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Data Evaluation Report on the Reproductive Effects of JAU 6476 - Desthio (Prothioconazole - Desthio) on *Colinus virginianus*

PMRA Submission Number 2004-0843 EPA MRID Number 46246043

Data Requirement:	PMRA DATA CODE	9.6.3.1
	EPA DP Barcode	D303488, D303495
	OECD Data Point	IIA 8.1.4
	EPA MRID	46246042
	EPA Guideline	§71-4a

Test material: JAU 6476 - Desthio **Purity:** 96.8-97.6%
Common name: Prothioconazole - Desthio
Chemical name: IUPAC: 2-(1-Chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazole-1-yl)-propan-2-ol
CAS name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole
CAS No.: 120983-64-4
Synonyms: SXX 0665

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CITATION: Barfknecht. R. 2002. JAU6476-Desthio techn.ai.: Effects of a Subchronic Dietary Exposure to the Northern Bobwhite Quail Including Effects on Reproduction and Behavior. Unpublished study performed by Bayer AG, Leverkusen, Germany. Laboratory Study No. E 2981830-1. Study submitted by Bayer CropScience, Research Triangle Park, NC. Study initiated May 8, 2000 and completed January 7, 2002.

The one-generation reproductive toxicity of JAU 6476 - Desthio (prothioconazole - desthio) to groups (20 pens/treatment level) of 1 male and 1 female of >16-week old Northern Bobwhite quail (exact age not known) was assessed over approximately 22 weeks. JAU 6476 - Desthio was administered to the birds in the diet at nominal concentrations of 0 (negative control), 60, 173, and 500 ppm. Mean-measured concentrations were 59.5, 173.0, and 506.7 ppm a.i.(control feed was not analyzed for a.i. content).

There were no significant treatment-related effects on any adult parameter. In addition, no treatment-related effects were observed on egg production or quality, fertility, embryonic development, hatchability, or clinical effects, food consumption, or body weights of chicks during the 14-day observation period.

The study author's statistical analysis indicated that survival rate of chicks was adversely affected by treatment at the 506.7 ppm a.i. level, with significant reductions in the percentage of 14-day old survivors of self hatched chicks (87.1 versus 96.7% for the control). The increase of chick mortality at the 506.7 ppm a.i. level was due to an increase in chick deaths due to unknown causes. However, reviewer-conducted statistical analyses indicated that there were no significant, treatment-related effects on any reproductive endpoints. The difference in conclusions between the reviewer and the original study author is likely the result of different statistical tests, as described below. The reviewer determined NOAEC was 506. 7 ppm a.i.

This study is scientifically sound, fulfills guideline requirements for the reproductive toxicity of JAU 6476 - Desthio (prothioconazole - desthio) to Northern Bobwhite quail (§71-4a), and is classified as ACCEPTABLE.

Results Synopsis

Test Organism Size/Age: At least 16 weeks old (hatch in autumn 1999, exact date of hatch was not available) (165-252 g)

NOAEC: 506.7 ppm a.i.
LOAEC: >506.7 ppm a.i.
Endpoint(s) Affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures of the U.S. EPA Pesticide Assessment Guidelines, Series 71-4 (1986); and OECD Guideline 206 (1984). Deviations from §71-4 are:

1. Pre-test mortality was not reported.
2. Control feed was not analyzed for active ingredient.
3. The maximum anticipated field residue was not specified.
4. Egg storage temperature ranged from 10-15°C, which is slightly lower than the recommended temperature of 16°C.
5. The day the chicks were removed from the hatcher and counted was not clearly specified.
6. The temperature of the hatching chamber ranged from 33.1 to 38.1°C, which is slightly lower than the recommended 39°C.

These deviations did not affect the scientific validity or acceptability of the study.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. This study was conducted in accordance with the principles of GLP in Chemicals Law (ChemG) of July 25, 1994, Annex 1, and the current OECD principles of GLP.

A. MATERIALS:

1. Test Material JAU 6476 - Desthio (prothioconazole - desthio)

Description: White powder

Lot No./Batch No.: RUX76-105/9 (mixed batch)

Purity: 97.6% (reported a.i.) and 96.8% (re-analysis)

Stability of Compound Under Test Conditions: Verified stable (≥93% of initial values) in treated feed for up to 7 days under test conditions, or for up to 41 days under frozen conditions (p. 16).

Storage conditions of test chemical: Room temperature

OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound. OECD requirements were not reported.

2. Test organism:

Table 1: Test organism.

Parameter	Details	Remarks *Criteria*
Species (common and scientific names):	Northern Bobwhite quail (*Colinus virginianus*)	*EPA requires: a wild waterfowl species, preferably the mallard, Anas platyrhynchos, or an upland game species, preferably the northern bobwhite, Colinus virginianus.*

Parameter	Details	Remarks *Criteria*
Age at Study Initiation:	At least 16 weeks old	It was stated that birds were approaching their first breeding season. *EPA requires: birds should be approaching their first breeding season.*
Body Weight: (mean and range)	Males: Overall range (n=80) 170 to 252 g, with group means of 194 to 199 g. Females: Overall range (n=80) 165 to 236 g, with group means of 194 to 204 g.	Individual body weights were recorded at Weeks 0, 2, 4, 6, 8, 10, and 22 (test termination). *EPA requires that body weights should be recorded at test initiation and at biweekly intervals up to week eight or up to the onset of egg laying and at termination.*
Source:	Geflugelzucht H.&E. Kuberich, Wiesentheid, Germany	Birds were from the same hatch, and were phenotypically indistinguishable from wild birds. *EPA requires that all birds should be from the same source.*

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study - A range-finding study was not conducted. The chosen dietary concentrations in the definitive study were calculated in consideration to the environmental exposure situation in agricultural practice (actual application rates and expected exposure conversions were not provided; p. 14).

b. Definitive Study

Table 2: Experimental Parameters.

Parameter	Details	Remarks *Criteria*
Acclimation period: Conditions (same as test or not): Feeding: Health (any mortality observed):	3 weeks Same as test A standard quail diet for adult breeding birds [0729-Extrudat (mash form; batch no's. 170800/0939 and 211100/0714) from Altromin GmbH] and Monheim City municipal water were provided *ad libitum*. It was noted that mortality of the control group was 0% during 1 week of acclimation (p. 6). Otherwise, not reported.	After arrival, all birds were examined, and birds with obvious anomalies and injuries were discarded. Only well developed birds were selected and set into the test facility. *EPA recommends a 2-3 week health observation period prior to selection of birds for treatment. Birds must be generally healthy without excess mortality. Feeding should be ad libitum, and sickness, injuries or mortality be noted.*
Test duration pre-laying exposure: egg-laying exposure: withdrawal period, if used:	Approximately 12 weeks Approximately 10 weeks None	*EPA requires* ***Pre-laying exposure duration*** *At least 10 weeks prior to the onset of egg-laying.* ***Exposure duration with egg-laying*** *At least 10 weeks.* ***Withdrawal period*** *If reduced reproduction is evident, a withdrawal period of up to 3 weeks should be added to the test phase.*

Parameter	Details	Remarks *Criteria*
Pen (for parental and offspring) size:	Parents (one pair) were housed in cages measuring 75 x 50 x 25 cm. Offspring (by set and group) were housed in 100 x 200 x 50 cm poultry brooders.	
construction materials:	Parental pens were constructed of PU-coated wire grids (bottom) and stainless steel sheeting (sides and top covers). Offspring pens were constructed of plastic-sheeting with a floor covering of corrugated cardboard paper.	*Pens* *Adequate room and arranged to prevent cross contamination* *Materials* *Nontoxic material and nonbinding material, such as galvanized steel.* *Number* *At least 5 replicate pens are required for mallards housed in groups of 7. For other arrangements, at least 12 pens are required, but considerably more may be needed if birds are kept in pairs. Chicks are to be housed according to parental grouping.*
number:	20 parental pens (replicates) per treatment level	
Number of birds per pen (male:female)	2 birds/pen (1 male:1 female)	*EPA requires one male and 1 female per pen. For quail, 1 male and 2 females is acceptable. For ducks, 2 males and 5 females is acceptable.*
Number of pens per group/treatment negative control: solvent control: treated:	20 pens N/A 20 pens/treatment	*EPA requires at least 12 pens, but considerably more if birds are kept in pairs. At least 16 is strongly recommended.*

Parameter	Details	Remarks *Criteria*
Test concentrations (ppm diet) nominal: measured:	0 (negative control), 60, 173, and 500 ppm diet 59.5, 173.0, and 506.7 ppm a.i.	Mean-measured concentrations were determined from fresh batches of diet prepared every 4 weeks (pp. 17-18). The control diets were not analyzed for active ingredient. *EPA requires at least two concentrations other than the control are required; three or more are recommended.*
Maximum labeled field residue anticipated and source of information:	Not specified	It was reported that the chosen dietary concentrations were calculated in consideration to the environmental exposure situation in agricultural practice (p. 12). *EPA requires that the highest test concentrations should show a significant effect or be at or above the actual or expected field residue level. The source [i.e., maximum label rate (in lb ai/A & ppm), label registration no., label date, and site should be cited]*
Solvent/vehicle, if used type: amount:	N/A	 *EPA requires corn oil or other appropriate vehicle not more than 2% of diet by weight*

Parameter	Details	Remarks *Criteria*
Was detailed description and nutrient analysis of the basal diet provided? (Yes/No)	Yes. Basal diets contained 19.7-19.9% protein, 2.80-3.17% crude fat, 4.6% crude fiber, and 3.02-3.55% calcium (Appendix XIV, pp. 95-98).	Adults received Altromin 0729 Extrudat batch no. 170800/0939 for diet preparations 2 through 5, and batch no. 211100/0714 for diet preparations 6 and 7 (p. 12). Offspring received a special chick starter diet for quails (Altromin 0719A, batch no.'s 021200/1441 and 120201/0719, p. 12). A detailed description of the starter diet is provided in Appendix XVII, pp. 99-101. *EPA requires a commercial breeder feed (or its equivalent) that is appropriate for the test species.*
Preparation of test diet	The appropriate amount of test material was directly combined with basal ration (not further described, p. 14). Treated diets were prepared every 4 weeks, immediately sub-divided into four weekly portions, and stored frozen (-29 to -19°C, p. 20) until needed.	*A premixed containing the test substance should be mechanically mixed with basal diet. If an evaporative vehicle is used, it must be completely evaporated prior to feeding.*
Indicate whether stability and homogeneity of test material in diet determined (Yes/No)	Yes	
Were concentrations in diet verified by chemical analysis?	Yes	Samples from all treated levels were collected for all prepared batches (p. 17).

