
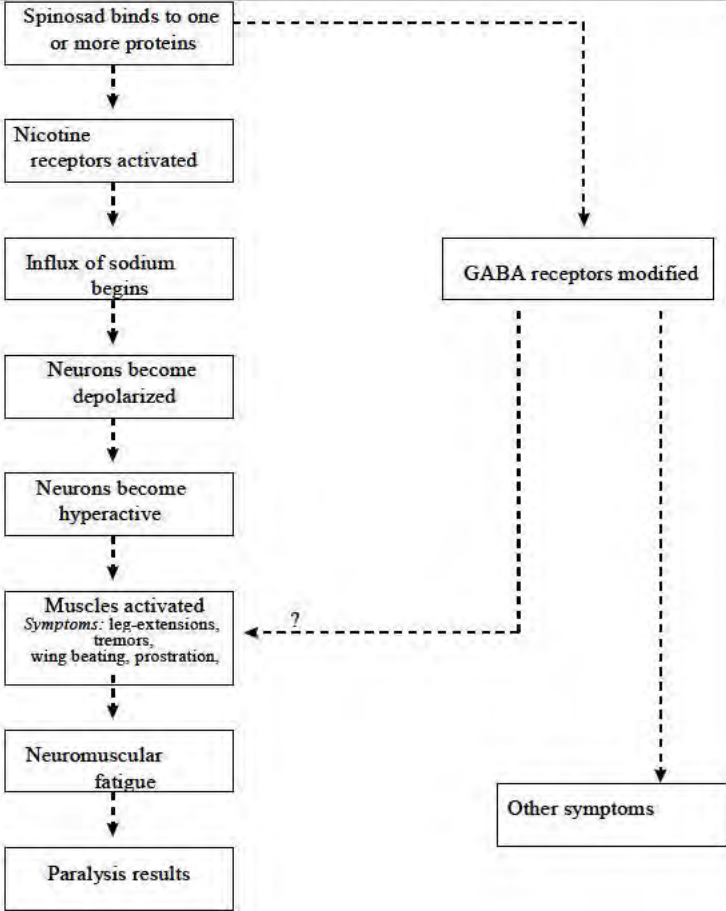



Section A5 Annex Point IIA, V.5.1-5.8	Effectiveness against target organisms and intended uses	
Subsection		Official use only
5.1 Function (IIA5.1)	Insecticide	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)	<i>Headline only</i>	
5.2.1 Organism(s) to be controlled (IIA5.2)	House fly <i>Musca domestica</i>	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	Protection of animals in animal housing (e.g. poultry, pork, dairy, beef, horses.)	X1
5.3 Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)	<i>Headline only</i>	
5.3.1 Effects on target organisms (IIA5.3)	<p>Contact and stomach poison causing death</p> <p>Because the nature of the product is a bait, efficacy is principally demonstrated with the product rather than the active substance. Laboratory studies are presented that show the product is intrinsically effective in controlling <i>Musca domestica</i>, and that the proposed field rate of 1% w/w spinosad is justified as it offers greater and more reliable fly control than lower rates tested, and that this level of control and reliability is not enhanced by increasing the rate above the proposed field rate. Field studies are presented that show that the product achieves effective fly population control for up to 6 weeks after application, and that it is as good as or better than the current comparative commercial standards. Laboratory and field studies are also presented that show that the spinosad granular fly bait can be applied by a variety of application techniques to ensure it is adaptable to placement in all animal housing.</p> <p>Please see section 5.3 summary table below</p>	X2
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	<p>The use pattern and the use concentration will be identical throughout the European Community.</p> <p> spy.pdf</p> <p>Enclosed file shows pictures of the application possibilities of the Spinosad Fly Bait (code number GF-739).</p>	X3

