA New Zealand to assess the risk to bees [Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC, SANCO/ 10329/2002 rev. 2 final, 17 October 2002].

Hazard Quotient (HQ) = 20 / > 114.1 (oral) = < 0.175

Hazard Quotient (HQ) = 20 / > 285.7 (contact) = < 0.07

Application rate: the maximum single application rate (g active ingredient/ha).

LD<sub>50</sub>: µg active ingredient/bee.

If the oral and contact HQ < 50, low risk to bees is concluded.

Additional semi-field studies conducted have shown low level effects to bee colonies.

### Overall Summary of Terrestrial Invertebrate (Bees) Risk Assessments

The quantitative assessment of the risks to bees at the proposed rate shows that the use of the substance at this rate presents a low risk to bees. This compares the results using the current maximum application rate, which identified there was a low risk to bees. Overall, therefore, there is no significant increase in the risks to bees at the proposed application rate.

## TERRESTRIAL INVERTEBRATES (EXCL-BEES) RISK ASSESSMENT

### PROPOSED APPLICATION RATE

The invertebrate toxicity assessment was performed according to EU (2002).

#### Exposure

In-field exposure is estimated using the formula:

$$\text{In-field exposure} = \text{application rate} \times \text{MAF}$$

Where:

- MAF is a multiple application factor listed in the guidance document. In accordance with the guidance the MAF is not applied for bees, only for other non-target invertebrates.
- Table D9: Terrestrial invertebrates- in-field exposure

Crop	Application rate (g ai/ ha)	Application frequency	MAF <sup>1</sup>	In-field exposure (g ai/ha)
turf	300	1	1	300
	300	2	1.7	510

1: MAF= multiple application factor. In the absence of field data, default values are used.

For the off-field exposure ERMA New Zealand used the formula:

$$\text{Off field exposure} = \text{application rate} \times \text{MAF} \times (\text{drift factor}/ \text{vegetation distribution factor})$$

Where

- MAF is a multiple application factor
- The drift factors used in the model differ from the drift factors in GENECC2 modelling. The values used were recommended for use with this model (Rautmann et al, 2001).

- The vegetation distribution factor estimates the interception of drift by vegetation. For a generic assessment a value of 1 was used corresponding to the worst case assessment of no interception.

The estimated off field concentrations are shown in Table D10.

**Table D10: Terrestrial invertebrates- off field exposure**

Crop	Application rate (g ai/ ha)	Application frequency	MAF <sup>1</sup>	Drift factor (= % drift/ 100)	Vegetation distribution factor	Off field exposure (g ai/ha)
turf	300	1	1	0.0238	1	7.14
	300	2	1.7	0.0238	1	12.14

1: MAF= multiple application factor. In the absence of field data, default values are used.

### Risk assessment

**Table F9: Terrestrial invertebrates - in-field**

Crop	In field exposure (g ai/ha)	LR <sub>50</sub> (g ai/ha)		Hazard quotient	
		<i>Episyrphus balteatus</i>	<i>Coccinella septempunctata</i>	<i>Episyrphus balteatus</i>	<i>Coccinella septempunctata</i>
turf	1 appl.: 300	12.6	79.5	1 appl.: 23.8	1 appl.: 3.8
	2 appl.: 510			2 appl.: 40.5	2 appl.: 6.4

Off-field risk quotients were estimated as:

$$\text{HQ off field} = (\text{off-field exposure} / \text{LR}_{50}) * \text{correction factor}$$

Where

- Off-field exposure is estimated in Appendix D (Table D10)
- The default for the correction factor is 10. The correction factor accounts for the extrapolation from the two test species to all off-field non-target arthropods.

The derived hazard quotients for the off-field situation are shown in Table F10.

**Table F10: Terrestrial invertebrates – off-field**

Crop	Off- field exposure (g ai/ha)	LR <sub>50</sub> (g ai/ha)		Hazard quotient Off-field	
		<i>Episyrphus balteatus</i>	<i>Coccinella septempunctata</i>	<i>Episyrphus balteatus</i>	<i>Coccinella septempunctata</i>
turf	1 appl.: 7.14	12.6	79.5	1 appl.:0.57	1 appl.: 0.09
	2 appl.: 12.14			2 appl.:9.63	2 appl.:4.53

For the off-field situation with 1 application the risk is considered to be low.

For both in-field (1 and 2 appl.) and off-field (2 appl.) exposure the risk quotients are greater than the cut-off of 2. Therefore higher tier testing and assessment are desirable. The applicant provided test data with aged residues for the previous application. It was noted that the effect of foliar residues took some time to decline and this may need to be taken into consideration against the biology, ecology and behaviour of non-target species. Overall, the Agency considers there is a risk for non-target species.