Parameter	Details	Remarks *Criteria*
Did chemical analysis confirm that diet was stable? and homogeneous?	Yes Yes	Stability was assessed prior to the definitive study in diets prepared at 60 and 1000 ppm (p. 16). Samples were stored for either 41 days under frozen conditions, or for 7 days under test conditions. After 41 days of frozen storage, recoveries averaged 96-98% of initial concentrations, and after 7 days of ambient storage, recoveries averaged 93-96% of initial concentrations. Homogeneity was assessed prior to the definitive study by randomly analyzing three of five samples collected from treated feed prepared at 60 and 1000 ppm (p. 15). Coefficients of variation were 2.37 and 4.79%, respectively.
Feeding and husbandry	Feeding and husbandry conditions appeared to be adequate, given guideline recommendations.	
Test conditions (pre-laying) temperature: relative humidity: photo-period:	 18-23°C 42-95% 7 hours light/day (with 30-minute transition periods) up through Week 8, then increased to 17 hours light/day (with 30-minute transition periods) thereafter.	The maximum light intensity for the individual cage front was 88.0-93.5 lux (at test initiation, p. 18). *EPA Requires* *Temperature:* *About 21 °C (70 °F)* *Relative humidity:* *About 55%* *Lighting* *First 8 weeks: 7 h per day.* *Thereafter: 16-17 h per day.* *At least 6 foot candles at bird level.*

Parameter	Details	Remarks *Criteria*
Egg Collection and Incubation		
Egg collection and storage collection interval: storage temperature: storage humidity:	Daily 10-15°C 60-98%	*EPA requires eggs to be collected daily; egg storage temperature approximately 16°C (61°F); humidity approximately 65%.*
Were eggs candled for cracks prior to setting for incubation?	Yes	*EPA requires eggs to be candled on day 0*
Were eggs set weekly?	Yes	
Incubation conditions temperature: humidity:	35.0-38.3°C 28.1-75.9%	Incubation and hatching occurred in the same incubator, in different compartments.
When candling was done for fertility?	Day 11 for fertility and Day 18 for viability.	*EPA requires:* *Quail: approx. day 11* *Ducks: approx. day 14*
When the eggs were transferred to the hatcher?	Day 21	*EPA requires:* *Bobwhite: day 21* *Mallard: day 23*
Hatching conditions temperature: humidity: photoperiod:	33.1-38.1°C 43.7-92.2% 17 hour light/7 hour dark cycle (p. 13)	Incubation and hatching occurred in the same incubator, in different compartments. *EPA requires:* *temperature of 39°C (102°F)* *humidity of 70%*
Day the hatched eggs were removed and counted	Within 48 hours after initiation of hatch (not otherwise specified).	*EPA requires Bobwhite: day 24* *Mallard: day 27*
Were egg shells washed and dried for at least 48 hrs before measuring?	Yes	

Parameter	Details	Remarks *Criteria*
Egg shell thickness no. of eggs used: intervals: mode of measurement:	All eggs laid on one day Every other week throughout the egg-laying period. Four points around the equatorial circumference were measured to the nearest 0.01 mm.	*EPA requires newly hatched eggs be collected at least once every two weeks. Thickness of the shell plus membrane should be measured to the nearest 0.01 mm; 3 - 4 measurements per shell.*
Reference chemical, if used	None used	

2. Observations:

Table 3: Observations.

Parameter	Details	Remarks/Criteria
Parameters measured		
Parental: (mortality, body weight, mean feed consumption)	- mortality - signs of toxicity, injury, or illness - body weight - food consumption - necropsy	At necropsy, specific examination was made on the gastro-intestinal tract, liver, kidneys, bile duct, heart, spleen, and reproductive organs. Other observations were recorded as necessary.
Egg collection and subsequent development: (no. of eggs laid, no. of eggs cracked, shell thickness, no. of eggs set, no. of viable embryos, no. of live 3 week embryos, no. hatched, no. of 14-day survivors, average weight of 14-day-old survivors, mortality, gross pathology, others)	- eggs laid - egg weight - eggs cracked - egg shell thickness - eggs set - fertile embryos - viable 3-week embryos - number of normal hatchlings - hatchling body weight - signs of toxicity and physical defects of hatchlings - number of 14-day-old survivors - 14-day-old survivor body weight - hatchling food consumption	*EPA requires:* • *Eggs laid/pen* • *Eggs cracked/pen* • *Eggs set/pen* • *Viable embryos/pen* • *Live 3-week embryos/pen* • *Normal hatchlings/pen* • *14-day-old survivors/pen* • *14-day-old survivors/pen* • *Weights of 14-day-old survivors (mean per pen)* • *Egg shell thickness* • *Food consumption (mean per pen)* • *Initial and final body weight (mean per pen)*
Indicate if the test material was regurgitated	No indications of dietary regurgitation.	
Observation intervals (for various parameters)	Mortality and signs of toxicity were observed daily and food consumption was observed weekly for adults and hatchlings. Parental body weights were recorded at Weeks 0, 2, 4, 6, 8, 10, and 22 (test termination). Offspring body weights were determined at 0 and 14 days.	*Body weights and food consumption must be measured at least biweekly.*
Were raw data included?	Yes, sufficient.	

I. RESULTS AND DISCUSSION:

A. MORTALITY:

No treatment-related mortality was observed during the study. However, ten birds died prematurely and their pen mates were sacrificed: one from the control group, and three birds each from the 60, 173, and 500 ppm groups (p. 23 and Tables 4 and 5, pp. 34-36). Six of the birds died due to injuries sustained on the head, foot, or bill. The other four birds were extremely emaciated, with two (the control and one 60 ppm bird) revealing signs of an internal infection upon necropsy. One bird from the 60 ppm group died without a concrete cause of death, and one bird from the 500 ppm group died with signs of diarrhea. None of the observed behavioral impacts showed a treatment-related response in either severity or distribution. The sex of the decedent birds was not specified, and it was not always apparent, based on necropsy findings, which of the pair was found dead and which was sacrificed as a pen-mate. Details of the necropsy results (Appendix III, pp. 47-50) are described below:

One control male was found dead during Week 18. At death, the bird was severely emaciated (102.1 g). Necropsy revealed an enlarged (3X normal size) liver; severely decomposed liver tissue interspersed with solid yellowish granules; enlarged spleen (10X normal size); spleen tissue interspersed with solid yellowish granules; small yellowish pancreas; and small green testicles. Necropsy of the pen-mate was unremarkable.

One male from the 60 ppm group was found dead during Week 18. Necropsy revealed slight emaciation (151.8 g); an enlarged liver, severely decomposed liver tissue interspersed with yellow granules; cloaca glued by excreta; yellow granules on outer wall of gizzard; reduced heart size; heart surface covered with yellowish granules; and one small greenish testicle. Necropsy of the female pen-mate (4 days earlier, see Reviewer's Comment section) revealed a slightly emaciated body (148.3 g), with one claw torn out from the left foot, and reduced ovaries. Two other females from the 60 ppm group were found dead during Week 20. Necropsy of one female revealed emaciation; fluffed, untidy plumage; scalped head skin; bloody neck; green liver tissue (from gall); black spleen; empty GI tract; green inner surface of gizzard (from gall); and fully-developed ovaries, with no yolk/egg in development. Necropsy of the pen-mate revealed a slightly emaciated body; inflamed, swollen, and partially scabby legs; and reduced (to ½ size) testicles. Necropsy of the other decedent female from the 60 ppm group revealed a severely emaciated body; fluffed, untidy plumage; empty GI tract; green inner surface of gizzard (from gall); bloody cloaca; reduced heart size; and fully-developed ovaries, with no yolk/egg in development. Necropsy of the pen-mate was unremarkable.

One hen from the 173 ppm group died during Week 11. At death, the bird was severely emaciated (96.5 g), with injuries to the foot and head (with scabbing). In addition, it was noted that the ovaries had not yet developed. Necropsy of the pen-mate noted injuries to the foot, and undeveloped testicles. Another female from the 173 ppm group died during Week 17. At death, the bird was severely emaciated (117.3 g), and exhibited injuries to the right foot; an orange discolored pancreas; and an enlarged gall bladder. Necropsy of the pen-mate was unremarkable. Another female from the 173 ppm group was found dead during Week 19. At death, the bird was severely emaciated (110.0 g), with injuries to the foot (one toe on left foot scabby) and bill (wide parts of the lower bill were missing and decomposed). In addition, the bird had a black liver, a green pancreas, and reduced ovaries. Necropsy of the pen-mate showed feather-loss areas of the breast and neck, but was otherwise unremarkable.

One hen from the 500 ppm group was found dead during Week 16, with severe injuries to the head (cause of death). In addition, granulated surfaces of the kidneys were observed. Necropsy of the pen-mate was unremarkable. One male from the 500 ppm group was found dead during Week 18. At death, the bird was severely emaciated (111 g), with injuries to the foot (right toe bloody) and bill (right side severely deformed and partially disintegrated - fungicidia seized). In addition, the spleen was small and anemic, and the kidneys were small. Necropsy of the pen-mate was unremarkable. The final mortality in the 500 ppm group was a hen that was found dead during Week 19. Necropsy revealed severe emaciation (128.5 g); cloaca glued by excreta; white discolored kidneys; reduced liver size; yellowish discolored liver; and reduced ovaries. Necropsy of the

pen-mate revealed emaciation (153.3 g); one claw torn off from left foot; decomposed liver tissue; and reduced testicles.