Section A5 Annex Point IIA, V.5.1-5.8	Effectiveness against target organisms and intended uses	
	<p>GF-739 (1% w/w Spinosad) is applied in the following ways and at the following application rates:</p> <ol style="list-style-type: none"> Scattered evenly in animal housing where flies gather (e.g. window sills, tops of walls, edges of walkways, etc.) <p>Application rate: 500 g product/200 m² floor space. Concentration of a.s. 0.025 g a.s./m²</p> <ol style="list-style-type: none"> Placed in bait stations or trays, which are positioned in areas where flies gather. <p>Application rate: 50 g product/bait station; 10 bait stations/200 m² floor space. Concentration of a.s. used 0.025 g a.s./m²</p> <ol style="list-style-type: none"> Sprinkled onto moistened hang-boards/cards, which are hung where flies gather. <p>Application rate: 100 g product/m² of board; 25 boards/200 m² floor space using 5 m² of boards/200 m² floor space. Concentration of a.s. 0.025 g a.s./m²</p> <ol style="list-style-type: none"> Diluted in water and sprayed where flies gather. <p>Application rate: 250 g product/0.5 L water; 1 L of diluted product/200 m² floor space Concentration of a.s. in diluted form: 5 g a.s./L. (0.025 g a.s./m²)</p> <ol style="list-style-type: none"> Diluted with water and painted onto surfaces in areas where flies gather. <p>Application rate: 250 or 500 g product/0.5 L water. 1 L of the 250 g/0.5 L diluted product or 0.5 L of the 500 g/0.5 L diluted product /200 m² floor space Concentration of a.s. in diluted form: 5 or 10 g a.s./L. (0.025 g a.s./m²).</p>	

Section A5 Annex Point IIA, V.5.1-5.8	Effectiveness against target organisms and intended uses	
	Either one of a combination of all application methods can be used at any one time, targeting the areas where flies are known to rest or feed, but total application rate does not exceed 500g product/200 m ² floor space	
PT18	Insecticide for professional use only.	
5.4 Mode of action (including time delay) (IIA5.4)	<i>Headline only</i>	
5.4.1 Mode of action	<p>CTB Comments at Completeness Check March 2006:</p> <p>In the document is referred to ref. PZ07, Z60, Z61, Z62 and PZ05. These studies have not been submitted nor evaluated before.</p> <p>Submit all studies.</p> <p>Dow AgroSciences Response March 2006:</p> <p>The mentioned reference reports can be found in Doc. IV-B.</p> <p>PZ07 = B5.8/01</p> <p>Z60 = B5.8/02</p> <p>Z61 = B5.8/03</p> <p>Z62 = B5.8/04</p> <p>PZ05 = B5.8/05</p> <p>One of the key attributes of spinosad is its novel mode of action. The mode of action has been extensively studied in the Dow AgroSciences Laboratories in Indianapolis, USA and summarised in report IIIB 5.8/01 (PZ07). Detailed studies on the physiology of the mode of action are presented in the research reports by Salgado (IIIB 5.8/02-05 (Z60, Z61, Z62 and PZ05).</p> <p>Spinosad consists of a mixture of two materials, spinosyn A and spinosyn D; as both are similar in activity, spinosyn A, the major component in the mixture, was used to identify the mode of action. Initial tests were made using assays for known insecticidal target sites. No activity was detected; in addition other trials were made by external laboratories in more than 60 assays on various drug and toxin sites with no significant effects. These results all indicated that the target site was novel.</p> <p>A study of the symptomology of intoxicated insects showed common effects. Intoxicated insects exhibited tremors and lack of co-ordination, paralysis and death. The tremors observed in Lepidopterous larvae were characterised by continuous movement of the mandibles and constant flexing of the crochets on the pseudopodia. Onset of paralysis was quite rapid. These symptoms all indicated an effect on the insect nervous system. Electrophysiological recordings from the motor neurones confirmed that they become continuously activated when treated with spinosyn A with a corresponding excitation of muscle. After many hours of excitation insects become paralysed from</p>	

