

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

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

Test material: JAU 6476 Technical **Purity:** 98.7%
Common name: Prothioconazole
Chemical name: IUPAC: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione
CAS name: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione
CAS No.: 178928-70-6
Synonyms: JAU6476

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CITATION: Frieling, W.J.A.M. 2000. Reproduction Study in Bobwhite Quail with JAU 6476 (By Dietary Admixture). Unpublished study performed by NOTOX B.V., DD's-Hertogenbosch, The Netherlands. Laboratory Project No. 259842. Study sponsored by Bayer AG, Leverkusen, Germany. Study initiated September July 14, 1999 and completed June 29, 2000.



EXECUTIVE SUMMARY:

The one-generation reproductive toxicity of JAU 6476 Technical (prothioconazole) to groups (16 pens/treatment level) of 1 male and 1 female of 24-week-old Northern Bobwhite quail was assessed over approximately 22 weeks. JAU 6476 Technical was administered to the birds in the diet at mean-measured concentrations of <LOD (negative control), 60, 251, and 982 ppm a.i. diet. Nominal concentrations were 0, 60, 245, and 1000 ppm diet. There were no significant treatment-related effects on any adult or offspring parameter. The NOAEC and LOAEC levels were 982 and >982 ppm a.i. diet, respectively.

This toxicity study is scientifically sound. However, since highest concentration tested did not elicit an adverse effect on any parental or reproductive parameter, a LOAEC was not established. The maximum expected field residue level was not provided, however, the highest level tested was at an appropriate level to approximate field exposure for this species based on currently proposed uses. This study fulfills guideline requirements for an avian reproduction study using the Northern Bobwhite quail (§71-4a) and is classified as ACCEPTABLE.

Results Synopsis

Test Organism Size/Age: 24 weeks old at test initiation (177-230 g)

NOAEC: 982 ppm a.i.

LOAEC: >982 ppm a.i.

Endpoint(s) Affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the OECD Guidelines for Testing of Chemicals, No. 206 (1984); the U.S. EPA CFR 40, Part 797.2130 (1991); the U.S. EPA FIFRA Pesticides Assessment Guidelines, §71-4 (1982); the U.S. EPA FIFRA Accelerated Re-registration Phase 3 Techn. Guidance, §71-4 (1989); and the U.S. EPA OPPTS, Series 850.2300 (*draft*, 1996). Deviations from §71-4a are:

1. The highest concentration tested did not elicit an adverse effect; therefore, a LOEL was therefore not established. Furthermore, the maximum labeled field residue was not reported, so it is unknown if the highest level tested was an appropriate level to approximate field exposure for this species.
2. Egg storage temperature ranged from 13.8 to 15.0°C, which is slightly lower than the recommended temperature of 16°C.
3. The temperature of the hatching chamber ranged from 36.5 to 37.6°C, which is slightly lower than the recommended 39°C.
4. The analytical LOD and/or LOQ were not reported.
5. The day the chicks were removed from the hatcher and counted was not clearly specified
6. It was not specified how long the opened eggshells (used for thickness measurements) were dried.
7. The number of eggs laid/hen/day was not assessed.

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

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. This study was conducted in accordance with OECD GLP standards.

A. MATERIALS:

1. Test Material JAU 6476 Technical (prothioconazole)

Description: White powder

Lot No./Batch No.: FL 6233/0031 (mixed batch)

Purity: 98.7%

Stability of Compound

Under Test Conditions: Numerous stability experiments were conducted both prior to and during the definitive test (Appendix VII, pp. 185-205). A summary of results is provided below. Due to instability of the test material in treated feed under ambient test-room conditions, fresh feed was provided on a daily basis.

Relative Recovery from Time 0 (%)

Test Level, ppm	Storage Conditions							
	1 Day Ambient	2 Days Ambient	3 Days Ambient	7 Days Ambient	7 Days Frozen	29 Days Frozen	28 Days Frozen + 1 Day Ambient	58.5 Days Frozen + 12 hours Ambient
60	78	83	71	52	102	111	100	88
1000	88	89	80	72	97	113	105	94

Storage conditions of test chemical:

At room temperature in the dark.

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 (<i>Colinus virginianus</i>)	<i>EPA requires: a wild waterfowl species, preferably the mallard, Anas platyrhynchos, or an upland game species, preferably the northern bobwhite, Colinus virginianus.</i>
Age at Study Initiation:	24 weeks	<i>EPA requires: birds should be approaching their first breeding season.</i>
Body Weight: (mean and range)	Males: Overall range (n=64) 177-230 g Females: Overall range (n=64) 177-230 g	Individual body weights were recorded at Weeks 1, 3, 5, 7, 9, 11, and 23 (test termination). <i>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.</i>
Source:	K&L Quails, Oroville, CA	Birds were phenotypically indistinguishable from wild birds. <i>EPA requires that all birds should be from the same source.</i>

B. STUDY DESIGN:

1. Experimental Conditions

- a. Range-finding Study - Multiple preliminary tests were performed to assess the homogeneity, stability, and accuracy of the test material in treated feed prepared at 60 and 1000 ppm nominal levels (p. 21). Results of these analyses are provided in Appendix VII, pp. 185-205.
- b. Definitive Study

Table 2: Experimental Parameters.

Parameter	Details	Remarks
		Criteria
Acclimation period:	7 weeks	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 <u>ad libitum</u> , and sickness, injuries or mortality be noted.
Conditions (same as test or not):	Same as test	
Feeding:	Quail were offered a standard commercial quail breeder diet, Altromin, Lage, Germany (Type: 0770), <i>ad libitum</i> .	
Health (any mortality observed):	No pre-test mortality was observed.	
Test duration	Approximately 11 weeks	EPA requires <u>Pre-laying exposure duration</u> At least 10 weeks prior to the onset of egg-laying. <u>Exposure duration with egg-laying</u> At least 10 weeks. <u>Withdrawal period</u> If reduced reproduction is evident, a withdrawal period of up to 3 weeks should be added to the test phase.
pre-laying exposure:		
egg-laying exposure:		
withdrawal period, if used:		

Parameter	Details	Remarks
		Criteria
Pen (for parental and offspring) size: construction materials: number:	Parents (one pair) were housed in battery breeding cages measuring 55 x 91 x 30 cm. Offspring (by set and group) were housed in 100 x 60 x 25 cm brooders. Parental and offspring pens were constructed of wire mesh stainless steel. 16 parental pens (replicates) per treatment level	Parental pens had slanting floors and egg catchers. <u>Pens</u> Adequate room and arranged to prevent cross contamination <u>Materials</u> Nontoxic material and nonbinding material, such as galvanized steel. <u>Number</u> 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 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:	16 pens N/A 16 pens/treatment	EPA requires at least 12 pens, but considerably more if birds are kept in pairs. At least 16 is strongly recommended.
Test concentrations (ppm diet) nominal: measured:	0 (negative control), 60, 245, and 1000 ppm <LOD (control), 60, 251, and 982 ppm a.i. (reviewer-calculated)	Mean-measured concentrations were determined from treated feed prepared prior to Weeks 1, 10, and 22 and were corrected for corresponding procedural recoveries (p. 21 and Tables 10, 13, and 15 of Appendix VII, pp. 202, 204, and 205, respectively). EPA requires at least two concentrations other than the control are required; three or more are recommended.

