

# An Examination of Historical Control Data and Endpoint Sensitivity for Tier I Honey Bee Laboratory Studies

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## Abstract

Tier I laboratory honey bee testing as defined by the Environmental Protection Agency (EPA) Office of Pesticide Program includes test methods that are described by either draft or recently finalized OECD guidance. These tests include the larval acute oral exposure (OECD 237 Guideline), larval chronic oral exposure (OECD 239 Guidance Document), and adult chronic oral exposure (OECD 245 Guideline). Smithers Viscient has begun to compile data for the Tier I testing as a result of the recent influx of data-call-ins issued by the EPA for agrochemical product registration that require information from these exposures. In this poster, historical control data, primarily for the chronic exposures, is presented and compared against acceptability criteria. Control survival data points for the adult chronic exposure resulted in an 89% success rate. Control larval survival and adult emergence data points for the larval chronic exposure resulted in success rates of 88% and 85%, respectively. There was no clear pattern regarding the effects of seasonality on control data acceptability over the last three testing seasons. In general, the adult chronic exposure was conducted with some degree of success if initiated from March to November and the larval chronic exposure was conducted successfully if initiated from April to September. For the larval chronic exposure which includes a multi-endpoint design, the larval survival endpoint seems to drive the risk assessment across all compound classes. Information for all relevant chemicals with available larval acute, larval chronic and/or adult chronic endpoint data was also input into the EPA BEE-Rex screening level model for further assessment. As expected, insecticides had the lowest pass rate across the various exposures and, overall, the larval chronic exposure had the lowest pass rate at 61%. For chemicals in which both larval acute and chronic data were available, the BEE-Rex output was in agreement (i.e. either both pass or both fail) 83% of the time suggesting some predictability across the two larval exposures. The outcome of the BEE-Rex model in terms of pass or fail was in agreement for larval chronic and adult chronic data a total of 71% of the time when there was a co-occurrence of this data. However, the model outcome for these two exposures differed for insecticides at a rate of 63%. This is likely driven by insect growth regulators and compounds with novel modes of action that effect adult insect feeding behavior being broadly included in the insecticide category while clearly being effective on a specific life stage.

## Methods

- Control and solvent control data for testing (preliminary and definitive) were compiled for larval chronic (OECD 239 Guidance Document) and adult chronic (OECD 245 Guidance) exposures conducted over the last three testing seasons.
- Success rate in relation to control acceptability criteria and potential seasonal trends were assessed.
- Endpoint sensitivity for the larval chronic exposure was assessed across compound classes.
- Available data (endpoints, application rate, application method) were input into the EPA BEE-Rex model with a focus on larval acute/chronic testing and adult chronic testing. Pass rates (acute RQ <0.40 and chronic RQ <1.0) for each exposure and compound class were summarized. Where data for multiple exposures were available for a chemical, predictability across test types were also assessed and summarized.



**Figure 1:** Progression of development in the larval chronic exposure from first instar larvae (day 1) through pupation (day 15) and adult emergence (day 19). Photo courtesy of M. Patnaude.

