

US EPA ARCHIVE DOCUMENT

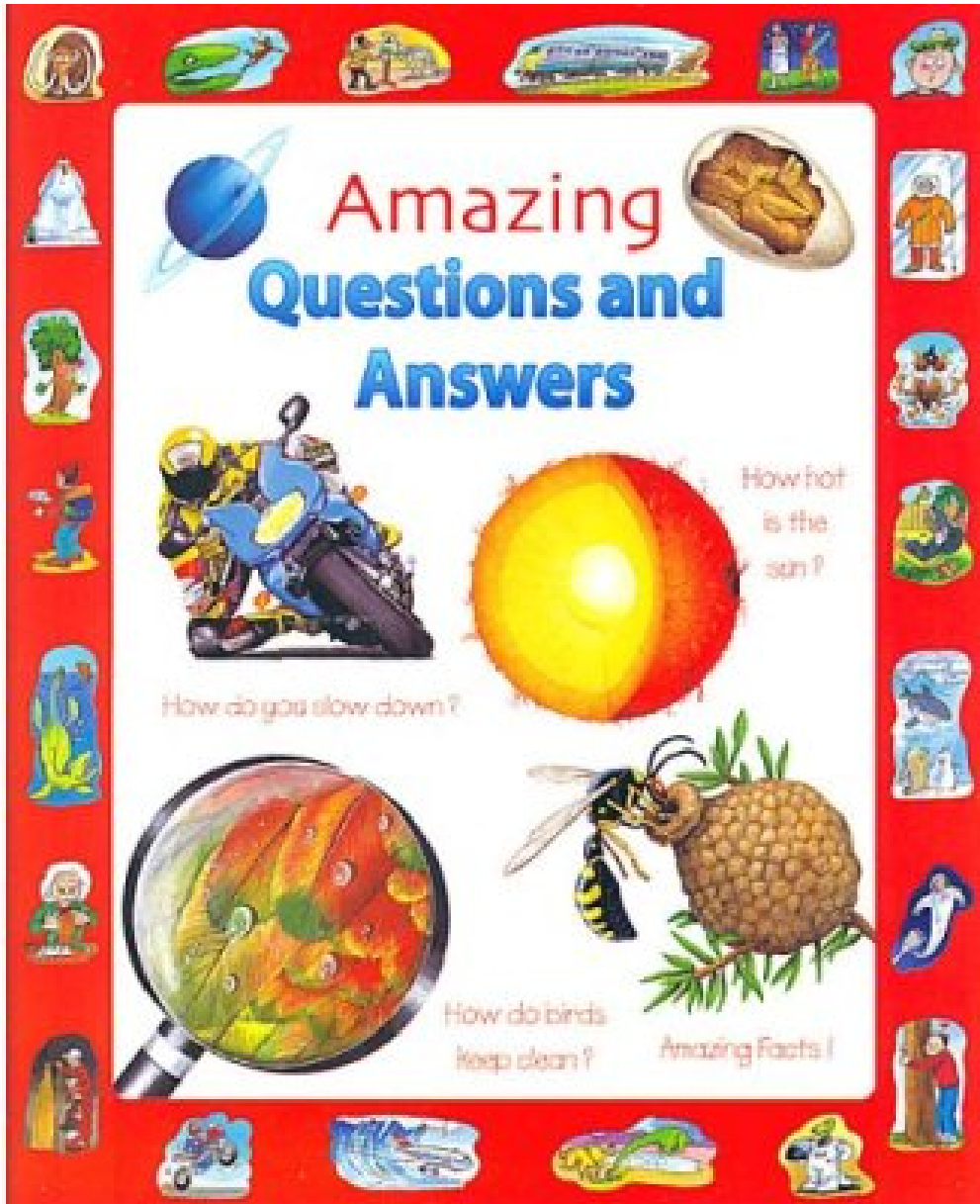
# Validity of intermittent sampling to determine First Confirmed Bite (FCB)

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# Amazing Questions and Answers



How do gas slow down?



How hot is the sun?



How do birds keep clean?



Amazing Facts!

*Q4. What is the rationale for the two different designs?*

# Response (Q4.1)

Bottom line – Are not standard designs

Are there standard designs?

Sort of...

- Relative protection (RP)/intermittent exposure
- RP/continuous exposure
- FCB/continuous exposure
- survivorship analyses

(a) Scope and Applicability.

(1) Purpose. This guideline describes tests that should generally meet requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, et seq.) for demonstrating product performance or effectiveness. This guideline recommends specific protocols for conducting product performance testing of insect and tick repellents intended for direct application to human skin, which may be formulated as lotions, liquids or pressurized sprays. It reflects the Agency's recommendations for minimum steps necessary to develop reliable data on repellent product performance. Deviations from this guideline are permissible, but should be fully explained and justified.

(2) Related Standards

(A) Any research conducted under this guideline is subject to FIFRA §12(a)(2)(P), which makes it unlawful "for any person to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test."