Parameter	Details	Remarks
		Criteria
Maximum labeled field residue anticipated and source of information:	Not specified	<i>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]</i>
Solvent/vehicle, if used type: amount:	None used	<i>EPA requires corn oil or other appropriate vehicle not more than 2% of diet by weight</i>
Was detailed description and nutrient analysis of the basal diet provided? (Yes/No)	Yes. Certificate of nutrient analysis of three batches of diet were provided; diets contained 22.9-24.9% protein, 6.45-6.90% fat, 3.44-4.60% fiber, and 2.56-3.39% calcium (Appendix IV, pp. 172-174).	<p>Offspring received free access to similar diet, without the addition of test substance.</p> <p>Results of contaminant analysis of the diet (batch no. not reported) are provided on pp. 175-177 of Appendix IV. Based on these results, the diets contained approximately 0.4 ppm lead, 0.04 ppm cadmium, 0.2 ppm arsenic, 0.17 ppm selenium, and 63 ppm fluorine.</p> <p><i>EPA requires a commercial breeder feed (or its equivalent) that is appropriate for the test species.</i></p>
Preparation of test diet	The appropriate amount of test material was combined with a portion of basal diet (premix), and subsequently mixed with the bulk of the diet (8, 18, or 20 kg in total). The diets were immediately stored at -20°C for up to 3 weeks until offering. New diets were prepared a few days prior to the start of Weeks 1, 4, 7, 10, 13, 16, 19, and 22.	<p>Due to instability of the test material in treated feed under ambient test-room conditions, fresh feed was provided on a daily basis.</p> <p><i>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.</i></p>

Parameter	Details	Remarks
		Criteria
Indicate whether stability and homogeneity of test material in diet determined (Yes/No)	Yes	
Were concentrations in diet verified by chemical analysis?	Yes	Samples were analyzed from feed prepared prior to Weeks 1, 10, and 22 (Tables 10, 13, and 15 of Appendix VII, pp. 202, 204, and 205, respectively).
Did chemical analysis confirm that diet was stable?	Numerous stability experiments revealed that the test substance was stable for up to 29 days under frozen (-20°C) storage conditions (97-113% of initial concentrations), stable under frozen conditions for 58.5 days followed by test room conditions for 12 hours (88-94%), and relatively stable under test room conditions for up to 2 days (78-89%). Thereafter, recoveries declined (52-72% of initial concentrations after 7 days of test room conditions). Due to instability of the test material in treated feed under ambient test-room conditions, fresh feed was provided on a daily basis.	Numerous stability experiments were performed both prior to and during the definitive study. Results are provided Appendix VII, pp. 185-205.
and homogeneous?	Yes. Homogeneity was assessed in the first batch of feed prepared for all concentrations levels by collecting samples from the 10, 50, and 90% depths (p. 21). Reviewer-calculated coefficients of variation were 1.3-4.0% for all concentration levels (Table 11 of Appendix VII, p. 203).	
Feeding and husbandry	Feeding and husbandry conditions appeared to be adequate, given guideline recommendations.	

Parameter	Details	Remarks
		Criteria
Test conditions (pre-laying) temperature:	19.5-21.5°C	Light intensity during the study ranged from 50-190 lux (p. 19).
relative humidity:	20-90%	
photo-period:	7 hr light/day up through Week 8; 17 hr light/day thereafter.	<i>EPA Requires</i> <i>Temperature:</i> <i>About 21 °C (70 °F)</i> <i>Relative humidity:</i> <i>About 55%</i> <i>Lighting</i> <i>First 8 weeks: 7 h per day.</i> <i>Thereafter: 16-17 h per day.</i> <i>At least 6 foot candles at bird level.</i>
Egg Collection and Incubation		
Egg collection and storage collection interval:	Daily	
storage temperature:	13.8-15.0°C	
storage humidity:	58-82%	<i>EPA requires eggs to be collected daily; egg storage temperature approximately 16°C (61°F); humidity approximately 65%.</i>
Were eggs candled for cracks prior to setting for incubation?	Yes	
		<i>EPA requires eggs to be candled on day 0</i>
Were eggs set weekly?	Yes	
Incubation conditions temperature:	37.3-38.0°C	
humidity:	45-65%	
When candling was done for fertility?	Day 11 for fertility and Day 18 for viability.	
		<i>EPA requires:</i> <i>Quail: approx. day 11</i> <i>Ducks: approx. day 14</i>
When the eggs were transferred to the hatcher?	Day 21	
		<i>EPA requires:</i> <i>Bobwhite: day 21</i> <i>Mallard: day 23</i>

Parameter	Details	Remarks
		Criteria
Hatching conditions temperature:	36.5-37.6°C	<i>EPA requires: temperature of 39°C (102°F) humidity of 70%</i>
humidity:	59-80%	
photoperiod:	14 hours light/day (chicks)	
Day the hatched eggs were removed and counted	Not clearly specified. Chicks hatched on Days 23-25, and were not taken out of the incubator until completely dry.	<i>EPA requires Bobwhite: day 24 Mallard: day 27</i>
Were egg shells washed and dried for at least 48 hrs before measuring?	Opened egg shells were washed and dried for an unspecified period of time.	The procedures outlined to measure eggshell thickness (under Definitions section, p. 16) specify that the shell and membrane are dried for at least 48 hours.
Egg shell thickness no. of eggs used:	All eggs laid on a single day.	<i>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.</i>
intervals:	Once weekly beginning in Week 14.	
mode of measurement:	Four points around the equatorial circumference were measured to the nearest 0.01 mm.	
Reference chemical, if used	None used	

2. Observations:

Table 3: Observations.

Parameter	Details	Remarks/Criteria
Parameters measured		
Parental: (mortality, body weight, mean feed consumption) 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)	- mortality - body weight - food consumption - signs of toxicity - necropsy - eggs laid - eggs cracked/broken - eggshell thickness - egg weight - eggs set - number of fertile eggs - number of live 11-day embryos - number of live 18-day embryos - number of normal hatchlings - number of 14-day survivors - hatchling body weight at 1 and 14 days - abnormalities of hatchlings	----- <i>EPA requires:</i> <ul style="list-style-type: none"> • 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)	Adult: mortality was recorded twice daily, signs of toxicity were recorded once daily; body weights were recorded at Weeks 1, 3, 5, 7, 9, 11, and 23 and food consumption was determined daily. Hatchling mortality and signs of toxicity were recorded weekly.	----- <i>Body weights and food consumption must be measured at least biweekly.</i>
Were raw data included?	Yes, sufficient.	

I. RESULTS AND DISCUSSION:

A. MORTALITY:

No mortality was observed in adult quail during the study (p. 28).

Table 4: Effect of JAU 6476 Technical (prothioconazole) on Mortality of *Colinus virginianus*.

Treatment, ppm a.i. 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	0	0
60 (60)	0	0	0	0	0	0
245 (251)	0	0	0	0	0	0
1000 (982)	0	0	0	0	0	0

B. REPRODUCTIVE AND OTHER ENDPOINTS:

Abnormal Effects/Behavior: No treatment-related signs of toxicity were observed (p. 28). Ventro-lateral recumbency, hunched and abnormal posture, lethargy, abnormal gait, uncoordinated movements, alopecia, ruffled plumage, scabs, swelling, wounds, nodules, and emaciation were noted in all dose groups including the control group to a comparable degree (Table 1, pp. 35-45). Findings such as wounds, scabs, and swelling at legs and/or feet and abnormal posture were considered to be an effect of excessive aggression between cage-mates.