Section A5 Annex Point IIA, V.5.1-5.8	Effectiveness against target organisms and intended uses	
	<p>neuromuscular fatigue. Subsequent studies showed that a solution of only 20 nanomolar spinosyn A would depolarise cockroach neurones; this effect could be blocked by α-bungarotoxin, a known nicotinic acetylcholine receptor agonist. This confirmed that spinosyn A depolarises insect neurones by activating nicotinic acetylcholine receptors and in the prime site of action.</p> <p>Nicotine and the new chloronicotinyll compound such as imidacloprid also affect the nicotinic acetylcholine receptor but do so by mimicking the action of the neurotransmitter acetylcholine at its binding site and antagonise any response to applied acetylcholine. Spinosyn A prolongs the action of applied acetylcholine indicating a different site of action. It activates the receptor alone and prolongs the effect of acetylcholine resulting in the excitatory symptomology.</p> <p>Another neurotransmitter is γ amino butyric acid GABA, an inhibitory neurotransmitter which is released at nerve synapses and opens up chloride ion channels in the nerve membrane. Spinosyn has shown some effects on GABA receptors resulting in inhibition but effects on these receptors appear to be secondary in importance.</p> <p>The activity of spinosad is summarised in the chart.</p>	

<p>Section A5 Annex Point IIA, V.5.1-5.8</p>	<p>Effectiveness against target organisms and intended uses</p>	
	 <pre> graph TD A[Spinosad binds to one or more proteins] -.-> B[Nicotine receptors activated] B -.-> C[Influx of sodium begins] C -.-> D[Neurons become depolarized] D -.-> E[Neurons become hyperactive] E -.-> F[Muscles activated Symptoms: leg-extensions, tremors, wing beating, prostration.] F -.-> G[Neuromuscular fatigue] G -.-> H[Paralysis results] A -.-> I[GABA receptors modified] I -.-> J[Other symptoms] I -.-> F </pre> <p>Fig. 1 Schematic mode of action of spinosad.</p>	
<p>5.4.2 Time delay</p>	<p>Action on the insect pest is rapid following contact with spinosad. Symptoms appear within minutes and complete mortality occurs within hours. Once first symptoms have appeared no recovery occurs.</p>	
<p>5.5 Field of use envisaged (IIA5.5)</p>	<p><i>Headline</i></p>	
<p>MG03: Pest control</p>	<p>PT 18 Insecticide for professional use only.</p>	
<p>Further specification</p>	<p>The detailed description of the exact use is given under point 5.3.2 of this document.</p>	
<p>5.6 User (IIA5.6)</p>	<p><i>Headline only</i></p>	
<p>Industrial</p>	<p>No industrial use envisaged for spinosad</p>	
<p>Professional</p>	<p>The professional farmer only</p>	<p>X4</p>
<p>General public</p>	<p>No use of the active substance / biocidal product is intended for the general public.</p>	

Section A5 Annex Point IIA, V.5.1-5.8	Effectiveness against target organisms and intended uses	
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)	<i>Headline only</i>	
5.7.1 Development of resistance	<p>The unique mode of action of spinosad eliminates the risk of cross-resistance due to altered target sites for existing insect control products. Studies conducted at Dow AgroSciences and external laboratories using insect strains showing a variety of resistance mechanisms support this conclusion. (References: B5.11.2/04, Ref. PZF04; B5.11.2/05, Ref. ZF17 and B5.11.2/06, Ref. PZF05)</p> <p>Similarly a range of studies investigating the potential cross resistance between spinosad and other existing insecticides has shown that overall there is an absence of cross resistance in <i>M domestica</i> between spinosad and a wide range of insecticides in other classes. (References B5.11.2/07, Ref. ZF22; B5.11.2/08, Ref. PZF09; B5.11.2/09, Ref. PZF10; B5.11.2/10, Ref. PZF11 and B5.11.2/11, Ref. ZF20).</p> <p>To date there is no evidence of resistance to spinosad in the target species, <i>M domestica</i> has been observed.</p> <p>However <i>M. domestica</i> as a species has shown great ability to develop resistance so it is assumed that it is a high risk organism. Therefore Dow AgroSciences has developed a global strategy to maximise the life of the product and reduce the risk of resistance. The following incorporates the main theme of the strategy as relevant for GF-739.</p> <p>Target the infestation early. Do not reduce the recommended dose rate of 500 g product for 200 m² floor area of the infested building. This product should not be used continuously against houseflies in intensive or controlled environment units as this could cause control failure due to insect resistance. If sequential treatments are required, rotate GF-739 with a product having a different active substance and, if necessary, a different control method (such as space sprays). Do not apply more than five treatment regimes of GF-739 per annum in the same structure. Rotate to another fly control product between each GF-739 application.</p>	X5
5.7.2 Management strategies	Please refer to Appendix I of this Form IIIA5 for Resistance Monitoring / Emergency Plan	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)		

