



Date Received - Date de réception :
Office Use Only - à usage interne seulement

**Notice of Objection to a Registration  
 Decision under Subsection 35(1) of  
 the Pest Control Products Act**

**Avis d'opposition à une décision  
 d'homologation en vertu du paragraphe 35(1)  
 de la Loi sur les produits antiparasitaires**

**1. Objector information - Information sur l'opposant**

Name - Nom / Corporation - société / Organization - organisation <i>Jennifer Burleigh - BC Ministry of Forests and Range</i>			
Postal Address - Adresse postale <i>PO Box 9513 Str. Prov. Govt.</i>			
City/Town - Ville <i>Victoria</i>	Province/State - Province/État <i>British Columbia</i>	Country - Pays <i>Canada</i>	Postal Code/ZIP - Code postal/Zip <i>V8W 9C2</i>
Phone - Téléphone <i>(250) 356-6810</i>	Fax - Télécopieur <i>(250) 387-2136</i>	E-mail - Adresse électronique <i>Jennifer.Burleigh@gov.bc.ca</i>	

**2. Product information - Information sur le produit**

Name of active ingredient to which the decision relates:  
 Nom de la matière active à laquelle la décision se rapporte : *Bacillus thuringiensis*

Name of end-use product to which the decision relates:  
 Nom de la préparation commerciale à laquelle la décision se rapporte :

**3. Registration decision to which the objection relates -  
 Décision d'homologation pour laquelle vous déposez un avis d'opposition**

Decisions on application - Décision concernant la demande

Granting registration - Homologation accordée  
 Denying registration - Homologation rejetée  
 Granting an amendment of a registration - Modification à l'homologation accordée  
 Denying an amendment of a registration - Modification à l'homologation rejetée

Decisions on re-evaluation or special review - Décision concernant la réévaluation ou l'examen spécial

Confirming registration - Homologation confirmée  
 Cancelling registration - Homologation annulée  
 Amending registration - Modification à une homologation

**4. Date the decision statement was made public:  
 Date de la publication de l'énoncé de décision :**

**5. Area of scientific evaluation to which the objection relates - Volet de l'évaluation scientifique touché par l'avis d'opposition**

Health risk assessment (toxicology, food residue, occupational exposure) -  
 Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)

Environmental risk assessment (environmental fate, environmental toxicology) -  
 Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie)

Value and efficacy assessments (crop tolerance, value) -  
 Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

**6. Scientific basis for the objection Attachment included:  Yes  No  
 Fondement scientifique de l'opposition Pièce jointe incluse :  Oui  Non**

*See Attached for details*  
*- No scientific support for the recommended changes to Personal Protective Equipment*

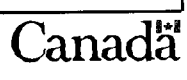
<i>Jennifer Burleigh</i> 7. Signature of objector or representative - Signature de l'opposant ou de son représentant	<i>Jennifer Burleigh</i> Printed Name - Nom en lettres moulées
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Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Information required to process the notice of objection may include some personal information as defined in the *Privacy Act*. In accordance with that Act, such personal information may be made public as authorized by the *Pest Control Products Act* and its regulations. Under the *Privacy Act*, individuals have the right to look at their personal information. For more information on how PMRA manages personal information, contact the PMRA Information Services at 1-800-267-6315 within Canada and 1-613-736-3799 outside of Canada or via e-mail at [pmra\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca).

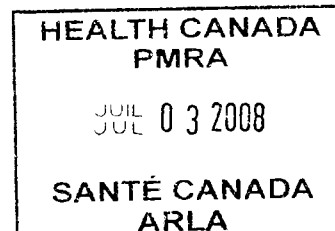
Les opposants qui soumettent des renseignements confidentiels (c.-à-d. des renseignements commerciaux confidentiels, des données d'essai confidentielles) sont responsables de les désigner comme tels dans leur envoi.