Food Consumption: No treatment-related effects on food consumption were observed (p. 28). Overall feed consumption averaged 18 g/bird/day for all treatment and control groups (Table 4, pp. 50-51).

Body Weight: No treatment-related effects on body weight or body weight gains were observed (p. 28 and Tables 2 and 3, pp. 46-49).

Necropsy: No treatment-related findings were observed at necropsy (p. 29 and Table 5, p. 52).

Reproductive Effects: No treatment-related effects were observed on any reproductive parameter assessed at any treatment level, including egg production, egg quality, fertility, embryonic development, hatchability, or chick survival (Tables 6-8, pp. 53-55). Egg weight was statistically-increased at the 1000 ppm level compared to the control (10.7 versus 10.5 g), and egg shell thickness was statistically-reduced at the 60 and 245 ppm levels compared to the control group (0.21 mm for each compared to 0.22 mm for the control group). However, since a dose-response was not evident, and since the values were slight and within laboratory historical control values, the differences were not considered to be related to treatment.

In addition, there were no treatment-related clinical effects during the 14-day chick maintenance period, and no treatment-related effects on chick body weights (Tables 8-9, pp. 55-56). The most common clinical observations were weak and crippled chicks. Incidental observations included abnormal gait, head down, and

splayed legs; findings were noted in the control and test groups to a comparable degree and were not considered to be related to treatment (p. 29).

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

Parameter	Control	60 ppm	245 ppm	1000 ppm	NOAEC/ LOAEC
Eggs laid	849	810	737	828	N/A
Eggs laid/hen	53.1	50.6	46.1	51.8	1000 ppm >1000 ppm
Eggs laid/hen/day	Not determined.				
Eggs cracked	4	9	7	4	N/A
Eggs cracked/eggs laid (%)	0.5	1.1	0.9	0.5	1000 ppm >1000 ppm
Eggs broken	9	8	2	5	N/A
Eggs broken/eggs laid (%)	1.1	1.0	0.3	0.6	1000 ppm >1000 ppm
Mean egg weight (g ± SD)	10.5 ± 0.8	10.5 ± 0.6	10.5 ± 0.8	10.7 ± 0.9*	1000 ppm >1000 ppm
Shell thickness (mm ± SD)	0.22 ± 0.01	0.21 ± 0.02*	0.21 ± 0.01*	0.22 ± 0.01	1000 ppm >1000 ppm
Eggs set	779	734	682	753	N/A
Fertile eggs/egg set (%)	94.1	98.1	97.4	96.0	1000 ppm >1000 ppm
Viable 11-day old embryos	716	711	656	711	N/A
Viable 11-day old embryos/eggs set (%)	91.9	96.9	96.2	94.4	1000 ppm >1000 ppm
Live 18-day old embryos	712	705	653	707	N/A
Live 18-day old embryos/eggs set (%)	91.4	96.0	95.7	93.9	1000 ppm >1000 ppm
Live 18-day old embryos/fertile eggs (%)	97.1	97.9	98.3	97.8	1000 ppm >1000 ppm
No. of normal hatchlings	685	698	647	687	N/A
No. of normal hatchlings/eggs set (%)	87.9	95.1	94.9	91.2	1000 ppm >1000 ppm

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Parameter	Control	60 ppm	245 ppm	1000 ppm	NOAEC/ LOAEC
No. of normal hatchlings/fertile eggs (%)	93.5	96.9	97.4	95.0	1000 ppm >1000 ppm
No. of normal hatchlings/live 11-day old embryos (%)	95.7	98.2	98.6	96.6	1000 ppm >1000 ppm
No. of normal hatchlings/live 18-day old embryos (%)	96.2	99.0	99.1	97.2	1000 ppm >1000 ppm
Hatchling weight (g)	7.4	7.4	7.4	7.6	1000 ppm >1000 ppm
No. of 14-day old survivors	672	685	635	663	N/A
No. of 14-day old survivors/hen	42.0	42.8	39.7	41.4	1000 ppm >1000 ppm
No. of 14-day old survivors/No. of normal hatchlings (%)	98.1	98.1	98.1	96.5	1000 ppm >1000 ppm
14-day old survivors weight (g)	25.4	25.5	25.5	25.6	1000 ppm >1000 ppm
Mean adult food consumption (g/pen/day)	18	18	18	18	1000 ppm >1000 ppm
Weight of adult males, g at start of treatment: at Week 11: at Week 23 (study termination):	205 210 215	202 208 213	205 211 221	206 215 221	1000 ppm >1000 ppm
Weight of adult females, g at start of treatment: at Week 11: at Week 23 (study termination):	199 213 234	197 209 225	199 211 236	201 213 234	1000 ppm >1000 ppm
Gross pathology (proportion of birds with pathological incidents)	1/32	1/32	0/32	0/32	1000 ppm >1000 ppm

N/A = Not statistically-analyzed.

C. REPORTED STATISTICS:

Parental endpoints statistically analyzed included adult body weight, adult body weight gain, and adult food consumption. These variables were assumed to follow a normal distribution, and were analyzed using the Dunnett t-test.

Reproductive endpoints statistically analyzed included number of eggs laid per pen, percentage of eggs cracked of eggs laid, percentage of eggs broken of eggs laid, rate of viability (fertile/infertile eggs as percentage of eggs

set), live 11- and 18-day old embryos as percentage of eggs set, live 18-day old embryos as percentage of fertile eggs, normal hatchlings as percentage of eggs set, normal hatchlings as percentage of fertile eggs, normal hatchlings as percentage of 11-day old embryos, normal hatchlings as percentage of 18-day old embryos, early and late embryonic death as percentage of fertile eggs, number of 14-day old survivors as percentage of normal hatchlings, number of 14-day old survivors expressed per hen, mean eggshell thickness, mean egg weight on day of incubation, mean body weight of hatchlings and surviving chicks, and mean chicks growth rate.

Continuous variables (i.e., eggshell thickness, egg weights, chick weights, number of eggs laid per pen, normal hatchlings per pen, and 14-day old survivors per pen) were assumed to follow a normal distribution, and were analyzed using one-way ANOVA, followed by Dunnett's test (many-to-one t-test).

Ratio variables were assumed not to be normally distributed, and the data were first arc-sine transformed, then analyzed using one-way ANOVA, followed by Dunnett's t-test.

For reproductive endpoints, sample units were the individual pens within each experimental group, except for egg shell thickness, egg weights, and chick weights, where the sample unit was the individual measurement. Nominal concentrations were used for all comparisons.