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	X1, July 2007	
Comments	Section IIIA5.2.2, Products, organisms or objects to be protected: Pork should be replaced by pigs Dairy and beef should be replaced by cattle	
Conclusion	Protection of animals in animal housing (e.g. poultry, pigs, cattle, horses,)	
Reliability	-	
Acceptability	-	
Remarks	-	
	COMMENTS FROM...	
Date	<i>Give date of comments submitted</i>	
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>	
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	X2, July 2007	
Comments	Section IIIA5.3.1, effects on target organisms, summary table 5.3: <u>ref. B5.10.2/01: Reliability is 1 (no comments)</u> <u>ref. B5.10.2/02: Reliability is 2</u> The study is performed on a further 3 formulations (GF-52, C0846-6 and K-638), the methods and results of these tests are not mentioned in the summary. Yellow and red baits are compared as are 1% and 0.5% spinosad formulations. In the summary only 1% formulations are mentioned. Red bait and 1% spinosad bait affected flies more quickly in the first 24 hours after application. Application in bait stations also worked quicker than when applied on paint on cards. The results show that the 5 different formulations (GF-52, GF-53, GF-739, C0846-6 and K-638) and 2 different application methods (bait station and paint-on cards) used in the tests had very little effect on the final efficacy levels	

	<p>after 72 hours.</p> <p><u>ref. B5.10.2/03: Reliability is 3</u></p> <p>For the test, the protocol EA99T6P034 was followed. The results are not clearly presented for interpretation (Appendix 1-6). The summary test results is a copy from ref. B5.10.2/04</p> <p>Throughout the test comparative commercial standards (Golden Malrin, based on methomyl (1% bait) and SNIP, based on azamethiphos (1% bait) were shown to work fastest with 100% kill after 3-5 hours. The fastest working spinosad formulation (2% red bait) with typically 100% kills works after 8 hours. Red spinosad baits were in general faster acting than yellow.</p> <p><u>ref. B5.10.2/04: Reliability is 2</u></p> <p>For the test a protocol was followed. Some information in the summary test method is not found in the study report (alternative food source in arenas).</p> <p><u>ref. B5.10.2/05: (field trials) Reliability is 2</u></p> <p>No untreated control was used. Comparisons are made with two commercial standards.</p> <p><u>ref. B5.10.2/06: (field trials) Reliability is 3</u></p> <p>In the test, bait was diluted with water and painted onto surfaces. The application rate used was 400 g bait granules to 100 ml water applied at 500 g bait per 200 m². This is not in agreement with the intended uses of Spinosad. (250 or 500 g per 500 ml water applied at 500 g per 200 m²). The field tests were carried out using Muscafin (spinosad 1%). There is no mention of the formulation. In the summary the test substance is named GF-53 1% spinosad. This formulation has a red colour whereas the formulation GF-739 is yellow.</p> <p><u>ref. B5.10.2/07: (field trials) Reliability is 2</u></p> <p>In the untreated control a natural decrease of the fly populations was shown during the test period. This decrease was 22.2%, 32.4% and 56.0% shown in the three monitoring methods used.</p> <p>The efficacy was shown to be equal to that of the commercial standard (Golden Malrin, based on methomyl (1% bait)).</p>
Conclusion	<p>Efficacy has been shown with 1% formulation applied in different methods: hangboards, bait stations, painted and scattered methods. The effects of the different application methods were shown to be similar.</p> <p>Efficacy tests have been performed with formulations, there are no tests performed with the active ingredient.</p>
Reliability	Reliability is indicated for each individual study. (B5.10.2.01, 02,04,05 and 07)
Acceptability	Acceptable, laboratory and field studies have shown the basic efficacy of the proposed formulation.
Remarks	
	COMMENTS FROM...
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>

Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	X3, July 2007
Comment	Section IIIA5.3.2 Intended uses spinosad: (5.) Application rate when diluted with water and painted onto surfaces. In field test ref. B5.10.2/06 a different rate was used. (See 5.3.1)
Conclusion	The test (B5.10.2/06) has no consequences for the use pattern.
Reliability	-
Acceptability	Acceptable.
Remarks	-
COMMENTS FROM...	
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	X4, March 2009
Comment	Section IIIA.5.6User: The applicant has stated that the user will be "the professional farmer only". It is suggested that the users should be "professional users only", as to allow other professionals (such as pest controllers contracted to carry out a treatment on a farm) to conduct treatments.
Conclusion	

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

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	X5, July 2007	
Materials and methods	<p>Section IIIA 5.7.1 development of resistance</p> <p>References B5.11.2/04-06 have not used insect strains showing a variety of resistance mechanisms supported by data. References are made to other studies, In references B5.11.2/07-11 spinosad shows very little (low level) cross resistance and not, no cross resistance. The risk of cross resistance is reduced not eliminated.</p> <p>References B5.11.2/07 and B5.11.2/08 show indications of oxidative metabolism and penetration mechanisms.</p>	
Conclusion	The tests have shown that the mode of action of spinosad reduces the risk of cross-resistance, but does not eliminate it.	
Reliability	-	
Acceptability	acceptable	
Remarks	-	
	COMMENTS FROM...	
Date	<i>Give date of comments submitted</i>	
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>	
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
Insecticide	Professional use only	XDE-105 applied topically and NAF-85 applied alone or as a 0.048% spinosad experimental baits	House Fly <i>Musca domestica</i>	Spinosad was either applied by topical application to individual flies at 0.05µg and 0.5µg spinosad/fly, or presented alone or mixed with dry fly diet on a small weigh tray with alternative food sources available in a small cage choice test. For both application methods the flies were held in 5.5-litre cylindrical cages with a screened lid. Assessments of knockdown and mortality were made at 24 and 48 hours.	The cages were held at ambient laboratory conditions temperature: approximately 22° C, 50-60% RH, and 13 hours light, 11 hours darkness for 48 hours .	Knockdown and mortality of <i>Musca domestica</i> were recorded at 24 and 48 hours after flies had been placed in the arena. Applied topically at 0.5µg/fly spinosad gave 100% mortality at 48 hours. Applied as nominal bait as NAF-85 in combination with dry fly food gave 99% mortality at 48 hours, which was slightly better than the 89% control of 1% azamethiphos bait. Thus demonstrating the intrinsic activity of spinosad on flies and the very strong potential for the use of spinosad as a bait for the effective control of houseflies	B5.10.2/01
Insecticide	Professional use only	GF-739 (1% w/w spinosad) GF-53 (1% w/w spinosad)	House Fly <i>Musca domestica</i>	A large room study was performed to investigate the comparative performance against houseflies of two formulations of 1% Spinosad fly bait (GF-739 and , GF-53)applied using two delivery methods (bait station and pain-on cards). All baits were applied at 500g bait per 200m2 floor space. An	The arenas were held at 23C +/- 2C and 60-70% RH, with a 16:8 hour light: dark cycle.	This laboratory study has shown that there are some differences between formulations in efficacy within the first 24 hours of application formulations however after 24 hours both formulations are equivalent and gave effective 94-98% control by 48 hours after treatment I. Therefore it is considered justifiable to use data from either or both formulations to support the efficacy requirements for this product. Results also show that the method of delivery of the baits (station or paint-on) used had no significant effect on the final efficacy levels achieved by either formulation.	B5.10.2/02