No other mortalities were observed during the study, and due to the nature of lesions observed at necropsy, none of the mortalities were considered to be related to treatment.

Table 4: Effect of JAU 6476 - Desthio (Prothioconazole - Desthio) on Mortality of *Colinus virginianus*.

Treatment, ppm measured (and nominal) concentrations	Observation Period					
	Week 7		Week 14		Week 22	
	No. Dead		No. Dead		No. Dead	
	Male	Female	Male	Female	Male	Female
Control	0	0	0	0	1	0
59.5 (60)	0	0	0	0	1	2
173.0 (173)	0	0	0	1	0	3
506.7 (500)	0	0	0	0	1	2

B. REPRODUCTIVE AND OTHER ENDPOINTS:

Abnormal Effects/Behavior: No treatment-related effects on parental birds were observed (p. 23). Injury (generally the feet and head) was the most commonly observed effect, with secondary effects of fluffed feathers or reduced vigilance also observed (Table 5, p. 36). Single birds from all treatment groups (two at 60 ppm, one at 173 ppm, and two at 500 ppm) were emaciated, and diarrhea was also observed.

Food Consumption: No treatment-related effects on food consumption were observed (p. 23 and Table 3, p. 33). Statistically-significant decreases from the control group were observed during Weeks 15 though 17 at the 60 ppm level, and during Weeks 15 through 18 at the 500 ppm level. However, final feed rates at test termination were homogeneous over all study groups including the control, and adverse effects by treatment were not recognizable. Overall feed consumption averaged 36.7, 36.0, 37.2, and 35.8 g/pair/day for the control, 60, 173, and 500 ppm test groups, respectively.

Body Weight: No treatment-related effects on the differences in body weights were observed (p. 23, and Table 2, p. 32). Statistically-significant decreases in relative body mass changes from the control group were observed during Weeks 1-2 in males from all test levels, during Weeks 1-2 in females from the 500 ppm group, and during Weeks 6-8 in males from the 60 ppm group. Since the effects were transient without any influence on behavior or food intake of the birds, the differences were not considered to be a result of treatment.

Necropsy: No treatment-related findings were observed at necropsy (p. 24, and Table 4, pp. 34-35, and Appendix III, pp. 47-50). Findings from all treatment and control groups included primary injuries to the head, neck, and/or feet, with secondary effects associated with injury including sore cloaca, and reduced ovaries and testicles. Enlarged gall bladder (caused by reduced foot intake) was observed in three birds at 60 ppm, seven birds at 173 ppm, and eight birds at 500 ppm. The study author reported that due to the absence of signs of longer-lasting starvation (i.e., emaciation), this represents only the actual feeding situation before final sacrifice.

Single cases of discoloration or changes in size and appearance of the liver and pancreas were found at all control and treatment levels.

Reproductive Effects: No treatment-related effects on egg production or quality, fertility, embryonic development, or hatchability were observed at any test level (pp. 25-26; and Tables 6-7, pp. 37-40).

Statistically-significant increases in egg mass were observed at the 173 ppm (10.6 g) and 500 ppm (10.7 g) levels compared to the control (10.0 g). Since the higher egg mass had no effects on hatchability and eggshell thickness, it was not considered to be an adverse effect and was not included in the NOAEC estimation (p. 25).

The survival rate of chicks was adversely affected by treatment at the 500 ppm level, with statistically-significant reductions in the percentage of 14-day old survivors of self hatched chicks (87.1 versus 96.7% for the control). The increase of chick mortality at the 500 ppm level was due to an increase in chick deaths due to unknown causes (p. 27 and Table 9, p. 42). Other causes of death that were not attributable to treatment included perosis; yolk-sac not redeveloped at hatch; accidental deaths (injuries, drowning in the water reservoir, or escaping from the cages and dying from hypothermia). The NOAEC for chick survival was 173 ppm.

No treatment-related adverse effects on chick body weights (at hatch or after 14 days) or on food consumption were observed (pp. 26-27; and Tables 6-8, pp. 37-41).

Table 5: Reproductive and other parameters (nominal concentrations; study author-reported).

Parameter	Control	60 ppm	173 ppm	500 ppm	NOAEC/ LOAEC
Eggs laid/hen	50.1	39.6	46.3	41.3	500 ppm >500 ppm
Eggs cracked/hen	0.2	0.4	0.2	0.3	500 ppm >500 ppm
Eggs cracked/eggs laid (%)	0.5	1.4	0.4	1.9	500 ppm >500 ppm
Mean egg weight (g)	10.0	10.3	10.6	10.7	500 ppm >500 ppm
Eggshell thickness (mm)	0.22	0.22	0.22	0.22	500 ppm >500 ppm
Eggs set/hen	46.5	36.3	42.8	38.1	500 ppm >500 ppm
Fertile (11-day old) embryos/hen	41.7	30.3	39.8	36.1	500 ppm >500 ppm
Fertile embryos/eggs set (%)	86.5	77.8	88.1	95.4	500 ppm >500 ppm
Viable (18-day old) embryos/hen	40.0	29.7	39.2	35.5	500 ppm >500 ppm

Parameter	Control	60 ppm	173 ppm	500 ppm	NOAEC/ LOAEC
Viable embryos/eggs set (%)	83.7	76.3	86.5	92.5	500 ppm >500 ppm
Viable embryos/fertile embryos (%)	95.7	97.8	98.2	97.1	500 ppm >500 ppm
No. of total hatchlings/hen	27.4	19.8	30.5	22.5	500 ppm >500 ppm
Self hatched chicks/eggs set (%)	55.0	49.9	66.9	61.4	500 ppm >500 ppm
Self hatched chicks/fertile embryos (%)	58.7	64.3	76.4	64.7	500 ppm >500 ppm
Self hatched chicks/viable embryos (%)	60.0	65.6	77.6	67.2	500 ppm >500 ppm
Hatchling weight (g)	7.4	7.1	7.4	7.7	500 ppm >500 ppm
14-day old survivors/hen	26.4	18.8	29.1	20.0	500 ppm >500 ppm
14-day old survivors/eggs set (%)	55.3	47.4	63.9	52.9	500 ppm >500 ppm
14-day old survivors/self hatched chicks (%)	96.7	95.1	95.8	87.1*	173 ppm 500 ppm
14-day old survivors weight (g)	27.6	26.7	31.2	26.9	500 ppm >500 ppm
Mean adult food consumption (g/pen/day)	36.7	36.0	37.2	35.8	500 ppm >500 ppm
Weight of adult males, g at start of treatment: at Week 10: at Week 22 (study termination):	 194 205 209	 199 211 210	 199 209 223	 197 205 209	 500 ppm >500 ppm
Weight of adult females, g at start of treatment: at Week 10: at Week 22 (study termination):	 202 218 235	 194 220 221	 204 218 243	 202 223 235	 500 ppm >500 ppm
Gross pathology (proportion of surviving birds with pathological incidents)	29/38	24/34	27/34	25/34	500 ppm >500 ppm

C. REPORTED STATISTICS:

The following variables were statistically analyzed: adult body weights at 0, 2, 4, 6, 8, 10, and 22 Weeks; relative body mass changes (2-week intervals) of parental birds; and weekly mean feed consumption of parental birds and offspring. In addition, the following reproductive endpoints were statistically analyzed on a weekly and overall bases: eggs laid/hen; eggs cracked/hen; eggs set/hen; fertile eggs/hen; viable embryos/hen; hatchlings/hen; 14-day-old survivors/hen; egg mass/hen; egg shell thickness; mass of hatchlings; mass of 14-day-old survivors; percent of cracked eggs/eggs laid; percent of fertile eggs/eggs set; percent of viable embryos/eggs set; percent of viable embryos/fertile eggs; percent of self hatched chicks/eggs set; percent of self-hatched chicks/fertile eggs; percent of self hatched chicks/viable embryos; percent of 14-day-old survivors/eggs set; and percent of 14-day-old survivors/self-hatched chicks.

All variables were analyzed using STATGRAPHICS-Plus statistical software using nominal concentrations. Data were first assessed for homogeneity of variance using Bartlett's test. If the data set passed the tests for homogeneity, an analysis of variance (ANOVA) was performed to determine statistically-significant differences between groups. If significant differences were indicated, then the Fisher's test or comparable F-test was used to determine the NOAEC. If the variance was not homogeneous, the data were analyzed by Mann-Whitney/Wilcoxon test.

To comply with U.S. requirements, overall data were also analyzed using the TOXSTAT statistical program. Data were assessed for normality using the Chi-Square test and for equal variance using Levene's test. If variances were equal, then the data were analyzed using ANOVA followed by Dunnett's test or Bonferroni's t-test (for unequal numbers of replicates). If the variances were unequal, then the data were transformed using an appropriate transformation (e.g., square-root arcsine for percentage data), and then subjected to Levene's test again, followed by ANOVA. If variances of the transformed data were unequal, non-parametric procedures were required.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Analysis was conducted using "chicks.sas" (Ver. 3; March 2002), a SAS program provided by EFED/OPP/USEPA. Data for all endpoints were examined graphically using box plots to determine if they exhibited a dose-dependent response, which was ultimately used to select the multiple comparison test to detect LOAEC and NOAEC. Data for each endpoint were tested to determine if their distributions were normal and if their variances were homogeneous using Shapiro-Wilk's and Levene's tests, respectively. Data that satisfied these assumptions were subjected to Dunnett's and William's tests and data that did not satisfy these assumptions were subjected to the non-parametric MannWhitney-U (with a Bonferroni adjustment) and Jonckheere's tests. Data for dead birds were excluded from the analyses. See Appendix I for output of reviewer's statistical verification and graphs for affected endpoints to support any reviewer-generated conclusions that may differ from those reported in the study.

