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Agenda Item 14: Scientific Session

Phytosanitary Security Based on a Probit 9 Treatment Standard

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Article VII.1 of the IPPC 1997 states:

Contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:

(a) prescribe and adopt phytosanitary measures concerning the importation of plants, plant products and other regulated articles, including, for example, **inspection, prohibition …, and treatment**.

Top 3 Phytosanitary Measures

- **Inspection**

  – ISPM Nos. 23 & 31

- **Treatment**

  – ISPM Nos. 18 & 28

- **Prohibition**

  – ISPM No. 20 (Sec. 4.2.3)

Treatment is a measure…

And therefore:

- Must be technically justified

  – IPPC Article VII.2(a)

- Subject to equivalence

  – ISPM 24

- Appropriate for the strength of measures

Strength of measures

PRA: The process of evaluating biological or other scientific and economic evidence to determine whether an **organism** is a **pest**, whether it should be regulated, <u>and the strength of any **phytosanitary measures** to be taken against it</u> [Article II and ISPM 5]

"Least restrictive measure" [Article 5 of the SPS Agreement and Article VII.2g of the IPPC]

Purpose of treatments

For the purpose of [ISPM 28], phytosanitary treatments should … be effective in killing, inactivating or removing pests, or rendering pests infertile or for devitalization associated with a regulated article.

Scientific basis

… be well documented to show that the efficacy data has been generated using appropriate scientific procedures, including where relevant an <u>appropriate experimental design</u>. The data supporting the treatment should be verifiable, reproducible, and <u>based on statistical methods</u> and/or on established and accepted international practice; preferably the research should have been published in a peer-reviewed journal. [ISPM 28]

Efficacy of treatment

The level of efficacy of the treatment should be stated (quantified or expressed statistically). Where experimental data is unavailable or insufficient, other evidence that supports the efficacy (i.e. historical and/or practical information/experience) should be provided. [ISPM 28]

Level of efficacy = Strength of measure

Feasibility of treatment

… be feasible and applicable for use primarily in international trade or for other purposes (e.g. to protect endangered areas domestically, or for research). [ISPM 28]

Required response

A specified level of effect for a **treatment.**

1. a precise description of required response

2. the statistical level of response required

[ISPM 18]

probit 9   **mortality**

↑   ↑

statistical metric   required response

What is probit?

- A statistical methodology which fits a dose-response curve to tolerance data

- Based on the assumption that a response is demonstrated above some threshold of tolerance

- Represented by a linear regression when the distribution of the tolerance is lognormal

What is probit 9?

- Proposed by Baker in 1939 as an objective for quarantine treatment of fruit flies

- Assumes that a lognormal transformation relates high mortality to length of exposure in a linear fashion

- Response = 99.9968% or $LD_{99.9968}$

- 0.0032 survival (32 from 1 million)

What does it mean?

Probit 9 mortality means that a minimum of 93,613 insects are tested with no survivors,

or 32 survivors or less predicted in 1 million insects*

Note: 99.99% efficacy requires that 29,956 insects are tested with no survivors*

*95% confidence

Why is it used?

- A conservative level of quarantine security

- A quick and easy way to overcome quarantine restrictions

- Covers most possibilities and uncertainty with worst-case assumptions

- Easily calculated (using a table or computer)

- Well known methodology for pesticides

When is it most useful?

- Host is suitable and easily infested

- High infestation rate

- Distribution of the pest is highly clumped

- Pest is internal or difficult to detect

- Efficacy data "fits" well

- Constant lot size/volume/infestation rate

What's wrong with it?

- <u>Inconsistent</u> (insufficient for high infestation or high volume and overkill for low infestation)

- Risk is from <u>survivors</u>. The initial infestation rate must be estimated to understand the level of survivors.

- Does not account for variables contributing to the probability of establishment

For example…

A consignment of 50,000 units with a prevalence of 1% infestation would require a probit 8 (0.998 mortality) for less than one survivor.

If the probability of survival in transit is 0.4, and 0.2 for transfer to a suitable host, and 0.3 for reproduction, then a treatment of only probit 6 (0.834 mortality) is needed to provide the same level of quarantine security.

Other problems

- Rearing insects or sufficient numbers of insects is often not feasible

- Not appropriate for applications other than insects (e.g. fungi)

- Other models may be more appropriate for dose-response data (e.g. logit, log-log)

- Does not account for probability of establishment

Needed perspective

- NOT a standard

- Requires technical justification

    – Appropriate strength of measures

    – Least restrictive measure

- Must consider the data and risk

- Must aim for consistency in managing risk

Summary

1. Probit analysis can be a useful statistical methodology for evaluating treatment efficacy

2. Probit 9 is usually an excessive efficacy objective

3. Probit 9 must be tied to an estimated infestation rate to be meaningful for risk management

4. Applying probit 9 as a standard will result in inconsistent levels of efficacy

http://cqtstats.cphst.org/index.cfm

CQT Stats Calculations

- Probability of one or more mating pairs

- Required level of probit mortality based on the survival rate of the pest species

- Alternate treatment efficacy

- Maximum pest limit

- Confidence limits and sample size

- Hypergeometric sample size

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