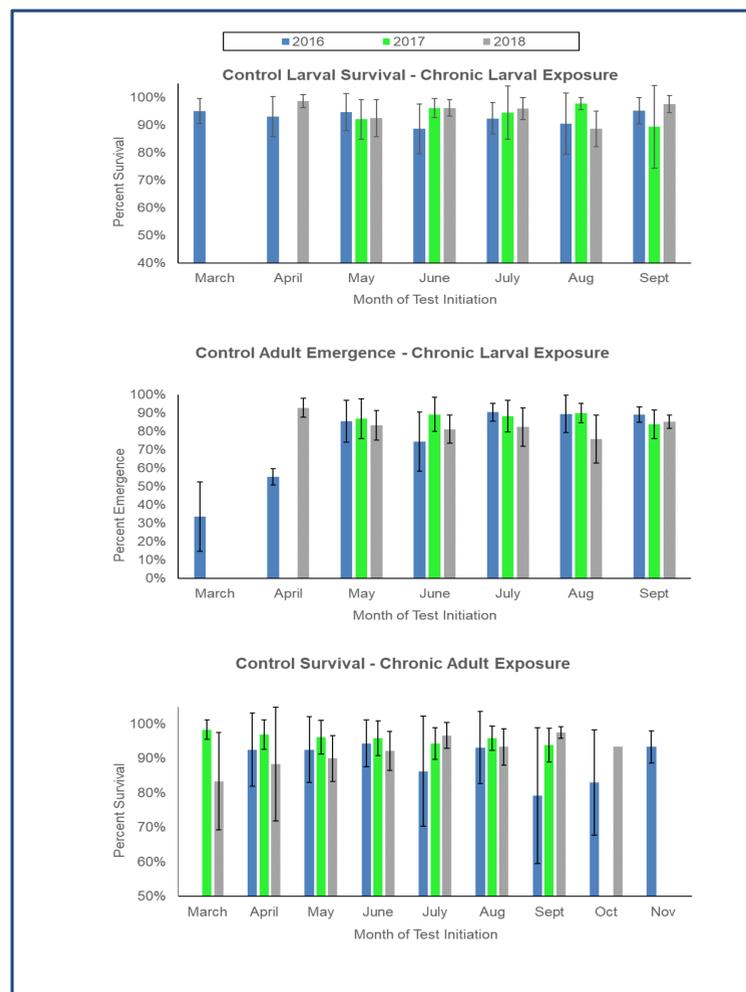


**Figure 2:** Adult chronic exposure replicate test vessel with feeding syringe containing sucrose solution. Photo courtesy of M. Patnaude.

## Data Compilation and Summarization

Test Type - Endpoint	N	Success Rate
Larval Chronic - Survival	259	88%
Larval Chronic - Emergence	243	85%
Adult Chronic - Survival	180	89%

**Figure 3:** Summary of success rate for all control and solvent control data points. Success is defined as meeting or exceeding the guidance acceptability criteria.



**Figure 4:** Monthly mean control values for the last three testing seasons. Acceptability criteria for the larval survival and emergence endpoint is  $\geq 85\%$  and  $\geq 70\%$ , respectively. Acceptability criteria for the adult survival endpoint is  $\geq 85\%$ . Error bars represent standard deviation.

Compound Class	Larval Acute Pass Rate	Larval Chronic Pass Rate	Adult Chronic Pass Rate
Insecticide	10% (N = 11)	30% (N = 10)	30% (N = 10)
Fungicide	85% (N = 13)	64% (N = 14)	83% (N = 12)
Herbicide	93% (N = 15)	76% (N = 17)	75% (N = 16)
Overall	74% (N = 39)	61% (N = 41)	66% (N = 38)

**Figure 6:** Pass rates for each compound class and modern exposure type with respect to the BEE-Rex screening assessment.

Compound Class	BEE-Rex Output Both Pass	BEE-Rex Output Both Fail	BEE-Rex Output Differs
Insecticide (N = 9)	33%	67%	0%
Fungicide (N = 12)	58%	17%	25%
Herbicide (N = 15)	73%	7%	20%
Overall (N = 36)	58%	25%	17%

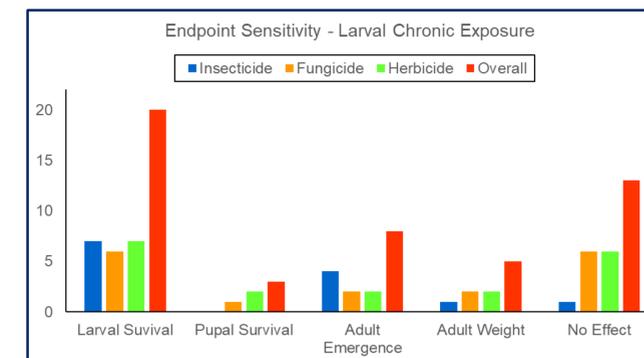
### Larval Acute and Larval Chronic BEE-Rex Output Comparison

**Figure 7:** Percentage of the time that the BEE-Rex output was either in agreement or differed for compounds in which both larval acute and larval chronic data co-occurred.

Compound Class	BEE-Rex Output Both Pass	BEE-Rex Output Both Fail	BEE-Rex Output Differs
Insecticide (N = 8)	0%	38%	63%
Fungicide (N = 11)	64%	9%	27%
Herbicide (N = 16)	69%	19%	13%
Overall (N = 35)	51%	20%	29%

### Larval Chronic and Adult Chronic BEE-Rex Output Comparison

**Figure 8:** Percentage of the time that the BEE-Rex output was either in agreement or differed for compounds in which both larval chronic and adult chronic data co-occurred.



**Figure 5:** Frequency distribution comparing sensitivity of endpoints across compound classes for the larval chronic exposure.

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## General Conclusions

- Chronic exposures can be conducted with a high success rate aided by clear guidance documents and laboratory experience.
- Seasonality has minimal effect on control performance during the core of the bee testing season (April-Sept).
- The larval survival endpoint within the larval chronic exposure has the highest sensitivity. No effect exposures are common for non-insecticidal compounds.
- Insecticides have a low pass rate of screening level risk assessments as expected.
- Based on output of the BEE-Rex model, there is some predictability across exposure types.