Table 6. Reproductive and other parameters (mean-measured concentrations; reviewer-reported).

Parameter	Control	59.5 ppm	173.0 ppm	506.7 ppm	NOAEC/ LOAEC
Eggs laid/pen	51.2	43.6	50.6	46.4	507 ppm >507 ppm
Eggs cracked/pen	0.16	0.41	0.22	0.29	507 ppm >507 ppm

Parameter	Control	59.5 ppm	173.0 ppm	506.7 ppm	NOAEC/ LOAEC
Eggs not cracked/eggs laid (%)	99.6	98.6	99.6	99.2	507 ppm >507 ppm
Eggs set/pen	47.5	39.8	46.7	42.7	507 ppm >507 ppm
Shell thickness	0.22	0.22	0.21	0.22	507 ppm >507 ppm
Eggs set/eggs laid (%)	93.0	90.5	92.6	91.6	507 ppm >507 ppm
Viable embryo/pen	42.4	33.5	43.6	40.4	507 ppm >507 ppm
Viable embryos/eggs set (%)	85.9	77.8	88.3	94.8	507 ppm >507 ppm
Live embryos/pen	41.6	32.9	42.9	39.8	507 ppm >507 ppm
Live embryo/viable embryo (%)	95.6	98.4	98.5	98.5	507 ppm >507 ppm
No. of hatchlings/pen	28.0	21.9	33.6	24.9	507 ppm >507 ppm
No. of hatchlings/eggs laid (%)	51.0	45.8	63.1	54.7	507 ppm >507 ppm
No. of hatchlings/eggs set (%)	55.1	50.6	68.5	59.9	507 ppm >507 ppm
No. of hatchlings/live embryos (%)	60.3	66.3	79.6	64.6	507 ppm >507 ppm
Hatchling survival/pen	27.1	20.8	32.0	22.2	507 ppm >507 ppm
Hatchling survival/eggs set (%)	53.4	47.8	65.5	53.6	507 ppm >507 ppm
Hatchling survival/no. of hatchlings (%)	96.8	94.3	95.5	90.3	507 ppm >507 ppm
Hatchling weight (g)	7.8	7.5	8.2	7.7	507 ppm >507 ppm
Survivor weight (g)	27.3	27.2	30.8	28.2	507 ppm >507 ppm

Parameter	Control	59.5 ppm	173.0 ppm	506.7 ppm	NOAEC/ LOAEC
Mean food consumption (g/bird/day)	36.8	36.6	37.7	36.4	507 ppm >507 ppm
Male weight gain (g)	15.9	8.8	23.8	12.0	507 ppm >507 ppm
Female weight gain (g)	33.5	28.1	38.8	32.3	507 ppm >507 ppm

E. STUDY DEFICIENCIES:

There were no significant deviations from U.S. EPA guideline §71-4a that affected the validity or acceptability of this study.

F. REVIEWER'S COMMENTS:

Results of the reviewer's statistical analysis differed slightly from those of the study author. The study author's analysis detected a significant reduction in chick survival (14-day survivors/self-hatched chicks) at the highest treatment level; the reviewer's analysis of 14-day survivors/number hatched did not reveal any differences. Discrepancies between the reviewer's and the study author's conclusions were likely due to the slight differences in endpoint data (self-hatched chicks vs. number hatched) and/or the statistical methods used to determine these differences. Specifically, the study author used all parametric analyses while the reviewer used non-parametric methods when the data did not satisfy assumptions required for parametric analysis. The reviewer's statistical results are reported in the Conclusions and Executive Summary sections and are based on the mean-measured concentrations.

For Cage 50 of the 60 ppm group, it was unclear why the dates of death differed (by 4 days) for the male and female birds, as it was reported that pen-mates were sacrificed upon discovery of a decedent animal (p. 48 of individual gross necropsy findings, Appendix III, pp. 47-50). In Table 4 (pp. 34-35), it was reported that two females and one male from the 60 ppm group died prematurely, and based upon individual necropsy findings of all mortality at the 60 ppm level, it appeared that the male was the decedent bird of the pair in Cage 50. However, the dates of the female findings were 4 days prior to the male.

G. CONCLUSIONS:

This study is scientifically sound, fulfills U.S. EPA guideline §71-4a, and is classified as CORE.

NOAEC: 506.7 ppm a.i.
LOAEC: >506.7 ppm a.i.
Endpoint(s) Affected: No statistically-significant effects.

III. REFERENCES:

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APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

Bobwhite quail repro, Prothioconazole, MRID 46246043
PRINTOUT OF RAW DATA

Obs	TRT	EL	EC	ENC_EL	ES	ES_EL	VE	VE_ES	LE	LE_VE	NH	NH_EL	NH_ES
1	Ctrl	4	0	100.00	4	100.00	2	50.00	1	50.00	0	0.00	0.00
2	Ctrl	49	0	100.00	45	91.84	45	100.00	45	100.00	33	67.35	73.33
3	Ctrl	55	1	98.18	52	94.55	47	90.38	45	95.74	31	56.36	59.62
4	Ctrl	58	0	100.00	54	93.10	51	94.44	49	96.08	29	50.00	53.70
5	Ctrl	42	1	97.62	38	90.48	33	86.84	33	100.00	23	54.76	60.53
6	Ctrl	.	.	.	.	.	.	.	.	.	.	.	.
7	Ctrl	34	0	100.00	31	91.18	29	93.55	29	100.00	24	70.59	77.42
8	Ctrl	47	0	100.00	44	93.62	42	95.45	41	97.62	24	51.06	54.55
9	Ctrl	54	0	100.00	51	94.44	50	98.04	49	98.00	24	44.44	47.06
10	Ctrl	54	0	100.00	51	94.44	51	100.00	49	96.08	31	57.41	60.78
11	Ctrl	44	0	100.00	41	93.18	40	97.56	40	100.00	20	45.45	48.78
12	Ctrl	64	0	100.00	59	92.19	54	91.53	54	100.00	43	67.19	72.88
13	Ctrl	68	0	100.00	63	92.65	59	93.65	58	98.31	38	55.88	60.32
14	Ctrl	60	0	100.00	55	91.67	54	98.18	54	100.00	35	58.33	63.64
15	Ctrl	54	0	100.00	50	92.59	50	100.00	48	96.00	39	72.22	78.00
16	Ctrl	70	0	100.00	65	92.86	65	100.00	64	98.46	56	80.00	86.15
17	Ctrl	64	0	100.00	59	92.19	32	54.24	29	90.63	20	31.25	33.90
18	Ctrl	33	1	96.97	30	90.91	1	3.33	1	100.00	0	0.00	0.00
19	Ctrl	57	0	100.00	52	91.23	52	100.00	52	100.00	42	73.68	80.77
20	Ctrl	62	0	100.00	58	93.55	49	84.48	49	100.00	21	33.87	36.21
21	Dose1	59	0	100.00	54	91.53	53	98.15	52	98.11	35	59.32	64.81
22	Dose1	66	0	100.00	62	93.94	61	98.39	60	98.36	41	62.12	66.13
23	Dose1	.	.	.	.	.	.	.	.	.	.	.	.
24	Dose1	45	0	100.00	41	91.11	39	95.12	39	100.00	26	57.78	63.41
25	Dose1	36	0	100.00	33	91.67	31	93.94	31	100.00	18	50.00	54.55
26	Dose1	62	0	100.00	57	91.94	46	80.70	43	93.48	22	35.48	38.60
27	Dose1	64	0	100.00	59	92.19	51	86.44	49	96.08	24	37.50	40.68
28	Dose1	66	1	98.48	61	92.42	61	100.00	59	96.72	50	75.76	81.97
29	Dose1	14	0	100.00	12	85.71	9	75.00	9	100.00	5	35.71	41.67
30	Dose1	.	.	.	.	.	.	.	.	.	.	.	.
31	Dose1	17	0	100.00	16	94.12	7	43.75	7	100.00	6	35.29	37.50
32	Dose1	67	1	98.51	61	91.04	50	81.97	49	98.00	30	44.78	49.18
33	Dose1	35	0	100.00	32	91.43	0	0.00	0	.	0	0.00	0.00
34	Dose1	.	.	.	.	.	.	.	.	.	.	.	.
35	Dose1	15	0	100.00	14	93.33	8	57.14	8	100.00	6	40.00	42.86
36	Dose1	21	3	85.71	16	76.19	11	68.75	11	100.00	11	52.38	68.75
37	Dose1	26	1	96.15	22	84.62	18	81.82	18	100.00	8	30.77	36.36
38	Dose1	52	1	98.08	48	92.31	44	91.67	44	100.00	33	63.46	68.75
39	Dose1	70	0	100.00	65	92.86	64	98.46	64	100.00	52	74.29	80.00
40	Dose1	26	0	100.00	24	92.31	17	70.83	16	94.12	6	23.08	25.00
41	Dose2	68	1	98.53	62	91.18	61	98.39	60	98.36	42	61.76	67.74
42	Dose2	53	0	100.00	49	92.45	49	100.00	49	100.00	42	79.25	85.71
43	Dose2	62	0	100.00	59	95.16	57	96.61	57	100.00	43	69.35	72.88
44	Dose2	.	.	.	.	.	.	.	.	.	.	.	.
45	Dose2	60	1	98.33	55	91.67	55	100.00	54	98.18	45	75.00	81.82
46	Dose2	63	1	98.41	57	90.48	53	92.98	53	100.00	40	63.49	70.18
47	Dose2	17	0	100.00	15	88.24	14	93.33	14	100.00	13	76.47	86.67
48	Dose2	52	1	98.08	47	90.38	46	97.87	45	97.83	41	78.85	87.23
49	Dose2	.	.	.	.	.	.	.	.	.	.	.	.
50	Dose2	52	0	100.00	48	92.31	48	100.00	47	97.92	34	65.38	70.83
51	Dose2	48	0	100.00	43	89.58	43	100.00	43	100.00	30	62.50	69.77
52	Dose2	49	0	100.00	45	91.84	41	91.11	41	100.00	19	38.78	42.22
53	Dose2	53	0	100.00	49	92.45	48	97.96	48	100.00	39	73.58	79.59
54	Dose2	51	0	100.00	47	92.16	44	93.62	39	88.64	28	54.90	59.57
55	Dose2	67	0	100.00	62	92.54	61	98.39	59	96.72	48	71.64	77.42
56	Dose2	67	0	100.00	63	94.03	63	100.00	63	100.00	52	77.61	82.54
57	Dose2	62	0	100.00	58	93.55	58	100.00	58	100.00	50	80.65	86.21
58	Dose2	37	0	100.00	35	94.59	11	31.43	11	100.00	11	29.73	31.43