To reduce the risk to non-target species the application frequency may be restricted to once a year.

### **CURRENT MAXIMUM APPLICATION RATE**

Chlorantraniliprole is sprayed at a maximum application rate of 20 g a.i./ha x 3 applications (minimum interval 7 days).

For individual application (20 g a.i./ha x 1):

The LR<sub>50</sub> for the hoverfly (*Episyrphus balteatus*) is 12.6 g ai/ha.

Consequently, DuPont Coragen insecticide (scenario: low boom) results in a risk quotient of  $20/4.64 = 4.31$  for the LR<sub>50</sub>.

Based on the reproductive effects data, a conservative NOER for the hoverfly (*Episyrphus balteatus*) was set at < 0.5 g ai/ha.

Consequently, DuPont Coragen insecticide (scenario: low boom) results in a risk quotient of  $20/<0.5 = >40$  for the NOER.

The LR<sub>50</sub> for the ladybird beetle (*Coccinella septempunctata*) is 79.5 g ai/ha.

Consequently, DuPont Coragen insecticide (scenario: low boom) results in a risk quotient of  $20/79.5 = 0.25$  for the LR<sub>50</sub>.

Based on the reproductive effects data, a conservative NOER for the ladybird beetle (*Coccinella septempunctata*) was set at < 0.5 g ai/ha.

Consequently, DuPont Coragen insecticide (scenario: low boom) results in a risk quotient of  $20/<0.5 = >40$  for the NOER.

Non-target invertebrates (in field): The risk is high

### **Overall Summary of Terrestrial Invertebrate (Excl-Bees) Risk Assessments**

The quantitative assessment of the risks to other non-target invertebrates at the proposed rate shows that the use of the substance at this rate presents a high risk via either in field or off field exposure. This compares the results using the current maximum application rate, which identified there was a high risk to non-target invertebrates (excluding bees). Overall, therefore, there is no significant increase in the risks to non-target invertebrates at the proposed application rate.

## **GROUND WATER RISK ASSESSMENT**

In the original assessment of the active ingredient the Agency identified a risk to groundwater. The Agency concluded that chlorantraniliprole has the potential to leach into groundwater. This risk remains valid at the revised application rate.

To limit the potential for groundwater contamination the Agency considers that the application rate, proposed by the applicant and modeled for the aquatic and terrestrial risk assessments, be set as the maximum application rate and that the maximum application frequency be restricted to once per year when the substance is applied to turf.

## Appendix 3: List of Controls for DuPont Coragen Insecticide

**Table A3.1: Revised controls for DuPont Coragen Insecticide – codes, regulations and variations.**

Control Code <sup>8</sup>	Regulation <sup>9</sup>	Topic	Variations
<b>Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001</b>			
E1	32-45	Limiting exposure to ecotoxic substances	No EEL values are set at this time and the default EELs are deleted.
E2	46-48	Restrictions on use within application area	As no EELs have been set, no application rate is required to be set under this control at this time.  However, an application rate is set as an additional control under Section 77A.
E5	5(2), 6	Requirements for keeping records of use	
E6	7	Requirements for equipment used to handle hazardous substances	
E7	9	Approved handler requirements	The following control is <b>substituted</b> for Regulation 9(1) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001:  <i>(1). The substance must be under the personal control of an approved handler when the substance is –</i>  <i>(a) applied in a wide dispersive manner; or</i>  <i>(b) used by a commercial contractor.</i>
<b>Hazardous Substances (Identification) Regulations 2001</b>			
I1	6, 7, 32-35, 36 (1)-(7)	General identification requirements  Regulation 6 – Identification duties of suppliers  Regulation 7 – Identification duties of persons in charge  Regulations 32 and 33 – Accessibility of information  Regulations 34, 35, 36(1)-(7) –	

<sup>8</sup> Note: The numbering system used in this column relates to the coding system used in the ERMA New Zealand Controls Matrix. This links the hazard classification categories to the regulatory controls triggered by each category. It is available from the ERMA New Zealand website [www.ermanz.govt.nz/resources](http://www.ermanz.govt.nz/resources) and is also contained in the ERMA New Zealand User Guide to the HSNO Control Regulations.

<sup>9</sup> These Regulations form the controls applicable to this substance. Refer to the cited Regulations for the formal specification, and for definitions and exemptions.