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	60 ppm	251 ppm	982 ppm	NOAEC/ LOAEC
Eggs laid/pen	53.1	50.6	46.1	51.8	982 ppm >982 ppm
Eggs cracked/pen	0.25	0.56	0.44	0.25	982 ppm >982 ppm
Eggs not cracked/eggs laid (%)	99.5	98.9	99.0	99.4	982 ppm >982 ppm
Eggs set/pen	48.7	45.9	42.6	47.1	982 ppm >982 ppm
Shell thickness	0.69	0.21	1.92	0.22	982 ppm >982 ppm

Parameter	Control	60 ppm	251 ppm	982 ppm	NOAEC/ LOAEC
Eggs set/eggs laid (%)	91.5	90.8	92.4	90.2	982 ppm >982 ppm
Viable embryo/pen	45.8	45.0	41.5	45.2	982 ppm >982 ppm
Viable embryos/eggs set (%)	91.8	97.3	96.8	96.0	982 ppm >982 ppm
Live embryos/pen	44.5	44.1	40.8	44.2	982 ppm >982 ppm
Live embryo/viable embryo (%)	97.2	97.6	97.3	97.5	982 ppm >982 ppm
No. of hatchlings/pen	42.8	43.6	40.4	42.9	982 ppm >982 ppm
No. of hatchlings/eggs laid (%)	78.7	85.6	86.8	82.6	982 ppm >982 ppm
No. of hatchlings/eggs set (%)	86.0	94.2	93.9	91.4	982 ppm >982 ppm
No. of hatchlings/live embryos (%)	96.2	99.2	98.8	97.6	982 ppm >982 ppm
Hatchling survival/pen	42.0	42.8	39.7	41.4	982 ppm >982 ppm
Hatchling survival/eggs set (%)	84.4	92.5	92.4	88.4	982 ppm >982 ppm
Hatchling survival/no. of hatchlings (%)	98.0	98.2	98.4	96.5	982 ppm >982 ppm
Hatchling weight (g)	8.6	7.4	8.4	7.6	982 ppm >982 ppm
Survivor weight (g)	24.9	25.4	25.0	25.6	982 ppm >982 ppm
Mean food consumption (g/bird/day)	28.6	17.9	30.1	20.3	982 ppm >982 ppm
Male weight gain (g)	11.3	11.0	13.2	14.6	982 ppm >982 ppm
Female weight gain (g)	32.8	28.6	36.9	33.6	982 ppm >982 ppm

E. STUDY DEFICIENCIES:

This study is considered scientifically valid, and the deficiencies listed were generally considered minor by the reviewer. The study was conducted at concentrations that did not elicit an adverse effect, and although the maximum labeled field residue was not provided, under currently proposed uses, the highest level tested was at an appropriate level to approximate field exposure for this species. This study fulfills guideline requirements for the reproductive toxicity of JAU 6476 Technical (prothioconazole) to the Northern Bobwhite quail (§71-4a).

F. REVIEWER'S COMMENTS:

Results of the reviewer's statistical analyses agreed with those of the study author. The discrepancies between the reviewer's conclusions and the study author's conclusions were due to the fact that the reviewer based NOAEC and LOAEC values on mean-measured concentrations, whereas the study author used nominal values. Mean-measured concentrations are reported in the Conclusions and Executive Summary sections.

Procedural recoveries were conducted concurrently with sample analysis (Appendix VII, pp. 185-205). Mean recoveries of JAU 6476 from feed fortified with JAU 6476 (prothioconazole) in acetonitrile at 58.4 to 1018 ppm ranged from 60 to 104% of nominal concentrations (Table 9 of Appendix VII, p. 201). Sample concentrations were corrected for the mean procedural recovery analyzed on the same day and concentration level.

The study author reported that due to excessive aggression, a few pairs from each group were separated by dividing the cage in two parts for a longer period of time (p. 20). These birds were together for at least 30 minutes a day, if possible. In case the wounds were extremely severe, the birds were separated for the whole day until the wounds had healed sufficiently. Since no dose-dependency was observed, this aggression was not considered to be an effect of treatment, and since no effect on the fertility of the affected animals was observed, the separation was considered not to have any effect on the study integrity.

G. CONCLUSIONS:

This study is scientifically sound and fulfills guideline requirements. This study is classified as ACCEPTABLE.

NOAEC: 982 ppm a.i.

LOAEC: >982 ppm a.i.

Endpoint(s) Affected: None

III. REFERENCES:

- Dunnett, C.W. 1955. A Multiple Comparison Procedure for Comparing Several Treatments with a Control. J. Amer. Stat. Assoc. 50:1096-121.
- Miller, R.G. 1981. Simultaneous Statistical Inference. Springer Verlag. New York.

**Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian
Species *Colinus virginianus***

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

SAS. 1988. SAS Institute Inc., SAS/STAT User's Guide. Release 6.03 Edition. Cary, NC: SAS Institute Inc.
1028 pp.

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

Bobwhite quail repro, Prothioconazole, MRID 46246042

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	69	1	98.55	63	91.30	62	98.41	61	98.39	60	86.96	95.24
2	Ctrl	53	0	100.00	50	94.34	49	98.00	47	95.92	44	83.02	88.00
3	Ctrl	63	0	100.00	60	95.24	60	100.00	60	100.00	59	93.65	98.33
4	Ctrl	41	0	100.00	39	95.12	30	76.92	30	100.00	29	70.73	74.36
5	Ctrl	68	0	100.00	63	92.65	63	100.00	61	96.83	58	85.29	92.06
6	Ctrl	67	0	100.00	60	89.55	58	96.67	53	91.38	52	77.61	86.67
7	Ctrl	64	0	100.00	55	85.94	55	100.00	55	100.00	55	85.94	100.00
8	Ctrl	47	2	95.74	42	89.36	42	100.00	42	100.00	39	82.98	92.86
9	Ctrl	61	0	100.00	57	93.44	57	100.00	57	100.00	49	80.33	85.96
10	Ctrl	53	0	100.00	50	94.34	36	72.00	33	91.67	33	62.26	66.00
11	Ctrl	46	0	100.00	43	93.48	43	100.00	43	100.00	43	93.48	100.00
12	Ctrl	37	1	97.30	32	86.49	22	68.75	21	95.45	19	51.35	59.38
13	Ctrl	8	0	100.00	7	87.50	5	71.43	5	100.00	5	62.50	71.43
14	Ctrl	54	0	100.00	50	92.59	48	96.00	48	100.00	47	87.04	94.00
15	Ctrl	55	0	100.00	51	92.73	48	94.12	41	85.42	38	69.09	74.51
16	Ctrl	63	0	100.00	57	90.48	55	96.49	55	100.00	55	87.30	96.49
17	Dose1	39	0	100.00	35	89.74	35	100.00	34	97.14	34	87.18	97.14
18	Dose1	57	2	96.49	50	87.72	50	100.00	50	100.00	47	82.46	94.00
19	Dose1	58	0	100.00	52	89.66	52	100.00	52	100.00	52	89.66	100.00
20	Dose1	57	0	100.00	52	91.23	51	98.08	51	100.00	50	87.72	96.15
21	Dose1	61	0	100.00	56	91.80	55	98.21	54	98.18	54	88.52	96.43
22	Dose1	31	0	100.00	29	93.55	24	82.76	24	100.00	24	77.42	82.76
23	Dose1	68	2	97.06	59	86.76	57	96.61	52	91.23	50	73.53	84.75
24	Dose1	31	2	93.55	28	90.32	28	100.00	26	92.86	26	83.87	92.86
25	Dose1	63	1	98.41	56	88.89	56	100.00	56	100.00	55	87.30	98.21
26	Dose1	64	0	100.00	60	93.75	58	96.67	58	100.00	58	90.63	96.67
27	Dose1	59	1	98.31	54	91.53	54	100.00	52	96.30	52	88.14	96.30
28	Dose1	64	1	98.44	59	92.19	58	98.31	56	96.55	56	87.50	94.92
29	Dose1	42	0	100.00	38	90.48	38	100.00	37	97.37	37	88.10	97.37
30	Dose1	16	0	100.00	15	93.75	13	86.67	12	92.31	12	75.00	80.00
31	Dose1	59	0	100.00	54	91.53	54	100.00	54	100.00	54	91.53	100.00
32	Dose1	41	0	100.00	37	90.24	37	100.00	37	100.00	37	90.24	100.00
33	Dose2	24	0	100.00	22	91.67	22	100.00	22	100.00	22	91.67	100.00
34	Dose2	45	1	97.78	41	91.11	41	100.00	41	100.00	41	91.11	100.00
35	Dose2	53	2	96.23	47	88.68	47	100.00	47	100.00	46	86.79	97.87
36	Dose2	50	0	100.00	47	94.00	46	97.87	46	100.00	46	92.00	97.87
37	Dose2	59	0	100.00	57	96.61	56	98.25	56	100.00	55	93.22	96.49
38	Dose2	58	0	100.00	53	91.38	53	100.00	52	98.11	52	89.66	98.11
39	Dose2	47	0	100.00	42	89.36	42	100.00	41	97.62	41	87.23	97.62
40	Dose2	51	0	100.00	49	96.08	49	100.00	49	100.00	49	96.08	100.00
41	Dose2	48	0	100.00	44	91.67	43	97.73	43	100.00	43	89.58	97.73
42	Dose2	52	0	100.00	49	94.23	46	93.88	43	93.48	41	78.85	83.67
43	Dose2	38	2	94.74	35	92.11	35	100.00	34	97.14	34	89.47	97.14
44	Dose2	27	1	96.30	25	92.59	17	68.00	12	70.59	11	40.74	44.00
45	Dose2	70	0	100.00	65	92.86	64	98.46	64	100.00	64	91.43	98.46
46	Dose2	67	1	98.51	62	92.54	59	95.16	59	100.00	58	86.57	93.55
47	Dose2	33	0	100.00	30	90.91	30	100.00	30	100.00	30	90.91	100.00
48	Dose2	15	0	100.00	14	93.33	14	100.00	14	100.00	14	93.33	100.00
49	Dose3	35	0	100.00	33	94.29	33	100.00	33	100.00	33	94.29	100.00
50	Dose3	56	0	100.00	53	94.64	53	100.00	52	98.11	51	91.07	96.23
51	Dose3	55	0	100.00	51	92.73	51	100.00	50	98.04	46	83.64	90.20
52	Dose3	74	0	100.00	69	93.24	68	98.55	68	100.00	67	90.54	97.10
53	Dose3	41	0	100.00	32	78.05	30	93.75	30	100.00	30	73.17	93.75
54	Dose3	28	1	96.43	22	78.57	21	95.45	20	95.24	20	71.43	90.91
55	Dose3	27	0	100.00	24	88.89	24	100.00	24	100.00	23	85.19	95.83
56	Dose3	63	0	100.00	57	90.48	54	94.74	52	96.30	51	80.95	89.47
57	Dose3	34	1	97.06	29	85.29	24	82.76	22	91.67	22	64.71	75.86
58	Dose3	73	1	98.63	67	91.78	60	89.55	60	100.00	59	80.82	88.06