59	Dose2	35	0	100.00	33	94.29	32	96.97	31	96.88	27	77.14	81.82
60	Dose2	14	0	100.00	14	100.00	0	0.00	0	.	0	0.00	0.00
61	Dose3	41	0	100.00	38	92.68	37	97.37	36	97.30	23	56.10	60.53
62	Dose3	41	0	100.00	38	92.68	37	97.37	37	100.00	27	65.85	71.05
63	Dose3	45	1	97.78	41	91.11	40	97.56	39	97.50	24	53.33	58.54
64	Dose3	46	0	100.00	44	95.65	44	100.00	42	95.45	31	67.39	70.45
65	Dose3	43	1	97.67	38	88.37	38	100.00	36	94.74	31	72.09	81.58
66	Dose3	65	0	100.00	61	93.85	61	100.00	60	98.36	31	47.69	50.82
67	Dose3	66	0	100.00	62	93.94	54	87.10	53	98.15	38	57.58	61.29
68	Dose3	65	0	100.00	60	92.31	58	96.67	58	100.00	31	47.69	51.67
69	Dose3	67	0	100.00	62	92.54	42	67.74	42	100.00	30	44.78	48.39
70	Dose3	.	.	.	.	.	.	.	.	.	.	.	.
71	Dose3	53	0	100.00	49	92.45	48	97.96	48	100.00	39	73.58	79.59
72	Dose3	15	0	100.00	13	86.67	10	76.92	10	100.00	9	60.00	69.23
73	Dose3	29	0	100.00	26	89.66	26	100.00	26	100.00	19	65.52	73.08
74	Dose3	31	3	90.32	26	83.87	25	96.15	24	96.00	13	41.94	50.00
75	Dose3	.	.	.	.	.	.	.	.	.	.	.	.
76	Dose3	.	.	.	.	.	.	.	.	.	.	.	.
77	Dose3	65	0	100.00	60	92.31	60	100.00	60	100.00	24	36.92	40.00
78	Dose3	37	0	100.00	33	89.19	33	100.00	33	100.00	22	59.46	66.67
79	Dose3	33	0	100.00	32	96.97	32	100.00	32	100.00	13	39.39	40.63
80	Dose3	46	0	100.00	43	93.48	42	97.67	41	97.62	19	41.30	44.19

Bobwhite quail repro, Prothioconazole, MRID 46246043
PRINTOUT OF RAW DATA (continued)

Obs	TRT	NH_LE	HS	HS_ES	HS_NH	THICK	HATWT	SURVWT	FOOD	WTGAINM	WTGAINF
1	Ctrl	0.00	0	0.00	.	.	.	.	38	-7	15
2	Ctrl	73.33	31	68.89	93.94	0.20	7	25	35	12	36
3	Ctrl	68.89	30	57.69	96.77	0.23	7	26	38	16	35
4	Ctrl	59.18	25	46.30	86.21	0.22	7	25	36	6	37
5	Ctrl	69.70	23	60.53	100.00	0.23	7	27	35	32	34
6	Ctrl	.	.	.	.	.	.	.	.	.	.
7	Ctrl	82.76	24	77.42	100.00	0.24	8	31	36	25	-22
8	Ctrl	58.54	23	52.27	95.83	0.25	8	26	37	19	60
9	Ctrl	48.98	24	47.06	100.00	0.24	7	27	34	14	23
10	Ctrl	63.27	30	58.82	96.77	0.21	7	28	37	16	7
11	Ctrl	50.00	19	46.34	95.00	0.22	15	30	38	20	32
12	Ctrl	79.63	42	71.19	97.67	0.22	8	30	39	32	53
13	Ctrl	65.52	36	57.14	94.74	0.21	7	26	32	-1	34
14	Ctrl	64.81	34	61.82	97.14	0.22	7	25	39	12	32
15	Ctrl	81.25	38	76.00	97.44	0.21	8	25	39	10	29
16	Ctrl	87.50	53	81.54	94.64	0.21	7	26	37	13	57
17	Ctrl	68.97	20	33.90	100.00	0.21	8	28	36	13	57
18	Ctrl	0.00	0	0.00	.	0.23	.	.	37	15	26
19	Ctrl	80.77	42	80.77	100.00	0.21	7	30	34	35	49
20	Ctrl	42.86	21	36.21	100.00	0.21	8	29	43	20	42
21	Dose1	67.31	34	62.96	97.14	0.22	8	30	39	18	55
22	Dose1	68.33	41	66.13	100.00	0.21	7	27	37	6	44
23	Dose1	.	.	.	.	.	.	.	.	.	.
24	Dose1	66.67	26	63.41	100.00	0.22	8	30	38	-1	48
25	Dose1	58.06	18	54.55	100.00	0.21	8	33	37	10	14
26	Dose1	51.16	20	35.09	90.91	0.23	7	28	39	28	43
27	Dose1	48.98	23	38.98	95.83	0.24	8	30	38	-30	26
28	Dose1	84.75	47	77.05	94.00	0.21	8	28	39	34	47
29	Dose1	55.56	4	33.33	80.00	0.20	7	24	31	17	-14
30	Dose1	.	.	.	.	.	.	.	.	.	.
31	Dose1	85.71	5	31.25	83.33	0.22	7	32	42	14	52
32	Dose1	61.22	26	42.62	86.67	0.22	7	24	34	12	43
33	Dose1	.	0	0.00	.	0.21	.	.	35	33	1
34	Dose1	.	.	.	.	.	.	.	.	.	.
35	Dose1	75.00	6	42.86	100.00	0.21	8	19	34	13	-45
36	Dose1	100.00	10	62.50	90.91	0.21	7	14	36	-21	0
37	Dose1	44.44	8	36.36	100.00	0.22	8	23	37	-7	-14

38	Dose1	75.00	33	68.75	100.00	0.20	8	30	37	9	91
39	Dose1	81.25	47	72.31	90.38	0.25	8	32	39	28	49
40	Dose1	37.50	6	25.00	100.00	0.23	8	32	31	-13	38
41	Dose2	70.00	38	61.29	90.48	0.22	14	30	42	23	44
42	Dose2	85.71	39	79.59	92.86	0.21	7	29	42	18	41
43	Dose2	75.44	42	71.19	97.67	0.20	7	29	38	9	46
44	Dose2	.	.	.	.	.	.	.	.	.	.
45	Dose2	83.33	44	80.00	97.78	0.21	8	29	40	28	47
46	Dose2	75.47	31	54.39	77.50	0.23	8	30	42	16	61
47	Dose2	92.86	13	86.67	100.00	0.22	8	36	35	3	28
48	Dose2	91.11	41	87.23	100.00	0.21	9	30	34	9	39
49	Dose2	.	.	.	.	.	.	.	.	.	.
50	Dose2	72.34	34	70.83	100.00	0.21	8	31	41	26	46
51	Dose2	69.77	30	69.77	100.00	0.22	8	32	36	29	40
52	Dose2	46.34	18	40.00	94.74	0.20	8	32	33	1	44
53	Dose2	81.25	38	77.55	97.44	0.23	8	29	35	32	45
54	Dose2	71.79	27	57.45	96.43	0.22	8	34	35	63	35
55	Dose2	81.36	47	75.81	97.92	0.22	8	30	38	30	50
56	Dose2	82.54	50	79.37	96.15	0.23	8	31	36	23	40
57	Dose2	86.21	50	86.21	100.00	0.23	8	29	42	34	45
58	Dose2	100.00	11	31.43	100.00	0.20	8	37	34	48	49
59	Dose2	87.10	23	69.70	85.19	0.20	8	25	43	13	-40
60	Dose2	.	0	0.00	.	.	.	.	32	.	.
61	Dose3	63.89	18	47.37	78.26	0.21	8	27	39	13	17
62	Dose3	72.97	24	63.16	88.89	0.22	7	27	36	0	47
63	Dose3	61.54	18	43.90	75.00	0.21	8	27	41	2	-24
64	Dose3	73.81	25	56.82	80.65	0.22	7	27	38	12	20
65	Dose3	86.11	30	78.95	96.77	0.21	9	30	36	-4	45
66	Dose3	51.67	26	42.62	83.87	0.21	8	28	36	11	42
67	Dose3	71.70	32	51.61	84.21	0.25	8	28	36	-11	50
68	Dose3	53.45	30	50.00	96.77	0.20	8	26	37	27	40
69	Dose3	71.43	28	45.16	93.33	0.22	8	34	37	29	63
70	Dose3	.	.	.	.	.	.	.	.	.	.
71	Dose3	81.25	34	69.39	87.18	0.21	9	29	34	19	47
72	Dose3	90.00	9	69.23	100.00	0.20	8	33	39	35	35
73	Dose3	73.08	14	53.85	73.68	0.21	8	23	30	21	33
74	Dose3	54.17	13	50.00	100.00	0.19	7	29	33	-3	6
75	Dose3	.	.	.	.	.	.	.	.	.	.
76	Dose3	.	.	.	.	.	.	.	.	.	.
77	Dose3	40.00	23	38.33	95.83	0.24	7	25	35	32	33
78	Dose3	66.67	22	66.67	100.00	0.24	9	29	40	6	-21
79	Dose3	40.63	13	40.63	100.00	0.21	7	31	37	11	47
80	Dose3	46.34	19	44.19	100.00	0.22	8	26	34	4	69