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
				alternative food source (sugar) and water were supplied for each treatment. A total of 200 flies were introduced to each treatment, with four replicates per treatment. Knock down and mortality were recorded every two hours for 12 hours, and then at 24, 48 and 72 hours post infestation. In order to assess background mortality, one tank of control flies provided with food and water, was placed in the room during each experiment.			
Insecticide	Professional use only	GF-54: 2% w/w Spinosad granular fly bait GF-53: 1% w/w Spinosad granular fly bait GF-52: 0.5% w/w Spinosad granular fly bait GF-51: 0.25% w/w Spinosad granular fly	House Fly <i>Musca domestica</i>	A small cage trial was performed to investigate the comparative performance of several formulations of spinosad fly bait against houseflies: All baits were applied at 2.5g bait in a Petri dish. In a 4L arena, an alternative food source (Sugar) and water were supplied for each arena. A total of 25 flies were introduced to each treatment and there were	Ambient laboratory conditions 20-25°C, 70-75%RH, 16 hour daylight	The data show that in comparison with the commercial standards spinosad fly bait is slower to act within the first few hours after exposure of the flies to the baits than the standards s. It took 3-5 hours for the 1% and 2% spinosad baits to reach a level of control equivalent to the standards. At 12 hours the lower rate (0.25%) spinosad bait had not reached equivalence with the standard Golden Malrin. The level of control seen with GF-53 1% spinosad bait is greater than and more consistent than that seen with the lower rate baits (GF-52:0.5% spinosad bait, GF-51 0.25% bait) at 4 and 8 hours. It is also shown that there is little advantage in terms of control at any timing with the higher rate (2%) bait (GF-54) in comparison with the 1% bait GF-53. Therefore a dose rate of	B5.10.2/03

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
		bait		three replicates per treatment. Mortality was recorded hourly for 12 hours, then at 24 and 48 hours post exposure		1% spinosad is justified	
Insecticide	Professional use only	GF-54: 2% w/w Spinosad granular fly bait GF-53: 1% w/w Spinosad granular fly bait GF-52: 0.5% w/w Spinosad granular fly bait GF-51: 0.25% w/w Spinosad granular fly bait	House Fly <i>Musca domestica</i>	A small cage trial was performed to investigate the comparative performance of several formulations of spinosad fly bait against houseflies Each testing arena consisted of a plastic arena measuring 270mm X 270mm X 145mm, covered with a sheet of glass placed in such a manner to allow ventilation. The test product and an alternative food source of sugar were placed in the bottom of the arena. Water was also provided via a saturated cotton wool pad. Each replicate consisted of 30 flies per arena.	The arenas were held at ambient laboratory condition, with a maximum of 25°C, Min 20°C, RH 30-50%, and 14 hour day length	The data show that in comparison with the commercial standards spinosad fly bait is slower to act within the first few hours after exposure of the flies to the baits than the standards s. It took 3-5 hours for the 1% and 2% spinosad baits to reach a level of control equivalent to the standards. At 12 hours the lower rate (0.25%) spinosad bait had not reached equivalence with the standard Golden Malrin. The level of control seen with GF-53 1% spinosad bait is greater than and more consistent than that seen with the lower rate baits (GF-52:0.5% spinosad bait, GF-51 0.25% bait) at 4 and 8 hours. It is also shown that there is little advantage in terms of control at any timing with the higher rate (2%) bait (GF-54) in comparison with the 1% bait GF-53. Therefore a dose rate of 1% spinosad is justified	B5.10.2/04
Insecticide	Professional use only	GF-53: 1% w/w Spinosad granular fly bait GF-739: 1% w/w Spinosad granular fly bait	House Fly <i>Musca domestica</i>	The field trials took place in 11 pig production units with naturally occurring populations of <i>Musca domestica</i> . GF-739 was applied as paint-on, scatter, station/tray, hang	Field trials, naturally occurring populations of <i>Musca domestica</i> .	Assessments were made of the number of flies resting on marked areas within the fabric of the house, up to a total area of 40 m ² , at 14, 7, 2 and 1 days prior to treatment and 1, 3, 7, 14, 21, 28, 35 and 42 days post-treatment The percent control of the fly population was then calculated compared with an average of the pre-treatment populations for each unit. Application of 1% spinosad fly bait by either one	B5.10.2/05