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

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59	Dose3	66	0	100.00	62	93.94	62	100.00	60	96.77	60	90.91	96.77
60	Dose3	54	0	100.00	49	90.74	47	95.92	46	97.87	46	85.19	93.88
61	Dose3	66	0	100.00	62	93.94	59	95.16	58	98.31	58	87.88	93.55
62	Dose3	69	0	100.00	64	92.75	62	96.88	59	95.16	57	82.61	89.06
63	Dose3	19	0	100.00	18	94.74	18	100.00	17	94.44	17	89.47	94.44
64	Dose3	68	1	98.53	61	89.71	57	93.44	56	98.25	47	69.12	77.05

Bobwhite quail repro, Prothioconazole, MRID 46246042

PRINTOUT OF RAW DATA (continued)

Obs	TRT	NH_LE	HS	HS_ES	HS_NH	THICK	HATWT	SURVWT	FOOD	WTGAINM	WTGAINF
1	Ctrl	98.36	59	93.65	98.33	0.22	7	24	18	10	46
2	Ctrl	93.62	44	88.00	100.00	0.21	8	25	18	-3	31
3	Ctrl	98.33	59	98.33	100.00	0.20	7	25	19	21	40
4	Ctrl	96.67	28	71.79	96.55	0.21	7	25	16	10	50
5	Ctrl	95.08	57	90.48	98.28	0.21	8	27	18	6	76
6	Ctrl	98.11	51	85.00	98.08	0.22	8	28	18	9	50
7	Ctrl	100.00	54	98.18	98.18	0.23	7	23	15	9	28
8	Ctrl	92.86	39	92.86	100.00	0.23	7	23	17	18	26
9	Ctrl	85.96	48	84.21	97.96	0.24	8	26	22	16	54
10	Ctrl	100.00	31	62.00	93.94	0.23	8	24	18	13	19
11	Ctrl	100.00	42	97.67	97.67	0.19	7	25	18	22	49
12	Ctrl	90.48	18	56.25	94.74	0.22	8	27	18	3	-19
13	Ctrl	100.00	5	71.43	100.00	0.21	8	25	20	9	19
14	Ctrl	97.92	47	94.00	100.00	0.22	7	25	18	21	40
15	Ctrl	92.68	38	74.51	100.00	0.24	7	27	17	2	-17
16	Ctrl	100.00	52	91.23	94.55	7.70	26	19	188	15	.
17	Dose1	100.00	34	97.14	100.00	0.22	8	24	19	19	12
18	Dose1	94.00	47	94.00	100.00	0.20	7	24	16	13	13
19	Dose1	100.00	52	100.00	100.00	0.23	8	26	18	26	57
20	Dose1	98.04	50	96.15	100.00	0.22	7	26	17	13	56
21	Dose1	100.00	52	92.86	96.30	0.22	8	27	20	-20	40
22	Dose1	100.00	24	82.76	100.00	0.20	7	25	18	2	-2
23	Dose1	96.15	46	77.97	92.00	0.22	7	26	19	22	21
24	Dose1	100.00	25	89.29	96.15	0.24	8	24	17	13	-14
25	Dose1	98.21	55	98.21	100.00	0.21	7	27	17	17	54
26	Dose1	100.00	56	93.33	96.55	0.21	7	25	17	5	34
27	Dose1	100.00	52	96.30	100.00	0.20	8	27	19	21	54
28	Dose1	100.00	56	94.92	100.00	0.21	7	26	18	2	31
29	Dose1	100.00	36	94.74	97.30	0.22	7	25	15	13	37
30	Dose1	100.00	12	80.00	100.00	0.15	7	26	20	12	5
31	Dose1	100.00	53	98.15	98.15	0.21	8	24	18	16	38
32	Dose1	100.00	35	94.59	94.59	0.19	8	24	18	2	22
33	Dose2	100.00	22	100.00	100.00	0.19	6	25	17	10	30
34	Dose2	100.00	40	97.56	97.56	0.22	7	24	15	4	-11
35	Dose2	97.87	44	93.62	95.65	0.22	8	25	17	3	39
36	Dose2	100.00	46	97.87	100.00	0.23	8	26	17	11	34
37	Dose2	98.21	54	94.74	98.18	0.20	8	25	19	2	54
38	Dose2	100.00	49	92.45	94.23	0.23	8	26	21	16	46
39	Dose2	100.00	41	97.62	100.00	0.21	7	26	18	19	54
40	Dose2	100.00	47	95.92	95.92	0.22	7	24	16	5	24
41	Dose2	100.00	43	97.73	100.00	0.19	7	25	19	19	30
42	Dose2	95.35	41	83.67	100.00	0.21	8	26	18	25	27
43	Dose2	100.00	34	97.14	100.00	0.23	7	26	19	20	46
44	Dose2	91.67	11	44.00	100.00	0.21	8	26	17	23	35
45	Dose2	100.00	62	95.38	96.88	0.23	7	26	22	29	43
46	Dose2	98.31	58	93.55	100.00	0.20	8	28	22	57	71
47	Dose2	100.00	29	96.67	96.67	21.0	8	23	18	-3	31
48	Dose2	100.00	14	100.00	100.00	6.70	23	19	206	-28	.
49	Dose3	100.00	33	100.00	100.00	0.23	8	31	19	11	27
50	Dose3	98.08	50	94.34	98.04	0.24	9	28	21	16	45
51	Dose3	92.00	46	90.20	100.00	0.23	8	28	20	32	51
52	Dose3	98.53	66	95.65	98.51	0.22	8	25	23	-1	64
53	Dose3	100.00	30	93.75	100.00	0.21	7	23	17	9	36

**Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian
Species *Colinus virginianus***

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54	Dose3	100.00	18	81.82	90.00	0.22	7	24	19	11	-56
55	Dose3	95.83	22	91.67	95.65	0.21	8	28	21	14	27
56	Dose3	98.08	50	87.72	98.04	0.21	7	20	20	11	48
57	Dose3	100.00	22	75.86	100.00	0.20	8	27	20	12	15
58	Dose3	98.33	59	88.06	100.00	0.23	8	27	22	6	36
59	Dose3	100.00	60	96.77	100.00	0.22	7	24	20	25	43
60	Dose3	100.00	45	91.84	97.83	0.21	8	27	20	25	17
61	Dose3	100.00	52	83.87	89.66	0.22	8	24	21	13	48
62	Dose3	96.61	57	89.06	100.00	0.22	8	26	21	30	55
63	Dose3	100.00	17	94.44	100.00	0.20	7	25	20	2	37
64	Dose3	83.93	36	59.02	76.60	0.21	7	23	21	18	45

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*
PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
 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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.937	0.003	0.940	0.427	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	53.06	15.44	3.86	29.10	44.83, 61.29
Dose1	16	50.63	15.20	3.80	30.03	42.52, 58.73
Dose2	16	46.06	15.28	3.82	33.17	37.92, 54.20
Dose3	16	51.75	18.32	4.58	35.40	41.99, 61.51

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	54.50	8.00	69.00	.	.
Dose1	57.50	16.00	68.00	95.41	4.59
Dose2	49.00	15.00	70.00	86.81	13.19
Dose3	55.50	19.00	74.00	97.53	2.47

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	2.66	0.448

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	54.50	.	.
Dose1	57.50	1.000	0.319
Dose2	49.00	0.205	0.060
Dose3	55.50	1.000	0.326

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.758	<.001	3.257	0.028	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	0.25	0.58	0.14	230.94	0.00, 0.56
Dose1	16	0.56	0.81	0.20	144.70	0.13, 1.00
Dose2	16	0.44	0.73	0.18	166.27	0.05, 0.83
Dose3	16	0.25	0.45	0.11	178.89	0.01, 0.49

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	0.00	0.00	2.00	.	.
Dose1	0.00	0.00	2.00	225.00	-125.00
Dose2	0.00	0.00	2.00	175.00	-75.00
Dose3	0.00	0.00	1.00	100.00	0.00

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	1.94	0.584

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	0.112
Dose2	0.00	1.000	0.221
Dose3	0.00	1.000	0.473

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.722	<.001	1.732	0.170	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	99.47	1.24	0.31	1.25	98.81, 100.00
Dose1	16	98.89	1.84	0.46	1.86	97.91, 99.87
Dose2	16	98.97	1.75	0.44	1.77	98.04, 99.90
Dose3	16	99.42	1.15	0.29	1.16	98.80, 100.00

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	100.00	95.74	100.00	.	.
Dose1	100.00	93.55	100.00	99.41	0.59
Dose2	100.00	94.74	100.00	99.49	0.51
Dose3	100.00	96.43	100.00	99.94	0.06

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	1.81	0.613

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	0.117
Dose2	100.00	1.000	0.188
Dose3	100.00	1.000	0.434

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.937	0.003	1.377	0.258	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	48.69	14.24	3.56	29.25	41.10, 56.28
Dose1	16	45.88	13.64	3.41	29.73	38.61, 53.14
Dose2	16	42.63	14.35	3.59	33.66	34.98, 50.27
Dose3	16	47.06	17.73	4.43	37.67	37.62, 56.51

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	50.50	7.00	63.00	.	.
Dose1	52.00	15.00	60.00	94.22	5.78
Dose2	45.50	14.00	65.00	87.55	12.45
Dose3	52.00	18.00	69.00	96.66	3.34

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	2.43	0.487

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	50.50	.	.
Dose1	52.00	1.000	0.231
Dose2	45.50	0.212	0.057
Dose3	52.00	1.000	0.318

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.886	<.001	4.050	0.011	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	91.53	3.02	0.75	3.29	89.93, 93.14
Dose1	16	90.82	2.03	0.51	2.23	89.74, 91.90
Dose2	16	92.44	2.12	0.53	2.29	91.32, 93.57
Dose3	16	90.24	5.28	1.32	5.86	87.42, 93.05

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	92.62	85.94	95.24	.	.
Dose1	90.85	86.76	93.75	99.22	0.78
Dose2	92.32	88.68	96.61	101.00	-1.00
Dose3	92.25	78.05	94.74	98.58	1.42

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	3.02	0.389

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	92.62	.	.
Dose1	90.85	0.559	0.178
Dose2	92.32	1.000	0.755
Dose3	92.25	1.000	0.665

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.924	<.001	0.710	0.550	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	45.81	15.96	3.99	34.85	37.31, 54.32
Dose1	16	45.00	14.00	3.50	31.12	37.54, 52.46
Dose2	16	41.50	14.60	3.65	35.17	33.72, 49.28
Dose3	16	45.19	17.15	4.29	37.96	36.05, 54.33

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	48.50	5.00	63.00	.	.
Dose1	51.50	13.00	58.00	98.23	1.77
Dose2	44.50	14.00	64.00	90.59	9.41
Dose3	52.00	18.00	68.00	98.64	1.36

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	1.65	0.647

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	48.50	.	.
Dose1	51.50	1.000	0.360
Dose2	44.50	0.424	0.120
Dose3	52.00	1.000	0.375

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042

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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.744	<.001	5.661	0.002	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	91.80	11.87	2.97	12.93	85.47, 98.13
Dose1	16	97.33	5.12	1.28	5.26	94.60, 100.00
Dose2	16	96.83	7.91	1.98	8.17	92.62, 100.00
Dose3	16	96.01	4.72	1.18	4.92	93.50, 98.53

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	97.33	68.75	100.00	.	.
Dose1	100.00	82.76	100.00	106.03	-6.03
Dose2	100.00	68.00	100.00	105.48	-5.48
Dose3	96.40	82.76	100.00	104.59	-4.59

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	3.93	0.270

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	97.33	.	.
Dose1	100.00	1.000	0.937
Dose2	100.00	1.000	0.927
Dose3	96.40	1.000	0.540

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.928	0.001	0.565	0.640	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	44.50	15.76	3.94	35.43	36.10, 52.90
Dose1	16	44.06	13.92	3.48	31.59	36.64, 51.48
Dose2	16	40.81	15.13	3.78	37.06	32.75, 48.87
Dose3	16	44.19	16.98	4.25	38.43	35.14, 53.24