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE EL (Eggs Laid)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.957	0.016	2.417	0.074	USE PARAMETRIC TESTS

****
BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	51.21	15.44	3.54	30.14	43.77,	58.65
Dose1	17	43.59	20.88	5.06	47.90	32.85,	54.32
Dose2	18	50.56	15.84	3.73	31.33	42.68,	58.43
Dose3	17	46.35	15.32	3.72	33.05	38.48,	54.23

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	54.00	4.00	70.00	.	.
Dose1	45.00	14.00	70.00	85.12	14.88
Dose2	52.50	14.00	68.00	98.72	1.28
Dose3	45.00	15.00	67.00	90.51	9.49

****
PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
3	67	0.80	0.499

Dunnett - testing each trt mean signif. less than control
Williams - test assumes dose-response relationship, testing negative trend
Tukey - two-sided tests, all possible comparisons, not used for NOAEC or LOAEC

Level	Mean	Dunnett p-value	Isotonic mean	Williams p-value	Tukey p-values Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	51.21	.	51.21	.	0.538	0.999	0.827	.	.
Dose1	43.59	0.204	47.17	0.286	.	0.620	0.964	.	.
Dose2	50.56	0.712	47.17	0.302	.	.	0.884	.	.
Dose3	46.35	0.388	46.35	0.261	.	.	.	.	.

SUMMARY	NOAEC	LOAEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE NEG_EC (Eggs Cracked)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.615	<.001	1.965	0.128	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	0.16	0.37	0.09	237.27	0.00,	0.34
Dose1	17	0.41	0.80	0.19	193.12	0.00,	0.82
Dose2	18	0.22	0.43	0.10	192.51	0.01,	0.43
Dose3	17	0.29	0.77	0.19	262.39	0.00,	0.69

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	0.00	0.00	1.00	.	.
Dose1	0.00	0.00	3.00	260.78	-160.78
Dose2	0.00	0.00	1.00	140.74	-40.74
Dose3	0.00	0.00	3.00	186.27	-86.27

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	1.21	0.751

MannWhit(Bon) - testing each trt median signif. greater than control
Jonckheere - test assumes dose-response relationship, testing positive trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	0.00	.	.
Dose1	0.00	1.000	0.151
Dose2	0.00	1.000	0.318
Dose3	0.00	1.000	0.471

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE ENC_EL ((EL-EC)/EL (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.499	<.001	2.368	0.079	USE NON-PARAMETRIC TESTS

****
BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	19	99.62	0.93	0.21	0.93	99.17, 100.00
Dose1	17	98.64	3.50	0.85	3.55	96.84, 100.00
Dose2	18	99.63	0.72	0.17	0.72	99.27, 99.99
Dose3	17	99.16	2.40	0.58	2.42	97.93, 100.00

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	100.00	96.97	100.00	.	.
Dose1	100.00	85.71	100.00	99.02	0.98
Dose2	100.00	98.08	100.00	100.01	-0.01
Dose3	100.00	90.32	100.00	99.54	0.46

****
NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	0.98	0.807

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	100.00	.	.
Dose1	100.00	1.000	0.175
Dose2	100.00	1.000	0.388
Dose3	100.00	1.000	0.494

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE ES (Eggs Set)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.960	0.022	2.526	0.065	USE PARAMETRIC TESTS

****
BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf. Interval
Ctrl	19	47.47	14.36	3.29	30.25	40.55, 54.40
Dose1	17	39.82	19.70	4.78	49.46	29.70, 49.95
Dose2	18	46.72	14.58	3.44	31.21	39.47, 53.97
Dose3	17	42.71	14.66	3.55	34.32	35.17, 50.24

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	51.00	4.00	65.00	.	.
Dose1	41.00	12.00	65.00	83.89	16.11
Dose2	48.50	14.00	63.00	98.42	1.58
Dose3	41.00	13.00	62.00	89.96	10.04

****
PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
3	67	0.90	0.448

Dunnett - testing each trt mean signif. less than control
Williams - test assumes dose-response relationship, testing negative trend
Tukey - two-sided tests, all possible comparisons, not used for NOAEC or LOAEC

Level	Mean	Dunnett p-value	Isotonic mean	Williams p-value	Tukey p-values Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	47.47	.	47.47	.	0.479	0.999	0.806	.	.
Dose1	39.82	0.176	43.37	0.265	.	0.578	0.952	.	.
Dose2	46.72	0.702	43.37	0.279	.	.	0.878	.	.
Dose3	42.71	0.371	42.71	0.247	.	.	.	.	.

SUMMARY	NOAEC	LOAEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE ES_EL (EggsSet/EggsLaid (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.892	<.001	1.743	0.167	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	19	92.98	2.08	0.48	2.24	91.98, 93.99
Dose1	17	90.51	4.47	1.08	4.94	88.21, 92.81
Dose2	18	92.60	2.57	0.61	2.78	91.33, 93.88
Dose3	17	91.63	3.25	0.79	3.54	89.96, 93.30

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	92.65	90.48	100.00	.	.
Dose1	91.94	76.19	94.12	97.34	2.66
Dose2	92.38	88.24	100.00	99.59	0.41
Dose3	92.45	83.87	96.97	98.55	1.45

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	3.41	0.332

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	92.65	.	.
Dose1	91.94	0.144	0.042
Dose2	92.38	0.776	0.268
Dose3	92.45	0.571	0.298

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE VE (Viable Embryo(d14))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.947	0.005	2.710	0.052	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	42.42	17.01	3.90	40.11	34.22,	50.62
Dose1	17	33.53	22.08	5.35	65.84	22.18,	44.88
Dose2	18	43.56	18.22	4.29	41.83	34.50,	52.62
Dose3	17	40.41	13.47	3.27	33.33	33.49,	47.34

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	49.00	1.00	65.00	.	.
Dose1	39.00	0.00	64.00	79.04	20.96
Dose2	48.00	0.00	63.00	102.67	-2.67
Dose3	40.00	10.00	61.00	95.26	4.74

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	2.80	0.424

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	49.00	.	.
Dose1	39.00	0.454	0.144
Dose2	48.00	1.000	0.600
Dose3	40.00	0.558	0.361

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE VE_ES (ViableEmbryo/EggsSet (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.666	<.001	1.629	0.191	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	85.88	24.58	5.64	28.62	74.03,	97.72
Dose1	17	77.77	25.50	6.18	32.79	64.66,	90.88
Dose2	18	88.26	27.08	6.38	30.69	74.79,	100.00
Dose3	17	94.85	9.17	2.22	9.66	90.14,	99.57

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	94.44	3.33	100.00	.	.
Dose1	81.97	0.00	100.00	90.56	9.44
Dose2	97.92	0.00	100.00	102.77	-2.77
Dose3	97.67	67.74	100.00	110.45	-10.45

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	9.72	0.021

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	94.44	.	.
Dose1	81.97	0.166	0.049
Dose2	97.92	1.000	0.790
Dose3	97.67	1.000	0.975

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE LE (Live Embryo(d21))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.951	0.008	2.503	0.067	USE NON-PARAMETRIC TESTS

****
BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	19	41.58	16.93	3.88	40.72	33.42, 49.74
Dose1	17	32.88	21.60	5.24	65.68	21.78, 43.99
Dose2	18	42.89	18.06	4.26	42.11	33.91, 51.87
Dose3	17	39.82	13.40	3.25	33.65	32.93, 46.71

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	48.00	1.00	64.00	.	.
Dose1	39.00	0.00	64.00	79.08	20.92
Dose2	47.50	0.00	63.00	103.15	-3.15
Dose3	39.00	10.00	60.00	95.78	4.22

****
NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	2.72	0.437

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	48.00	.	.
Dose1	39.00	0.452	0.144
Dose2	47.50	1.000	0.616
Dose3	39.00	0.571	0.393

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE LE_VE (LiveEmbryo/ViableEmbryo (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.423	<.001	2.111	0.107	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	19	95.63	11.31	2.60	11.83	90.17, 100.00
Dose1	16	98.43	2.22	0.56	2.26	97.25, 99.61
Dose2	17	98.50	2.81	0.68	2.85	97.06, 99.95
Dose3	17	98.54	1.82	0.44	1.85	97.60, 99.47

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	98.46	50.00	100.00	.	.
Dose1	100.00	93.48	100.00	102.93	-2.93
Dose2	100.00	88.64	100.00	103.01	-3.01
Dose3	100.00	94.74	100.00	103.04	-3.04

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	0.93	0.817

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	98.46	.	.
Dose1	100.00	1.000	0.739
Dose2	100.00	1.000	0.832
Dose3	100.00	1.000	0.718

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE NH (Number Hatched)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.988	0.712	2.337	0.082	USE PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	28.05	13.62	3.12	48.54	21.49,	34.62
Dose1	17	21.94	16.38	3.97	74.65	13.52,	30.36
Dose2	18	33.56	14.68	3.46	43.75	26.25,	40.86
Dose3	17	24.94	8.55	2.07	34.27	20.55,	29.34

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	29.00	0.00	56.00	.	.
Dose1	22.00	0.00	52.00	78.21	21.79
Dose2	39.50	0.00	52.00	119.62	-19.62
Dose3	24.00	9.00	39.00	88.91	11.09

****

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
3	67	2.33	0.083

Dunnett - testing each trt mean signif. less than control
Williams - test assumes dose-response relationship, testing negative trend
Tukey - two-sided tests, all possible comparisons, not used for NOAEC or LOAEC

Level	Mean	Dunnett p-value	Isotonic mean	Williams p-value	Tukey p-values Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	28.05	.	28.05	.	0.540	0.612	0.903	.	.
Dose1	21.94	0.205	27.91	0.570	.	0.066	0.918	.	.
Dose2	33.56	0.982	27.91	0.604	.	.	0.252	.	.
Dose3	24.94	0.466	24.94	0.329	.	.	.	.	.

