



NAFTA Technical Working Group on Pesticides  
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas  
Groupe de travail technique de l'ALENA sur les pesticides

# Biopesticides Registration Workshop - Microbials

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# Value and Efficacy Data

- ◆ Data requirements specifically developed for these types of products are essentially harmonized between the Environmental Protection Agency (EPA) and the Pest Management Regulatory Agency (PMRA) .
- ◆ Both countries require efficacy data to be generated.
- ◆ California has concurrent review with EPA for microbial products.



# Value and Efficacy Data

- ◆ Applicant must provide objective information regarding:
  - ❖ Pest biology, type and extent of the damage and economics of the pest or disease problem,
  - ❖ Crops/sites which are affected by the pest,
  - ❖ Geographic distribution of the pest problem,
  - ❖ EP performance data to support proposed label claims (e.g., proposed rate, use conditions and control claims).
  - ❖ Contribution of the EP to risk reduction and sustainable pest management in the specific crop.
  - ❖ Summary of currently available pest management tools for proposed use.



# Value and Efficacy Data

- ◆ Laboratory and Growth Chamber Studies
  - ❖ studies designed to quantify dose response behaviour;
  - ❖ relative susceptibility of target pests;
  - ❖ the most susceptible life stages of the proposed target pests or hosts.



# Value and Efficacy Data

## ◆ Field Studies

- ❖ field testing of the proposed end use product under conditions of proposed use,
- ❖ performance criteria and the goals of treatment must be well defined,
- ❖ conducted using the EP formulation proposed for registration,
- ❖ conditions of application and rates proposed on the label should be used,
- ❖ each pest and host combination on the proposed product label should be assessed.



# Value and Efficacy Data

## ◆ Field Studies (cont'd)

- ❖ A minimum of three studies or trials should be conducted in the major geographical regions where the product is intended to be used.
- ❖ Trials should be conducted over at least two years to account for seasonal variation.
- ❖ Regional variability in climate, soil type, pest behaviour, host phenology, cultural practices, management goals, etc., may necessitate supplementary trials to adequately demonstrate performance claims under all conditions of application and in all sites and areas of intended use.



# Value and Efficacy Data

## ◆ Field Studies (cont'd)

- ❖ Trials should include an untreated check or control as an indicator of pest or disease pressure for comparison with treated areas.
- ❖ Positive controls, to allow comparison with reference products of known efficacy or normally accepted control practices should also be included where possible.
- ❖ Performance measurements such as reduction in pest population, effects on the quality and yield of treated crops should be measured.



# Product Performance Review

- ◆ Validate use claims and use recommendations on the proposed EP label.
- ◆ Data regarding EP pest/host range, the lowest effective dose and optimum application timing.
- ◆ Nature and extent of control or management of the pest or disease problem(e.g., reduce damage).
- ◆ Beneficial or adverse effects on the host crop and the crop production system are assessed.



# Product Performance Review

- ◆ Important to assess safety to non-target organisms,
- ◆ Relative effectiveness of proposed EP in comparison to currently available control options (chemical and non-chemical) and compatibility with IPM programs.



# Microbial Value Data Requirements

- ◆ Value (Including Efficacy)
- ◆ Summary
- ◆ Performance assessment
- ◆ Lab or growth chamber studies
- ◆ Field studies
- ◆ Treatment effects
- ◆ Phytotoxicity and phytopathogenicity
- ◆ Compatibility with crop protection and management practices



# Microbial Value Data Requirements

- ◆ Effects on MPCA performance
- ◆ Effects of the EP
- ◆ Crop or Resource Production Benefits
- ◆ Profile of the EP
- ◆ Nature and economics of pest or disease problem.
- ◆ Current crop protection tools and practices
- ◆ Contribution to IPM strategies and practices



# Microbial Value Data Requirements

- ◆ Other studies and data
- ◆ Summaries
- ◆ Foreign reviews
- ◆ Comprehensive summaries



