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The Benefits of Bayesian Statistics

Examples from the Revised OECD Document 54 Annexes

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OECD Document No. 54 and Its Annexes

- **OECD No. 54 (2006)** is a guide for analysing ecotoxicity study data.
- It stresses **good study design** and **clear, transparent reporting**.
- It compares three main analysis options: **concentration-response models**, **hypothesis testing**, and **mechanistic effect models**.
- The annexes to OECD No. 54 include **real case studies** (OECD TGs 201, 202, 211, 215, 236) for **algae, invertebrates, and fish**.
- OECD No. 54 is **currently being revised** to reflect updated practice since 2006 (Daniels *et al.*, 2025, Wolf *et al.*, 2026).
- **Bayesian methods** will be better represented in the revised OECD No. 54.

Bayesian Concentration-Response Models and Hypothesis Testing

- **Bayesian methods** combine the initial assumptions (the **prior** probability) with the data (the **likelihood**) to give an updated result (the **posterior** probability). **All assumptions are explicit** and the full **uncertainty is quantified**.
- **Models are fully versatile**: they can handle unusual data (non-normal distributions, measurement error, zero inflation, etc.) and combine several assumptions and endpoints.
- **Concentration-response endpoints** (*e.g.*, **EC_{50}**) can be derived directly from the posterior, with uncertainty included.
- Using the region of practical equivalence (**ROPE**; Kruschke *et al.*, 2005), both **difference and equivalence of effects** relative to the control can be tested, supporting statements about **effect presence** *and* **effect absence**.

Concentration-Response Analysis

Model formulation

Situation

In an OECD TG 201 experiment, *R. subcapitata* has been exposed to eight concentrations (x) of atrazine. Growth rates have been reported for individual replicates following the procedure suggested in OECD TG 201; growth rates are reported as estimate (y_n) and (observational) standard error (s_n).

Assumptions

Growth rates likely decrease with increasing atrazine concentrations, following a non-linear concentration-response relationship (log-logistic model, LL.4, *cf.* Ritz *et al.* 2019); x is a continuous variable. Overall, growth rates are assumed to arise from a normal distribution. No hard upper or lower asymptote limits are assumed (growth rates < 0 are biologically possible). The reported standard errors should be used in the modelling approach.

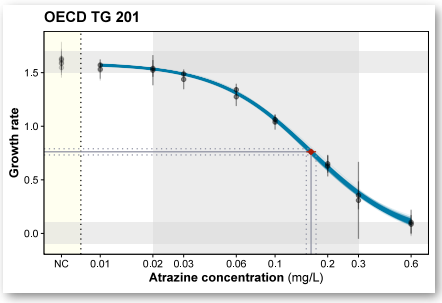
Model

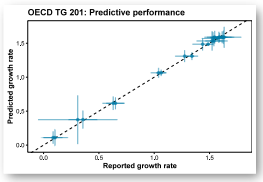
$$y_n \sim \text{Normal}(\mu_n, \sigma) \qquad \mu_n = \begin{cases} d, & x_n = 0 \\ c + \dfrac{d-c}{1+(x_n/e)^b}, & x_n > 0 \end{cases} \qquad \sigma = \sqrt{\sigma_{\text{res}}^2 + s_n^2}$$

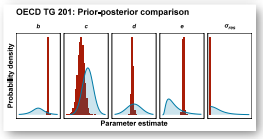
Prior formulation

	b	c	d	e	σ_{res}
Question	What is the expected non-linear slope?	What is the assumed maximum effect on the growth rate?	What is a typical control group growth rate?	What is an expected value for the EC_{50}?	What is the expected residual standard deviation?
Answer	Difficult to answer. The non-linear slope is not easily comparable to a linear slope.	High treatment concentration result in a full reduction of the growth rate.	OECD TG 201 states that typical growth rates for *R. sub-capitata* are between 1.5 and 1.7.	Based on the experimental design, the EC_{50} should be between the second lowest and second highest concentration.	Difficult to answer because of the observation standard error; likely the residual standard deviation is low.
Inter-pretation	A standard Student t distribution allows for a wide range of values due to its tails.	The growth rate should be 0, with the same standard deviation as for the d.	1.5 and 1.7 serve as 95% interval on the normal scale.	0.02 and 0.3 mg/L serve as a 95% interval on the log-normal scale.	A half-Student t distribution places most probability near 0, while also allowing for larger values due to its tail.
Prior	$b \sim \text{StudentT}(3,0,1)$	$c \sim \text{Normal}(0,0.1)$	$d \sim \text{Normal}(1.6,0.1)$	$e \sim \text{LogNormal}(-2.6,0.7)$	$\sigma_{\text{res}} \sim \text{HalfStudentT}(3,0,1)$

Framework	Estimate	Dispersion	Lower	Upper
Bayesian EC_{50}	0.161	0.005	0.151	0.171
*Frequentist EC_{50}**	*0.149*	—	*0.128*	*0.173*







Unbiased EC_{50} estimate (incl. observational error) and credible intervals

Hypothesis Testing

Model formulation

Situation

In an OECD TG 211 experiment, *D. magna* were exposed to six concentrations (x) of an unknown substance. Cumulative offspring (y_n) has been reported per individual, as well as mortality.