Control Code <sup>8</sup>	Regulation <sup>9</sup>	Topic	Variations
		Comprehensibility, Clarity and Durability of information	
I3	9	Priority identifiers for ecotoxic substances	
I9	18	Secondary identifiers for all hazardous substances	
I11	20	Secondary identifiers for ecotoxic substances	
I19	29-31	Alternative information in certain cases  Regulation 29 – Substances in fixed bulk containers or bulk transport containers  Regulation 30 – Substances in multiple packaging  Regulation 31 – Alternative information when substances are imported	
I21	37-39, 47-50	Documentation required in places of work  Regulation 37 – Documentation duties of suppliers  Regulation 38 – Documentation duties of persons in charge of places of work  Regulation 39 – General content requirements for documentation  Regulation 47 – Information not included in approval  Regulation 48 – Location and presentation requirements for documentation  Regulation 49 – Documentation requirements for vehicles  Regulation 50 – Documentation to be supplied on request	
I23	41	Specific documentation requirements for ecotoxic substances	
I29	51-52	Duties of persons in charge of places with respect to signage	

Control Code <sup>8</sup>	Regulation <sup>9</sup>	Topic	Variations
<b>Hazardous Substances (Packaging) Regulations 2001</b>			
P1	5, 6, 7 (1), 8	General packaging requirements  Regulation 5 – Ability to retain contents  Regulation 6 – Packaging markings  Regulation 7(1) – Requirements when packing hazardous substance  Regulation 8 – Compatibility  Regulation 9A and 9B – Large Packaging	
P3	9	Packaging requirements for substances packed in limited quantities	
P15	21	Packaging requirements for ecotoxic substances	
PG3	Schedule 3	The tests in Schedule 3 correlate to the packaging requirements of UN Packing Group III (UN PGIII).	
<b>Hazardous Substances (Disposal) Regulations 2001</b>			
D5	9	Disposal requirements for ecotoxic substances	
D6	10	Disposal requirements for packages	
D7	11, 12	Disposal information requirements	
D8	13, 14	Disposal documentation requirements	
<b>Hazardous Substances (Emergency Management) Regulations 2001</b>			
EM1	6, 7, 9-11	Level 1 emergency management information: General requirements	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12-16, 18-20	Level 2 emergency management documentation requirements	
EM11	25-34	Level 3 emergency management requirements – emergency response plans	
EM12	35-41	Level 3 emergency management requirements – secondary containment	The following subclauses shall be added after subclause (3) of regulation 36:  <i>(4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in</i>

Control Code <sup>8</sup>	Regulation <sup>9</sup>	Topic	Variations
			<p><i>pipework that is installed and operated so as to manage any loss of containment in the pipework it—</i></p> <ul style="list-style-type: none"> <li><i>(a) is not to be taken into account in determining whether a place is required to have a secondary containment system; and</i></li> <li><i>(b) is not required to be located in a secondary containment system.</i></li> </ul> <p><i>(5) In this clause, pipework—</i></p> <ul style="list-style-type: none"> <li><i>(a) means piping that—</i> <ul style="list-style-type: none"> <li><i>(i) is connected to a stationary container; and</i></li> <li><i>(ii) is used to transfer a hazardous substance into or out of the stationary container; and</i></li> </ul> </li> <li><i>(b) includes a process pipeline or a transfer line.</i></li> </ul> <p>The following subclauses shall be added after subclause (1) of regulation 37:</p> <p><i>(2) If pooling substances that do not have class 1 to 5 hazard classifications are held in a place above ground in containers each of which has a capacity of 60 litres or less—</i></p> <ul style="list-style-type: none"> <li><i>(a) if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of at least 25% of that total pooling potential:</i></li> <li><i>(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—</i> <ul style="list-style-type: none"> <li><i>(i) 5% of the total</i></li> </ul> </li> </ul>

Control Code <sup>8</sup>	Regulation <sup>9</sup>	Topic	Variations
			<p style="text-align: right;"><i>pooling potential; or</i></p> <p style="text-align: center;">(ii) 5,000 litres.</p> <p>(3) <i>Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that leakage of one substance may not adversely affect the container of another substance.</i></p> <p>The following subclauses shall be added after subclause (1) of regulation 38:</p> <p>(2) <i>If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers 1 or more of which have a capacity of more than 60 litres but none of which have a capacity of more than 450 litres—</i></p> <p>(a) <i>if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of either 25% of that total pooling potential or 110% of the capacity of the largest container, whichever is the greater:</i></p> <p>(b) <i>if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—</i></p> <p style="text-align: center;">(i) 5% of the total pooling potential; or</p> <p style="text-align: center;">(ii) 5,000 litres</p> <p>(3) <i>Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that the leakage of one substance may not adversely affect the container of another substance.</i></p>