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	47.50	5.00	61.00	.	.
Dose1	51.50	12.00	58.00	99.02	0.98
Dose2	43.00	12.00	64.00	91.71	8.29
Dose3	51.00	17.00	68.00	99.30	0.70

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	1.16	0.762

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	47.50	.	.
Dose1	51.50	1.000	0.367
Dose2	43.00	0.635	0.160
Dose3	51.00	1.000	0.394

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail reproto, Prothioconazole, MRID 46246042
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
0.614	<.001	0.930	0.432	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	97.19	4.32	1.08	4.45	94.89, 99.49
Dose1	16	97.62	3.06	0.77	3.14	95.99, 99.25
Dose2	16	97.31	7.34	1.84	7.55	93.40, 100.00
Dose3	16	97.51	2.44	0.61	2.50	96.21, 98.81

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	100.00	85.42	100.00	.	.
Dose1	99.09	91.23	100.00	100.44	-0.44
Dose2	100.00	70.59	100.00	100.12	-0.12
Dose3	98.08	91.67	100.00	100.33	-0.33

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	2.79	0.425

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	99.09	1.000	0.484
Dose2	100.00	1.000	0.829
Dose3	98.08	0.708	0.356

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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
0.939	0.003	0.372	0.774	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	42.81	15.38	3.85	35.93	34.62, 51.01
Dose1	16	43.63	13.70	3.42	31.40	36.33, 50.92
Dose2	16	40.44	15.07	3.77	37.27	32.41, 48.47
Dose3	16	42.94	16.37	4.09	38.12	34.22, 51.66

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	45.50	5.00	60.00	.	.
Dose1	50.00	12.00	58.00	101.90	-1.90
Dose2	42.00	11.00	64.00	94.45	5.55
Dose3	46.50	17.00	67.00	100.29	-0.29

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	0.74	0.864

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	45.50	.	.
Dose1	50.00	1.000	0.485
Dose2	42.00	0.882	0.239
Dose3	46.50	1.000	0.407

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042

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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.824	<.001	1.588	0.202	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	78.72	12.18	3.05	15.48	72.23, 85.21
Dose1	16	85.55	5.60	1.40	6.55	82.56, 88.53
Dose2	16	86.79	12.87	3.22	14.83	79.93, 93.65
Dose3	16	82.56	8.76	2.19	10.61	77.89, 87.23

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	83.00	51.35	93.65	.	.
Dose1	87.61	73.53	91.53	108.67	-8.67
Dose2	90.28	40.74	96.08	110.25	-10.25
Dose3	84.41	64.71	94.29	104.88	-4.88

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	10.72	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	83.00	.	.
Dose1	87.61	1.000	0.982
Dose2	90.28	1.000	1.000
Dose3	84.41	1.000	0.918

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042

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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.779	<.001	2.268	0.090	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	85.96	12.86	3.21	14.96	79.10, 92.81
Dose1	16	94.22	6.21	1.55	6.60	90.91, 97.53
Dose2	16	93.91	13.90	3.47	14.80	86.50, 100.00
Dose3	16	91.39	6.70	1.67	7.33	87.82, 94.96

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	90.03	59.38	100.00	.	.
Dose1	96.36	80.00	100.00	109.62	-9.62
Dose2	97.87	44.00	100.00	109.25	-9.25
Dose3	93.65	75.86	100.00	106.32	-6.32

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	12.44	0.006

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	90.03	.	.
Dose1	96.36	1.000	0.973
Dose2	97.87	1.000	0.999
Dose3	93.65	1.000	0.776

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042

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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.787	<.001	3.184	0.030	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	96.25	4.14	1.04	4.30	94.05, 98.46
Dose1	16	99.15	1.76	0.44	1.77	98.21, 100.00
Dose2	16	98.84	2.31	0.58	2.34	97.61, 100.00
Dose3	16	97.59	4.25	1.06	4.35	95.32, 99.85

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	98.01	85.96	100.00	.	.
Dose1	100.00	94.00	100.00	103.01	-3.01
Dose2	100.00	91.67	100.00	102.68	-2.68
Dose3	99.26	83.93	100.00	101.38	-1.38

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	98.01	.	.
Dose1	100.00	1.000	0.994
Dose2	100.00	1.000	0.989
Dose3	99.26	1.000	0.868

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.947	0.008	0.436	0.728	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	42.00	15.23	3.81	36.27	33.88, 50.12
Dose1	16	42.81	13.51	3.38	31.56	35.61, 50.01
Dose2	16	39.69	14.59	3.65	36.76	31.91, 47.46
Dose3	16	41.44	16.17	4.04	39.03	32.82, 50.06

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	45.50	5.00	59.00	.	.
Dose1	48.50	12.00	56.00	101.93	-1.93
Dose2	42.00	11.00	62.00	94.49	5.51
Dose3	45.50	17.00	66.00	98.66	1.34

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	0.72	0.869

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	45.50	.	.
Dose1	48.50	1.000	0.515
Dose2	42.00	0.864	0.242
Dose3	45.50	1.000	0.339

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042

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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.795	<.001	1.507	0.222	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	84.35	13.23	3.31	15.68	77.30, 91.40
Dose1	16	92.53	6.64	1.66	7.18	88.99, 96.06
Dose2	16	92.37	13.46	3.36	14.57	85.20, 99.54
Dose3	16	88.38	9.90	2.47	11.20	83.11, 93.65

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	89.24	56.25	98.33	.	.
Dose1	94.67	77.97	100.00	109.69	-9.69
Dose2	96.29	44.00	100.00	109.51	-9.51
Dose3	90.93	59.02	100.00	104.78	-4.78

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	9.61	0.022

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	89.24	.	.
Dose1	94.67	1.000	0.975
Dose2	96.29	1.000	0.996
Dose3	90.93	1.000	0.720

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042

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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.724	<.001	4.142	0.010	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	98.02	2.09	0.52	2.13	96.90, 99.13
Dose1	16	98.19	2.48	0.62	2.52	96.87, 99.51
Dose2	16	98.44	2.00	0.50	2.03	97.38, 99.51
Dose3	16	96.52	6.30	1.57	6.52	93.16, 99.87

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	98.23	93.94	100.00	.	.
Dose1	100.00	92.00	100.00	100.18	-0.18
Dose2	100.00	94.23	100.00	100.43	-0.43
Dose3	99.25	76.60	100.00	98.47	1.53

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	0.48	0.923

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	98.23	.	.
Dose1	100.00	1.000	0.676
Dose2	100.00	1.000	0.731
Dose3	99.25	1.000	0.591

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.372	<.001	5.800	0.002	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	0.69	1.87	0.47	272.55	0.00, 1.68
Dose1	16	0.21	0.02	0.01	9.63	0.20, 0.22
Dose2	16	1.92	5.34	1.33	278.37	0.00, 4.76
Dose3	16	0.22	0.01	0.00	5.17	0.21, 0.22

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	0.22	0.19	7.70	.	.
Dose1	0.21	0.15	0.24	30.51	69.49
Dose2	0.22	0.19	21.00	279.51	-179.51
Dose3	0.22	0.20	0.24	31.69	68.31

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	2.85	0.415

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	0.22	.	.
Dose1	0.21	0.187	0.055
Dose2	0.22	1.000	0.315
Dose3	0.22	1.000	0.437