SUMMARY	NOAEC	LOAEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE NH_EL (NumberHatched/EggsLaid (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.915	<.001	0.836	0.479	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	51.05	22.16	5.08	43.42	40.36,	61.73
Dose1	17	45.75	19.26	4.67	42.10	35.84,	55.65
Dose2	18	63.12	21.04	4.96	33.34	52.65,	73.58
Dose3	17	54.74	11.76	2.85	21.49	48.69,	60.79

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	55.88	0.00	80.00	.	.
Dose1	44.78	0.00	75.76	89.62	10.38
Dose2	70.50	0.00	80.65	123.65	-23.65
Dose3	56.10	36.92	73.58	107.24	-7.24

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	10.79	0.013

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	55.88	.	.
Dose1	44.78	0.534	0.171
Dose2	70.50	1.000	0.980
Dose3	56.10	1.000	0.863

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE NH_ES (NumberHatched/EggsSet (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.913	<.001	0.816	0.490	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	55.14	24.11	5.53	43.72	43.52,	66.76
Dose1	17	50.60	21.07	5.11	41.64	39.77,	61.43
Dose2	18	68.54	22.90	5.40	33.41	57.15,	79.92
Dose3	17	59.86	13.23	3.21	22.10	53.06,	66.67

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	60.32	0.00	86.15	.	.
Dose1	49.18	0.00	81.97	91.77	8.23
Dose2	75.15	0.00	87.23	124.30	-24.30
Dose3	60.53	40.00	81.58	108.57	-8.57

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	10.23	0.017

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	60.32	.	.
Dose1	49.18	0.750	0.243
Dose2	75.15	1.000	0.984
Dose3	60.53	1.000	0.880

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE NH_LE (NumberHatched/LiveEmbryo (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.931	<.001	1.548	0.211	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	60.31	24.44	5.61	40.53	48.53,	72.09
Dose1	16	66.31	16.89	4.22	25.47	57.31,	75.31
Dose2	17	79.57	12.08	2.93	15.18	73.36,	85.77
Dose3	17	64.63	15.08	3.66	23.33	56.88,	72.38

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	65.52	0.00	87.50	.	.
Dose1	66.99	37.50	100.00	109.94	-9.94
Dose2	81.36	46.34	100.00	131.92	-31.92
Dose3	66.67	40.00	90.00	107.16	-7.16

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	12.84	0.005

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	65.52	.	.
Dose1	66.99	1.000	0.604
Dose2	81.36	1.000	0.999
Dose3	66.67	1.000	0.848

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE HS (Hatching Survival(d14))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.990	0.841	2.777	0.048	USE NON-PARAMETRIC TESTS

****
BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf. Interval
Ctrl	19	27.11	13.06	3.00	48.20	20.81, 33.40
Dose1	17	20.82	15.52	3.76	74.54	12.84, 28.80
Dose2	18	32.00	14.26	3.36	44.56	24.91, 39.09
Dose3	17	22.24	7.39	1.79	33.22	18.44, 26.03

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	25.00	0.00	53.00	.	.
Dose1	20.00	0.00	47.00	76.82	23.18
Dose2	36.00	0.00	50.00	118.06	-18.06
Dose3	23.00	9.00	34.00	82.03	17.97

****
NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	8.06	0.045

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	25.00	.	.
Dose1	20.00	0.354	0.111
Dose2	36.00	1.000	0.857
Dose3	23.00	0.188	0.339

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE HS_ES (HatchingSurvival/EggsSet (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.920	<.001	1.494	0.224	USE NON-PARAMETRIC TESTS

****
BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf. Interval
Ctrl	19	53.36	23.44	5.38	43.92	42.06, 64.66
Dose1	17	47.83	20.43	4.95	42.70	37.33, 58.33
Dose2	18	65.47	22.50	5.30	34.37	54.28, 76.66
Dose3	17	53.64	11.87	2.88	22.12	47.54, 59.74

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	57.69	0.00	81.54	.	.
Dose1	42.86	0.00	77.05	89.64	10.36
Dose2	71.01	0.00	87.23	122.69	-22.69
Dose3	50.00	38.33	78.95	100.52	-0.52

****
NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	10.14	0.017

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	57.69	.	.
Dose1	42.86	0.499	0.159
Dose2	71.01	1.000	0.962
Dose3	50.00	0.735	0.656

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE HS_NH (HatchingSurvival/NumberHatched (%))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.925	<.001	7.775	<.001	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf. Interval
Ctrl	17	96.83	3.50	0.85	3.62	95.03, 98.63
Dose1	16	94.32	6.63	1.66	7.03	90.79, 97.86
Dose2	17	95.54	6.15	1.49	6.44	92.37, 98.70
Dose3	17	90.26	9.46	2.29	10.48	85.40, 95.13

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	97.14	86.21	100.00	.	.
Dose1	96.49	80.00	100.00	97.41	2.59
Dose2	97.67	77.50	100.00	98.66	1.34
Dose3	93.33	73.68	100.00	93.21	6.79

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	3.95	0.267

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	97.14	.	.
Dose1	96.49	0.780	0.252
Dose2	97.67	1.000	0.435
Dose3	93.33	0.120	0.057

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE THICK (Eggshell thickness)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.972	0.130	0.082	0.969	USE PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf. Interval
Ctrl	18	0.22	0.01	0.00	6.03	0.21, 0.23
Dose1	17	0.22	0.01	0.00	6.10	0.21, 0.22
Dose2	17	0.21	0.01	0.00	5.19	0.21, 0.22
Dose3	17	0.22	0.01	0.00	6.55	0.21, 0.22

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	0.22	0.20	0.25	.	.
Dose1	0.22	0.20	0.25	97.91	2.09
Dose2	0.22	0.20	0.23	96.42	3.58
Dose3	0.21	0.19	0.25	97.54	2.46

****

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
3	65	1.14	0.339

Dunnett - testing each trt mean signif. less than control
Williams - test assumes dose-response relationship, testing negative trend
Tukey - two-sided tests, all possible comparisons, not used for NOAEC or LOAEC

Level	Mean	Dunnett p-value	Isotonic mean	Williams p-value	Tukey p-values Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	0.22	.	0.22	.	0.719	0.282	0.604	.	.
Dose1	0.22	0.306	0.22	0.177	.	0.881	0.998	.	.
Dose2	0.21	0.093	0.21	0.083	.	.	0.945	.	.
Dose3	0.22	0.238	0.21	0.085	.	.	.	.	.

SUMMARY	NOAEC	LOAEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE HATWT (Hatchling Weight)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.557	<.001	1.130	0.344	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf. Interval
Ctrl	17	7.81	1.93	0.47	24.74	6.81, 8.80
Dose1	16	7.51	0.43	0.11	5.72	7.28, 7.74
Dose2	17	8.25	1.53	0.37	18.59	7.46, 9.04
Dose3	17	7.74	0.61	0.15	7.83	7.43, 8.05

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	7.40	6.50	15.00	.	.
Dose1	7.60	6.50	8.10	96.16	3.84
Dose2	7.90	7.00	14.00	105.73	-5.73
Dose3	7.60	6.60	8.90	99.17	0.83

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	8.29	0.040

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	7.40	.	.
Dose1	7.60	1.000	0.668
Dose2	7.90	1.000	0.996
Dose3	7.60	1.000	0.973

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE SURVWT (Survivor Wt (d14))

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.937	0.002	4.193	0.009	USE NON-PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf. Interval
Ctrl	17	27.29	2.05	0.50	7.53	26.24, 28.35
Dose1	16	27.25	5.26	1.31	19.30	24.45, 30.05
Dose2	17	30.76	2.86	0.69	9.30	29.29, 32.24
Dose3	17	28.18	2.77	0.67	9.82	26.75, 29.60

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	27.00	25.00	31.00	.	.
Dose1	29.00	14.00	33.00	99.84	0.16
Dose2	30.00	25.00	37.00	112.72	-12.72
Dose3	28.00	23.00	34.00	103.23	-3.23

****

NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	11.64	0.009

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	27.00	.	.
Dose1	29.00	1.000	0.777
Dose2	30.00	1.000	0.998
Dose3	28.00	1.000	0.897

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE FOOD (Food Consumption)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.985	0.569	2.655	0.056	USE PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	19	36.84	2.41	0.55	6.54	35.68, 38.00
Dose1	17	36.65	2.91	0.71	7.95	35.15, 38.15
Dose2	18	37.67	3.66	0.86	9.72	35.85, 39.49
Dose3	17	36.35	2.71	0.66	7.47	34.96, 37.75

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	37.00	32.00	43.00	.	.
Dose1	37.00	31.00	42.00	99.47	0.53
Dose2	37.00	32.00	43.00	102.24	-2.24
Dose3	36.00	30.00	41.00	98.67	1.33

****

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
3	67	0.64	0.592

Dunnett - testing each trt mean signif. less than control
Williams - test assumes dose-response relationship, testing negative trend
Tukey - two-sided tests, all possible comparisons, not used for NOAEC or LOAEC

Level	Mean	Dunnett p-value	Isotonic mean	Williams p-value	Tukey p-values Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	36.84	.	37.06	.	0.997	0.832	0.960	.	.
Dose1	36.65	0.680	37.06	0.673	.	0.739	0.991	.	.
Dose2	37.67	0.952	37.06	0.709	.	.	0.558	.	.
Dose3	36.35	0.551	36.35	0.410	.	.	.	.	.