<b>Control Code<sup>8</sup></b>	<b>Regulation<sup>9</sup></b>	<b>Topic</b>	<b>Variations</b>
EM13	42	Level 3 emergency management requirements – signage	
<b>Hazardous Substances (Personnel Qualification) Regulations 2001</b>			
AH1	4-6	Approved Handler requirements	See E7.
<b>Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004</b>			
Regulations 4 to 43 where applicable		The Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 prescribe a number of controls relating to tank wagons and transportable containers and must be complied with as relevant.	
<b>Section 77A Additional Controls</b>			
The controls relating to stationary container systems, as set out in Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (Supplement to the New Zealand Gazette, 26 March 2004, No. 35, page 767), as amended, apply to this substance, notwithstanding clause 1(1) of that schedule.			
Addition of subclauses after subclause (3) of Regulation 36, subclause (1) of Regulation 37 and subclause (1) of Regulation 38 of the Hazardous Substances (Emergency Management Controls) Regulations, refer control EM12.			
ADE (chlorantraniliprole) = 1.58 mg/kg bw/day PDE <sub>food</sub> (chlorantraniliprole) = 1.58 mg/kg bw/day			
The maximum application rate for DuPont Coragen insecticide shall be 0.30 kg ai/ha, once per year.			
DuPont Coragen insecticide shall not be applied onto or into water.			
The method of application of DuPont Coragen insecticide shall be limited to ground based application.			
When DuPont Coragen is applied by boom spray, boom heights should be kept as low as practicable to avoid spray drift.			
The label for DuPont Coragen insecticide shall state the following:  “The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in the substance leaching into ground water.”  “Harmful to some beneficial insects – particularly some foliage dwelling predators that may be used in Integrated Pest Management”  “Due to the persistent nature of chlorantraniliprole in soil, this product is expected to accumulate over successive seasons following repeated use.”			
DuPont (New Zealand) Limited shall make available to ERMA New Zealand the results of any soil accumulation trials for chlorantraniliprole upon their completion.			

## **APPENDIX 4: GOVERNMENT DEPARTMENTS, CROWN ENTITIES AND INTERESTED PARTIES NOTIFIED**

Aakland Chemicals (1997) Limited  
AgBio Research Limited  
Agcarm Incorporated  
AgResearch Limited  
Agronica New Zealand Limited  
AR and JA Drysdale Limited  
ARPPA  
Baldwins Intellectual Property  
BASF New Zealand Limited  
Bayer New Zealand Limited  
BOC Limited  
Chancery Green  
Chemagro New Zealand Limited  
Chemsafety Limited  
Community and Public Health  
Dow AgroSciences Australia Limited  
DuPont (New Zealand) Limited  
Environment Bay of Plenty  
Far North District Council  
Farmoz Pty Ltd  
Federated Farmers of New Zealand (Incorporated)  
Fish and Game Eastern Region  
Fruitfed Supplies Limited (PGG Wrightson Ltd)  
Grayson Wagner Company Ltd  
Greater Wellington - The Regional Council  
Green Party of Aotearoa New Zealand  
Hawkes Bay Regional Council  
IMCD New Zealand Limited  
Kaipara District Council  
Kawerau District Council  
Landcorp Farming Limited  
Lowndes Associates  
Ministry of Agriculture and Fisheries (MAF) Biosecurity New Zealand  
Ministry of Research Science and Technology (MoRST)  
Napier Health Centre - Public Health Unit  
National Beekeepers Association  
New Zealand Bee Industry Group - Federated Farmers  
New Zealand Chemical Industry Council Inc  
New Zealand Customs Service  
New Zealand Meatworkers Union  
New Zealand Press Association  
New Zealand Society of Gunsmiths Inc

Ngāti Kahungunu Iwi Incorporated  
Northland District Health Board  
Northland Regional Council  
Nufarm Ltd  
Pacific Growers Supplies Limited  
Pesticide Action Network Aotearoa New Zealand  
PharmVet Solutions  
Physicians and Scientists for Global Responsibility (PSGR)  
Rangitikei District Council  
Reckitt Benckiser  
Schering Plough Animal Health Limited  
Sigma Aldrich  
South Taranaki District Council  
Sustainability Council of New Zealand  
Syngenta Crop Protection Limited  
Taranaki Regional Council  
Tasman District Council  
Taupo District Council  
Technical Compliance Consultants Ltd  
Television New Zealand  
The Eden Park Trust  
The National Beekeepers Association of New Zealand  
The New Zealand Institute for Plant and Food Research Limited  
(Auckland)  
The New Zealand Institute for Plant and Food Research Limited  
(Motueka)  
The New Zealand Society for Risk Management Inc  
TMP Consultancy  
Zelam Limited  
7 private individuals