Assumptions

Cumulative offspring decreases under treatment conditions b_1–b_6. Cumulative offspring are assumed to be over-dispersed counts, thus following a negative binomial distribution on log-scale. The model will be partially-pooled to minimize type I and type II errors; x is a categorical variable. The region of practical equivalence (ROPE; Kruschke 2010) for cumulative offspring is set to the interval [60,120]. *Not shown: mortality was also modelled simultaneously.*

Model

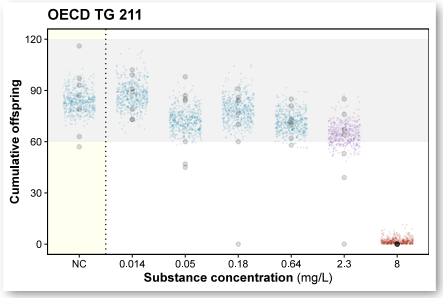
$$y_n \sim \text{NegBinomial}(\eta_{x_n}, \phi) \qquad \eta_{x_n} = a + x_n \cdot b_{c_n} \qquad b_{c_n} = \tau \cdot z_{c_n} \qquad \phi = (1/u)^2$$

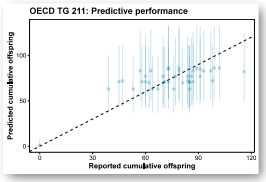
Prior formulation

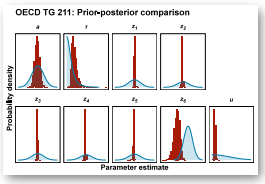
	a	τ	z	u
Question	What is the expected range of cumulative offspring?	What is the assumed average treatment effect on cumulative offspring?	What is a difference to the control cumulative offspring?	What is a realistic value for over-dispersion?
Answer	OECD TG 211 gives a lower limit of 60 for validity. 120 is a commonly observed higher value.	Difficult to estimate without prior knowledge.	Difficult to estimate without prior knowledge.	Over-dispersion itself can be difficult to estimate. Choosing a numerically stable proxy is better.
Inter-pretation	60 and 120 define a 95% interval on log-scale.	The effect size should be positive, and conservatively also allow for larger values.	A standard normal prior will be permissive enough, especially given τ.	Using a half-normal prior on the reciprocal square root is considered safe.
Prior	$a \sim \text{Normal}(4.4,0.2)$	$\tau \sim \text{HalfStudentT}(3,0,1)$	$z \sim \text{Normal}(0,1)$	$u \sim \text{HalfNormal}(0,1)$

Test	Pr(→)	Pr(∈ ROPE)	Pr(∉ ROPE)	Result
$b_1 \Leftrightarrow$ ROPE	0.624	0.996	0.004	Equivalent
$b_2 \Leftrightarrow$ ROPE	0.901	0.963	0.037	Equivalent
$b_3 \Leftrightarrow$ ROPE	0.725	0.990	0.010	Equivalent
$b_4 \Leftrightarrow$ ROPE	**0.921**	**0.956**	**0.044**	**Equivalent**
$b_5 \Leftrightarrow$ ROPE	0.985	0.755	0.245	Inconclusive
$b_6 \Leftrightarrow$ ROPE	**>0.999**	**<0.001**	**>0.999**	**Different**

Framework	"NOEC"	"LOEC"
Bayesian	0.64 mg/L	8.00 mg/L
*Frequentist**	*2.30 mg/L*	*8.00 mg/L*







Partial-pooling for robustness, equivalence and difference testing of the posterior

This poster demonstrates two Bayesian workflows examples for OECD TGs 201 and 211, producing familiar endpoints (EC_{50} and NOEC/LOEC equivalents) while making uncertainty explicit and decision-ready.

Bayesian methods are "good to go": They are fully compatible with routine data from experimental OECD TGs, without additional data requirements.

Clearer uncertainty for decisions: Bayesian outputs support credible intervals and decision-relevant probability statements (*e.g.*, the probability of exceeding a relevant effect level), improving transparency in regulatory interpretation.

Less reliance on "significant": Bayesian decision rules move away from binary *P*-value thresholds that can be sensitive to study power and design choices, instead focusing on interpretations of the posterior probabilities.

More robust EC_x/LC_x reporting: Bayesian model averaging combines predictive distributions across candidate models and can reduce sensitivity to choosing a single curve parametrisation.

ROPE-based hypothesis testing answers both questions on control equivalence (absence of effect) and difference (presence of effect), *de facto* enabling "NOEC/LOEC"-like interpretations with more robustness.

Fits "real world" ecotoxicology data: Bayesian models naturally accommodate endpoint-specific data structures (*e.g.*, quantal outcomes and zero-inflated reproduction counts), enabling consistent reporting across different TGs.

Regulatory advantage: robustness can be demonstrated using predictive diagnostics and prior sensitivity analysis, supporting traceable, reviewable conclusions. Bayesian workflows for "standard" OECD TGs are fully compatible with higher-tier analysis strategies, such weight-of-evidence approaches.

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