Designation: E 939 - 94 (Reapproved 2006)

Standard Test Method of Field Testing Topical Applications of Compounds as Repellents for Medically Important and Pest Arthropods (Including Insects, Ticks, and Mites): Mosquitoes<sup>1</sup>

This standard is issued under the fixed designation E 939; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method is used to evaluate the repellency of promising compounds that have undergone primary laboratory studies and have been approved for skin application for secondary testing.

1.2 This test method is designed for the study of mosquito repellents, but with some modifications this test method can be used to determine the repellency of candidate compounds for other flying insects that attack humans.

1.3 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

4.2 This test method is primarily designed to simulate a situation in which a person treated with a repellent is exposed to natural populations of attacking mosquitoes.

4.3 The simplicity of the test offers flexibility under a relatively wide range of circumstances and geographical locations. By following this test method, international testing with a variety of vector mosquito populations is no more difficult to accomplish than tests with various domestic species.

4.4 A number of people test topical applications of a repellent for the following reasons:

- 4.4.1 To determine how long the repellent is effective;
- 4.4.2 To establish the effective dosage range;
- 4.4.3 To establish the range of effectiveness on several mosquito genera and species in a number of geographical areas; and



Product Performance Test Guidelines

OPPTS 810.3700 Insect Repellents For Human Skin and Outdoor Premises

CTD/WHOES/IC/96.1 ENGLISH ONLY DISTR.: LIMITED

Report of the WHO Informal Consultation on the evaluation and testing of insecticides

WHO, Geneva 7-11 October 1996

# Response (Q4.2)

## Rationale for approach?

- logistic advantage
- borrowed from the laboratory
- minimize exposure
- maximize protection time estimates

*Why? Decreased exposure = reduced  
biting pressure = decreased likelihood of  
bite (first or confirming)*