# Efficacy Directives and Guidelines

## PMRA

- ◆ DIR93-07a Guidelines for Efficacy Assessment of Chemical Pesticides
- ◆ DIR93-07b Guidelines for Efficacy Assessment of Herbicides and Plant Growth Regulators
- ◆ Dir96-01 Guidelines for Efficacy Assessment of Fungicides, Bactericides and Nematicides
- ◆ T-1-215 Efficacy Data for Antimicrobial Products
- ◆ Documents 93-07a, 93-07b, 96-01 are being updated as PRO-XX
- ◆ documents available on the PMRA website:

<http://www.hc-sc.gc.ca/pmra-arla/>



# Efficacy Directives and Guidelines

## EPA

- ◆ **Pesticide Assessment Guidelines, Subsection G: Product Performance.**
- ◆ **California generally follows above guidelines for reduced risk products.**



# Value Review of Virosoft CP4 / BioTepp Inc.

- ◆ Virosoft CP4 proposed by BioTepp Inc., an insecticide formulated with a naturally occurring *Cydia pomonella* granulosis virus.
- ◆ Joint review by the PMRA and the US EPA under the NAFTA Technical Working Group on Pesticides Program for *Joint Review of Microbials and Semiochemicals*.



# Value Review of Virosoft CP4 / BioTepp Inc.

- ◆ Virosoft CP4 proposed for control of codling moth (*Cydia pomonella*) in commercial apple orchards.
- ◆ Proposed rate of application: 250 mL of formulated product ( $10^{13}$  virus particles per hectare).
- ◆ First application of Virosoft CP4 when 210 degree-days reached; repeat applications at intervals of two weeks.
- ◆ A total of four applications proposed per season.



# Value Review of Virosoft CP4 / BioTepp Inc.

## Results Laboratory Trials:

- ◆ Laboratory bioassays show that Virosoft CP4 is effective in killing codling moth larvae.
- ◆ Bioassays generated LC50 values ranging from  $1.33 \times 10^5$  to  $3.47 \times 10^5$  Obs/mL.
- ◆ Laboratory tests in which codling moth larvae were exposed to apples treated with prepared suspensions of virus generated LC50 values of  $1.99 \times 10^5$  to  $3.28 \times 10^7$  Obs/mL.



# Value Review of Virosoft CP4 / BioTepp Inc.

- ◆ Results from small-plot field trials:
- ◆ Results were variable but suggest that Virosoft CP4 is effective in reducing codling moth damage to fruit.
- ◆ Most significant effects with Virosoft CP4 were in terms of reduction in deep entry damage to fruit caused by third to fifth instar larvae.
- ◆ Virosoft CP4 did not appear to be as effective in reducing damage caused by first and second instar larvae (“stings”).



# Value Review of Virosoft CP4 / BioTepp Inc.

## Conclusions:

- ◆ Submitted studies do not allow for an assessment of the lowest effective rate of application or the optimum frequency or timing of application.
- ◆ Data are insufficient to draw definitive conclusions regarding the relative performance of Virosoft CP4 and commercial chemical insecticide treatments.



# Value Review of Virosoft CP4 / BioTepp Inc.

## Conclusions:

- ◆ Levels of fruit damage reported for the Virosoft CP4 treatments suggest this product may not be as effective as some commercial chemical insecticide treatments for codling moth.
- ◆ Virosoft CP4 is expected to have minimal impact on beneficial predators and parasites found in apple orchards, may be useful in an integrated pest management program for apple production.



# Value Review of Virosoft CP4 / BioTepp Inc.

## Conclusions:

- ◆ Proposed use instructions supported by the submitted efficacy studies.
- ◆ Apply first after 210 degree-days, up to 4 times in two-week intervals).



# Value Review of Virosoft CP4 / BioTepp Inc.

## Regulatory Decision

- ◆ PMRA issued a temporary registration for baculovirus *Cydia pomonella* granulosis virus and Virosoft CP4.
- ◆ Expected to pose low potential risk to human health and the environment, compared with conventional pesticides.
- ◆ BioTepp Inc. required to provide confirmatory efficacy information (and other data) as a condition of registration.