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
				boards, spray on and a combination of paint and stations. GF-53 was applied by paint on and station tray method. Applications of the commercial standard Golden Malrin were made by broadcast and the combined paint-on and station application methods. Application of the standard Snip was made by the station tray method		or a combination of the following application techniques: station/tray, scatter, hangboard, paint-on and spray on, gave significant reduction in fly population equivalent to that of Golden Malrin and Snip which was maintained for up to 6 weeks.	
Insecticide	Professional use only	GF-53: 1% w/w Spinosad granular fly bait	<i>Musca domestica</i>	The field trials took place in naturally occurring populations of <i>Musca domestica</i> in 17 livestock units on 6 farms with pig producing facilities Application was made either to hand-boards or directly as paint-on bait. On each trial location the infestation level was assessed during a 10-week trial period including a 2-week pre-treatment period, a 6-week period during treatment and a 2-week after-treatment period.	Field trials, naturally occurring populations of <i>Musca domestica</i> .	The assessments of efficacy were made on the basis of the results of the estimations of fly infestation levels by the DPIL Fly Index Method. For houseflies DPIL fly index level 3 (13-25 houseflies per animal) is defined as the nuisance threshold. It is considered effective if the fly control product could reduce and maintain the fly infestation level below nuisance level. The trials data show that 1% spinosad fly bait applied by either hang-boards or paint on method significantly reduced the fly infestation levels to below nuisance level within days of application, and remained effective for several weeks. The performance of 1% spinosad fly bait was as good as if not better than the performance of the comparative standards Snip and Golden Malrin. The data also show the need for correct placement of the bait in areas where flies are known to land or feed for effective use of the fly bait products	B5.10.2/06
Insecticide	Professional use only	GF-739: 1% w/w Spinosad granular fly	<i>Musca domestica</i>	The field trials took place in naturally occurring populations of	Field trials, naturally occurring populations of	More than one assessment type was carried out to determine the fly levels in this trial for the data presented from the marked area counts as the most	B5.10.2/07

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
		bait		<p><i>Musca domestica</i> in 7 poultry units.</p> <p>Application was made either by paint-on bait, granules in station/ trays or broadcast technique. The infestation level was assessed during prior to and for 8weeks post treatment</p>	<i>Musca domestica</i>	<p>consistent method of assessment through out the trials series in this dossier.</p> <p>Data are expressed in terms of absolute number and percent control is calculated relative to initial population.</p> <p>Spinosad 1% w/w fly bait gave more than 90% reduction in the fly population during the 8 week trial, irrespective of the application method used. The efficacy was equal to that obtained from the market standard Golden Malrin. GF-739 gave equal reduction in fly population to that of Golden Malrin, giving more than 90% reduction of the population in the 8 weeks of the trial. Efficacy was equivalent across all application techniques.</p>	

APPENDIX 1

Resistance monitoring

The strategy chosen for monitoring includes four components of which the first is the primary method for the early detection in any individual country.

1. Monitoring and follow up of efficacy failures by trained personnel.
A standard procedure (attached) is followed for investigating any efficacy failure which includes the determination of possible resistance, but only once other potential causes have been eliminated. If samples are collected, information regarding the establishment and product usage is also collected (attached) and the sample tested using a standard lethal dose bioassay (Straszewski, 2001, B5.11.2/01, Ref. ZF23 and B5.11.2/02, Ref. ZF24) or a diagnostic dose determined from the baseline sensitivity testing (Straszewski, 2005, B5.11.2/03, MJ92).
2. Tracking of efficacy and commercial use demonstration trials. Any results inconsistent with previous knowledge would be fully investigated as above.
3. Monitoring of resistance testing activities elsewhere globally. Every 2 years DPIL conduct a survey of *Musca domestica* sensitivity across Denmark. Whilst this is government funded the company also provides direct support to this activity.
4. Monitoring of reports of resistance to spinosad globally. Dow AgroSciences has a Global Intelligence system that collects information on all confirmed cases of resistance to its products globally.

Evidence collected from these four components would enable an immediate evaluation of the existing resistance management strategy and whether any changes needed to be made for example changes to the recommendation regarding number of treatments. This is in addition to any immediate action that would be taken at individual sites as described in

1. above

1 SPINOSAD RESISTANCE MANAGEMENT – EMERGENCY PLAN