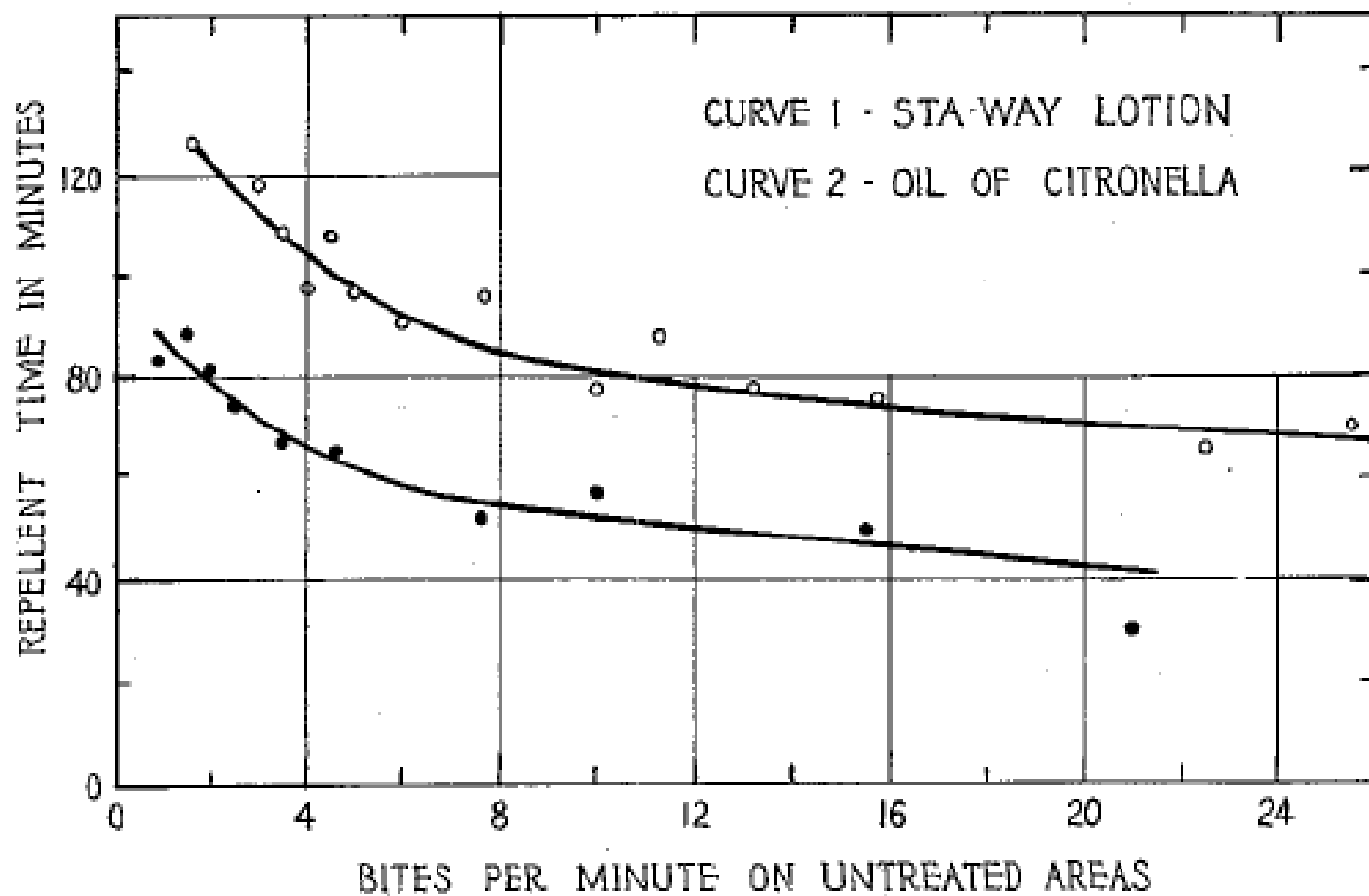
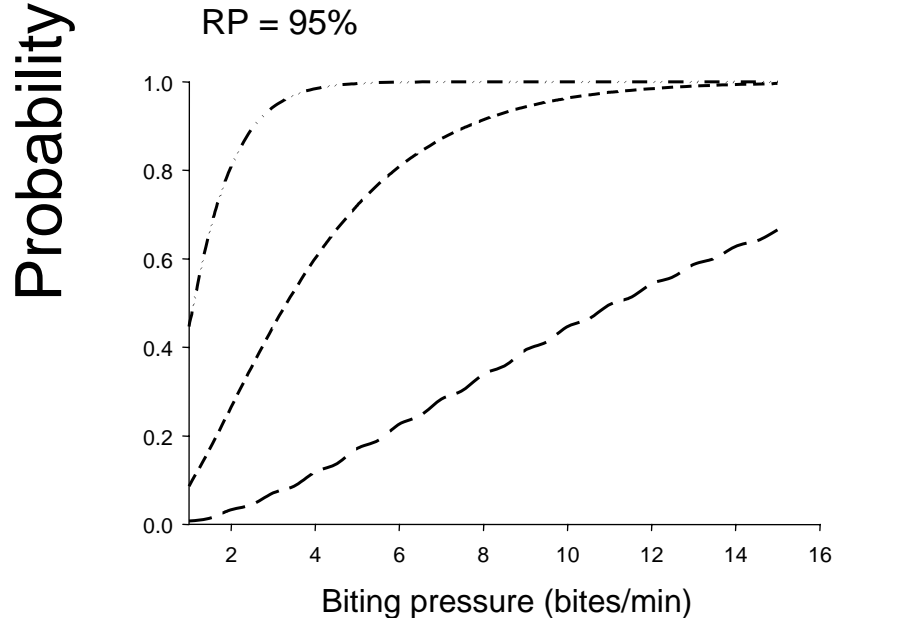
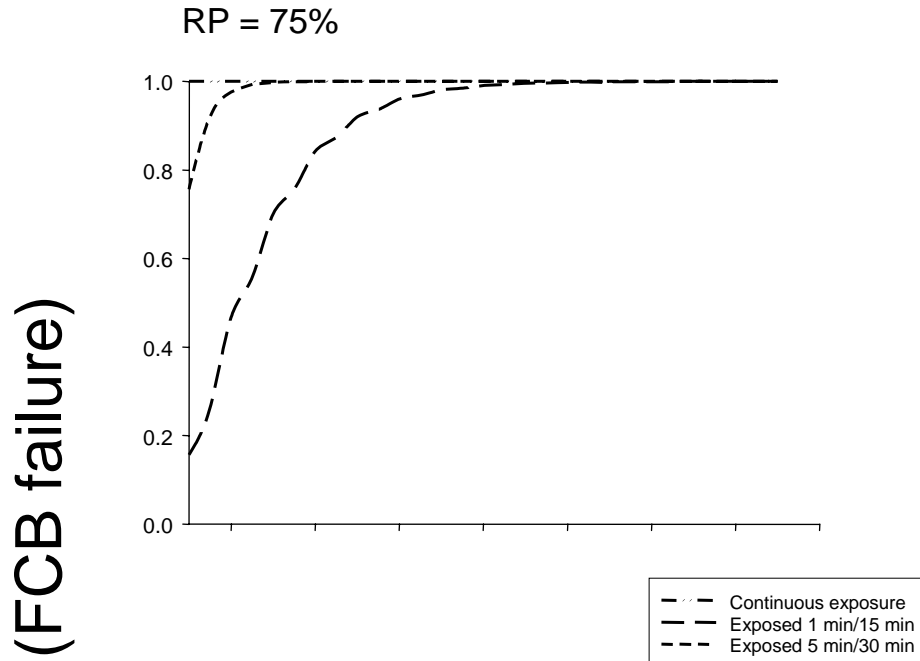


FIG. 1.—Relation between biting frequency and the repellent time afforded by *Sta-Way Lotion* and oil of citronella. Each circle represents an average of 2 to 7 tests.



*Q5. Which design is used more widely in the field? Why?*

## Response (Q5)

These designs are not widely used in peer-reviewed and published field studies

*Q6. Can potential effects of variation...be isolated...be predicted...accounted for...?*

# Response (Q6)

Not really...

Question premised on idea that we have a good handle on the impact of intermittent exposure on estimation of FCB...we don't!