SUMMARY	NOAEC	LOAEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE WTGAINM (Male wt gain)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.990	0.871	1.515	0.219	USE PARAMETRIC TESTS

****

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	15.89	10.55	2.42	66.38	10.81,	20.98
Dose1	17	8.82	18.35	4.45	207.98	-0.61,	18.26
Dose2	17	23.82	15.78	3.83	66.24	15.71,	31.94
Dose3	17	12.00	13.53	3.28	112.77	5.04,	18.96

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	15.00	-7.00	35.00	.	.
Dose1	12.00	-30.00	34.00	55.51	44.49
Dose2	23.00	1.00	63.00	149.88	-49.88
Dose3	11.00	-11.00	35.00	75.50	24.50

****

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
3	66	3.29	0.026

Dunnett - testing each trt mean signif. less than control
Williams - test assumes dose-response relationship, testing negative trend
Tukey - two-sided tests, all possible comparisons, not used for NOAEC or LOAEC

Level	Mean	Dunnett p-value	Isotonic mean	Williams p-value	Tukey p-values Dose1	Dose2	Dose3	Dose4	Dose5
Ctrl	15.89	.	16.17	.	0.480	0.378	0.858	.	.
Dose1	8.82	0.177	16.17	0.607	.	0.021	0.922	.	.
Dose2	23.82	0.995	16.17	0.642	.	.	0.099	.	.
Dose3	12.00	0.418	12.00	0.286	.	.	.	.	.

SUMMARY	NOAEC	LOAEC
Dunnett	Dose3	>highest dose
Williams	Dose3	>highest dose

Bobwhite quail repro, Prothioconazole, MRID 46246043
ANALYSIS RESULTS FOR VARIABLE WTGAINF (Female wt gain)

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS
Shapiro-Wilks test for Normality of Residuals -- alpha-level=0.01
Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=0.05
Use parametric analyses if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Test Stat	Shapiro-Wilks P-value	Levenes Test Stat	Levenes P-value	Conclusion
0.901	<.001	3.082	0.033	USE NON-PARAMETRIC TESTS

****
BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.	Interval
Ctrl	19	33.47	19.49	4.47	58.22	24.08,	42.87
Dose1	17	28.12	33.40	8.10	118.80	10.94,	45.29
Dose2	17	38.82	21.47	5.21	55.29	27.79,	49.86
Dose3	17	32.29	25.81	6.26	79.93	19.02,	45.57

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	34.00	-22.00	60.00	.	.
Dose1	43.00	-45.00	91.00	84.00	16.00
Dose2	44.00	-40.00	61.00	115.98	-15.98
Dose3	40.00	-24.00	69.00	96.48	3.52

****
NON-PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests
Kruskal-Wallis test - equality among treatment groups

Degrees of Freedom	TestStat	P-value
3	1.86	0.601

MannWhit(Bon) - testing each trt median signif. less than control
Jonckheere - test assumes dose-response relationship, testing negative trend

Level	Median	MannWhit(Bon adjust)p-value	Jonckheere p-value
Ctrl	34.00	.	.
Dose1	43.00	1.000	0.456
Dose2	44.00	1.000	0.879
Dose3	40.00	1.000	0.742

SUMMARY	NOAEC	LOAEC
MannWhit (Bonf adjust)	Dose3	>highest dose
Jonckheere	Dose3	>highest dose

EAD Assessment of USEPA DER

Reviewer: Émilie Larivière (#1269); PMRA Date: October 14, 2005

PMRA Submission Number: 2004-0843

Study Type: Avian Reproduction - Bobwhite Quail

Barfknecht. R. 2002. JAU6476-Desthio techn.ai.: Effects of a Subchronic Dietary Exposure to the Northern Bobwhite Quail Including Effects on Reproduction and Behavior. Unpublished study performed by Bayer AG, Leverkusen, Germany. Laboratory Study No. E 2981830-1. Study submitted by Bayer CropScience, Research Triangle Park, NC. Study initiated May 8, 2000 and completed January 7, 2002.

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EPA DP Barcode: D303488
OECD Data Point: IIA 8.1.4
EPA MRID: 46246043
EPA Guideline: §71-4a

Reviewing Agency: US EPA

EAD Executive Summary:

The one-generation reproductive toxicity of the transformation product JAU 6476-desthio (purity 97.6% / 96.8%) to groups (20 pens/treatment level) of 1 male and 1 female of >16-week old Northern Bobwhite quail (*Colinus virginianus*; exact age not known) was assessed over approximately 22 weeks. JAU 6476-desthio was administered to the birds in the diet at nominal concentrations of 0 (negative control), 60, 173, and 500 mg/kg. Mean measured concentrations were 59.5, 173.0, and 506.7 mg JAU6476-desthio/kg diet (control feed was not analyzed for JAU6476-desthio content). The study was based on procedures of the U.S. EPA Pesticide Assessment Guidelines, Series 71-4 (1986); and OECD Guideline 206 (1984), and was conducted in accordance with German and OECD Principles of GLP.

There were no significant treatment-related effects on any adult parameter. In addition, no treatment-related effects were observed on egg production or quality, fertility, embryonic development, hatchability, or clinical effects, food consumption, or body weights of chicks during the 14-day observation period.

The study author's statistical analysis indicated that survival rate of chicks was adversely affected by treatment at the 506.7 mg JAU6476-desthio/kg diet level, with significant reductions in the percentage of 14-day old survivors of self hatched chicks (87.1 versus 96.7% for the control).

The increase of chick mortality at the 506.7 mg JAU6476-desthio/kg diet level was due to an increase in chick deaths due to unknown causes. However, reviewer-conducted statistical analyses indicated that there were no significant, treatment-related effects on any reproductive endpoints. The difference in conclusions between the reviewer and the original study author is likely the result of different statistical tests. The reviewer-determined NOEC was 506. 7 mg JAU6476-desthio/kg diet.

Results Synopsis

Test Organism Size/Age: At least 16 weeks old (hatch in autumn 1999, exact date of hatch was not available) (165-252 g)

NOEC: 506.7 mg JAU6476-desthio/kg diet
LOEC: >506.7 mg JAU6476-desthio/kg diet.
Endpoint(s) Affected: None

Evaluator Comments:

1. The appropriate PMRA information (PMRA Submission Number, PMRA Data Code, PMRA company code, PMRA active ingredient code, PMRA use site category, OECD data point, name of PMRA secondary reviewer) was added to the EPA-DER as well as information on the chemical name (CAS number) available from other sources.

2. The validity criteria according to OECD Guideline 206 and U.S. EPA OPPTS 850.2300 are met. Mortality in the controls was less than 10%; the average number of 14-day old survivors per hen in the controls was greater than 12; the average eggshell thickness for the control group was greater than 0.19 mm.

3.The diet of the parental birds contained 0.01-0.042 mg/kg of malathione and 0.043-0.087 mg/kg of pirimiphos (-methyle), depending on the batch number (Appendix XVI, pp. 95 and 97).

4. The EAD reviewer verified the statistical analyses for the survival of 14 day hatchlings related to the number of eggs hatched and obtained no significant differences between treatments. Data were arcsin square root transformed prior to analysis. Data from dead birds were not included. The assumption of normality was not met and a non-parametric Kruskal-Wallis One Way ANOVA on Ranks was run. The study author used parametric analyses. The EAD reviewer ran a parametric ANOVA (ignoring that the assumption of equal variances was not met) and still did not observe a significant difference. The EAD agrees with the EPA reviewer that the differences are likely due to different statistical tests. The study author notes that "at weekly evaluation

(with the exception of week 2 at 500 mg a.i./kg food) all study groups, including control, showed comparable surviving rates (no statistical differences). This indicates that the observed effect was a rather weak one." The EAD reviewer agrees with the EPA reviewer that the NOEC should be set at 506.7 mg JAU6476-desthio/kg diet. The EAD reviewer reviewed the data and results for the other endpoints and did not feel that redoing other statistical analyses was warranted.

6. The EAD reviewer agrees with the conclusions of the EPA reviewer.

Study Acceptability: This study is scientifically sound, fulfills guideline requirements for the reproductive toxicity of JAU 6476-desthio to Northern Bobwhite quail, and is classified as ACCEPTABLE.

Statistical verification by the EAD reviewer:

14-d hatchling survival related to the number of hatched chicks

Data were arcsin square root transformed
Data from dead birds were excluded

One Way Analysis of Variance Friday, October 14, 2005, 14:47:22

Data source: Data 1 in Notebook

Normality Test: Failed (P = <0.001)

Test execution ended by user request, ANOVA on Ranks begun

Kruskal-Wallis One Way Analysis of Variance on Ranks Friday, October 14, 2005, 14:47:22

Data source: Data 1 in Notebook

Group	N	Missing	Median	25%	75%
control	17	0	80.270	76.995	90.000
60 mg/kg	16	0	79.245	72.195	90.000
173 mg/kg	17	0	81.230	76.180	90.000
500 mg/kg	17	0	75.040	65.715	90.000

H = 3.953 with 3 degrees of freedom. (P = 0.267)

The differences in the median values among the treatment groups are not great enough to exclude the possibility that the difference is due to random sampling variability; there is not a statistically significant difference (P = 0.267)

Parametric analysis (assumption of normality violated)

14 day old survivors of eggs hatched
Data were arcsin square root transformed
Data from dead birds were excluded

One Way Analysis of Variance Friday, October 14, 2005, 14:48:26

Data source: Data 1 in Notebook

Normality Test: Failed (P = <0.001)

Equal Variance Test: Passed (P = 0.020)

Group Name	N	Missing	Mean	Std Dev	SEM
control	17	0	82.012	6.730	1.632
60 mg/kg	16	0	79.942	10.010	2.503
173 mg/kg	17	0	80.897	8.645	2.097

500 mg/kg	17	0	75.310	11.571	2.806

Source of Variation	DF	SS	MS	F	P
Between Groups	3	441.932 1	47.311	1.667	0.183
Residual	63	5565.816	88.346		
Total	66	6007.748			

The differences in the mean values among the treatment groups are not great enough to exclude the possibility that the difference is due to random sampling variability; there is not a statistically significant difference (P = 0.183).

Power of performed test with alpha = 0.050: 0.178

The power of the performed test (0.178) is below the desired power of 0.800.
You should interpret the negative findings cautiously.