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.373	<.001	2.144	0.104	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	8.55	4.67	1.17	54.66	6.06, 11.04
Dose1	16	7.42	0.27	0.07	3.62	7.28, 7.56
Dose2	16	8.38	3.93	0.98	46.93	6.28, 10.47
Dose3	16	7.56	0.56	0.14	7.47	7.26, 7.86

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	7.45	6.70	26.00	.	.
Dose1	7.35	6.90	7.90	86.77	13.23
Dose2	7.55	6.20	23.00	97.95	2.05
Dose3	7.65	6.70	8.50	88.38	11.62

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	0.78	0.855

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	7.45	.	.
Dose1	7.35	1.000	0.590
Dose2	7.55	1.000	0.709
Dose3	7.65	1.000	0.809

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.936	0.003	2.117	0.107	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	24.88	2.13	0.53	8.54	23.74, 26.01
Dose1	16	25.38	1.15	0.29	4.52	24.76, 25.99
Dose2	16	25.00	1.97	0.49	7.87	23.95, 26.05
Dose3	16	25.63	2.66	0.66	10.36	24.21, 27.04

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	25.00	19.00	28.00	.	.
Dose1	25.50	24.00	27.00	102.01	-2.01
Dose2	25.50	19.00	28.00	100.50	-0.50
Dose3	25.50	20.00	31.00	103.02	-3.02

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	0.81	0.847

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	25.50	1.000	0.705
Dose2	25.50	1.000	0.629
Dose3	25.50	1.000	0.779

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.316	<.001	2.776	0.049	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	28.63	42.53	10.63	148.57	5.96, 51.29
Dose1	16	17.88	1.36	0.34	7.61	17.15, 18.60
Dose2	16	30.06	46.96	11.74	156.20	5.04, 55.09
Dose3	16	20.31	1.35	0.34	6.66	19.59, 21.03

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	18.00	15.00	188.00	.	.
Dose1	18.00	15.00	20.00	62.45	37.55
Dose2	18.00	15.00	206.00	105.02	-5.02
Dose3	20.00	17.00	23.00	70.96	29.04

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	15.51	0.001

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	18.00	.	.
Dose1	18.00	1.000	0.355
Dose2	18.00	1.000	0.607
Dose3	20.00	1.000	0.999

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.929	0.001	2.253	0.091	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	16	11.31	7.27	1.82	64.29	7.44, 15.19
Dose1	16	11.00	11.04	2.76	100.36	5.12, 16.88
Dose2	16	13.25	18.04	4.51	136.14	3.64, 22.86
Dose3	16	14.63	9.40	2.35	64.28	9.62, 19.63

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	10.00	-3.00	22.00	.	.
Dose1	13.00	-20.00	26.00	97.24	2.76
Dose2	13.50	-28.00	57.00	117.13	-17.13
Dose3	12.50	-1.00	32.00	129.28	-29.28

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	0.85	0.837

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	10.00	.	.
Dose1	13.00	1.000	0.626
Dose2	13.50	1.000	0.722
Dose3	12.50	1.000	0.819

SUMMARY

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

Data Evaluation Report on the Reproductive Effects of JAU 6476 Technical (Prothioconazole) on Avian Species *Colinus virginianus*

PMRA Submission Number 2004-0843

EPA MRID Number 46246042

Bobwhite quail repro, Prothioconazole, MRID 46246042
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	Shapiro-Wilks	Levenes	Levenes	Conclusion
Test Stat	P-value	Test Stat	P-value	
0.914	<.001	0.479	0.698	USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	Coef of Var	95% Conf.Interval
Ctrl	15	32.80	25.45	6.57	77.58	18.71, 46.89
Dose1	16	28.63	21.76	5.44	76.00	17.03, 40.22
Dose2	15	36.87	18.24	4.71	49.46	26.77, 46.97
Dose3	16	33.63	27.33	6.83	81.29	19.06, 48.19

Level	Median	Min	Max	%of Control(means)	%Reduction(means)
Ctrl	40.00	-19.00	76.00	.	.
Dose1	32.50	-14.00	57.00	87.27	12.73
Dose2	35.00	-11.00	71.00	112.40	-12.40
Dose3	40.00	-56.00	64.00	102.52	-2.52

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	1.04	0.793

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	40.00	.	.
Dose1	32.50	1.000	0.325
Dose2	35.00	1.000	0.646
Dose3	40.00	1.000	0.741

SUMMARY

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

EAD Assessment of USEPA DER

Reviewer: Émilie Larivière (#1269); PMRA

Date: September 16, 2005

PMRA Submission Number: 2004-0843

Study Type: Avian Reproduction - Bobwhite Quail

Frieling, W.J.A.M. 2000. Reproduction Study in Bobwhite Quail with JAU 6476 (By Dietary Admixture). Unpublished study performed by NOTOX B.V., DD's-Hertogenbosch, The Netherlands. Laboratory Project No. 259842. Study sponsored by Bayer AG, Leverkusen, Germany. Study initiated September July 14, 1999 and completed June 29, 2000.

PMRA DATA CODE: 9.6.3.1

EPA DP Barcode: D303488

OECD Data Point: IIA 8.1.4

EPA MRID: 46246042

EPA Guideline: §71-4a

Reviewing Agency: US EPA

EAD Executive Summary:

The one-generation reproductive toxicity of JAU 6476 Technical (prothioconazole; purity: 98.7%) to groups (16 pens/treatment level) of 1 male and 1 female of 24-week-old Northern Bobwhite quail (*Colinus virginianus*) was assessed over approximately 22 weeks. This study was conducted following OECD Guideline 206 (1984), U.S. EPA CFR 40, Part 797.2130 (1991), U.S. EPA §71-4 (1982), the U.S. EPA FIFRA Accelerated Re-registration Phase 3 Techn. Guidance, §71-4 (1989) and the U.S. EPA OPPTS, Series 850.2300 (*draft*, 1996). The study was conducted in compliance with OECD Principles of GLP. Prothioconazole was administered to the birds in the diet at mean measured concentrations of <LOD (negative control), 60, 251, and 982 mg a.i./kg diet. Nominal concentrations were 0, 60, 245, and 1000 mg a.i./kg diet. There were no significant treatment-related effects on any adult or offspring parameter. The NOEC and LOEC levels were 982 and >982 mg a.i./kg diet, respectively.

Results Synopsis

Test Organism Size/Age: 24 weeks old at test initiation (177-230 g)

NOEC: 982 mg a.i./kg diet

LOEC: >982 mg a.i./kg diet

Endpoint(s) Affected: None

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 (IUPAC name and synonym) available from the PMRA Chemistry review.

2. The maximum expected field residue level was not provided, however, the highest level tested was at an appropriate level to approximate field exposure for this species based on currently proposed uses. In addition, OECD Guideline 206 recommends a maximum test concentration of 1000 ppm, which was used in this study.

3. 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.

4. Upon reviewing the data and the study results, as well as those of the EPA reviewer, the EAD reviewer did not feel that redoing statistical analyses was warranted. The EAD reviewer agrees with the conclusions of the study author and of the EPA reviewer.

Study Acceptability: This toxicity study is scientifically sound. The maximum expected field residue level was not provided, however, the highest level tested was at an appropriate level to approximate field exposure for this species based on currently proposed uses. This study fulfills guideline requirements for an avian reproduction study using the Northern Bobwhite quail and is classified as ACCEPTABLE.