L'information requise pour traiter cet avis d'opposition peut comprendre certains renseignements personnels tels que définis dans la *Loi sur la protection des renseignements personnels*. Conformément à cette Loi, ces renseignements peuvent être rendus publics, ce qui est permis par la *Loi sur les produits antiparasitaires* et son Règlement. En vertu de la *Loi sur la protection des renseignements personnels*, tous les individus ont le droit de consulter leurs renseignements personnels. On peut obtenir des précisions sur la gestion des renseignements personnels auprès de l'Agence de réglementation de la lutte antiparasitaire (ARLA) en communiquant avec le Service de renseignements au 1-800-267-6315 au Canada, ou au 1-613-736-3799 de l'extérieur du Canada, ou par courrier électronique à [pmra\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca).



July 2, 2008

Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6606E  
Ottawa, Ontario  
K1A 0K9



Dear Sir/Madam:

**Notice of Objection by the Ministry of Forests and Range, Province of British Columbia, to Health Canada's PMRA Proposed Acceptability for Continuing Registration (PACR2006-09): Re-Evaluation of Bacillus thuringiensis**

We are filing this Notice of Objection in regards to the recommended requirements of Personal Protective Equipment (PPE) by applicators and mixers of *Bacillus thuringiensis* (Bt). Our objection to these new requirements is based on science, specifically on the lack of studies that have shown any potential for sensitization or any study the results of which would warrant the requirement of NIOSH-approved respirators with an N-95 filter in the application and mixing of Bt.

In 1999, The World Health Organization's International Programme on Chemical Safety characterised the exposure and effects specifically of Btk on humans as follows:

*"Human volunteers ingested and inhaled large quantities of a Btk formulation but experienced no adverse health effects. Antibody titres to the vegetative cells, spores and spore-crystal complexes have been demonstrated in workers who spray Bt products; however, no adverse health effects were reported."*

(<http://www.inchem.org/documents/ehc/ehc/ehc217.htm>)

Within the PACR2006-09 document, PMRA makes several statements on the lack of risk posed by Bt products including:

*"Products containing Bacillus thuringiensis do not present unacceptable risks to human health or the environment when used according to label direction"*

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Ministry of Forests  
and Range

Provincial Forest Entomologist

Location:  
727 Fisgard Street, 9<sup>th</sup> Floor  
Victoria BC V8W 1R8

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*“The risk from occupational exposure, however, was determined to be low given the lack of mammalian toxicity.”*

*“B thuringiensis has a long history of safe use as a pesticide”*

If there is a long history of safe use, low risk from occupational exposure and no present unacceptable risk, then, why is there a need to impose additional risk reduction measures? PMRA provides no science to support the new measures.

When comments were submitted to PMRA on PACR2006-09 regarding our concerns on these requirements, PMRA’s responses in RVD2008-18 is not based on science. Instead, PMRA dealt with potential sensitization, to which no evidence was presented, and that the required PPE was no more intrusive or threatening in appearance than disposable masks.

The label, as it appears on a product, is a legal document. It is not subject to interpretation by different groups as to intent. When people read the label for a product we are about to spray on their houses, playgrounds and parks requires applicators to a -95 NIOSH- approved respirator, which are used by health officials during infectious disease outbreaks such as SARS, tuberculosis and Avian Flu, we will be swamped with environmental appeals, will face outraged citizens at public protest, and will be vilified in the press over the perceived threat implied by the PPE requirements over what is stated as reduced risk, safe insecticide. The following statement, contained within the RVD2008-18 in response to our concerns over the new PPE requirements shows a complete lack of understanding of the very real public relations issues faced by land managers.

*“... the required NIOSH-approved respirators are not any more intrusive or threatening in appearance than disposable dust masks and other PPE. These protective measures are unlikely to raise public concern.”*

The increased requirements from PPE for applicators and mixers of these products indicate that Bt presents an unacceptable risk without a high level of protective equipment and this increased risk would also be perceived to extend to the general public. This is an important consideration given that Bt-based products are the only category of pesticides that are frequently applied aerially to residential areas including homes, playgrounds, and public spaces. The very high level of public scrutiny that occurs during these programs will result in the belief that Bt-based products are inherently dangerous, requiring respirators equivalent to those used to protect health officials during the SARS outbreak.

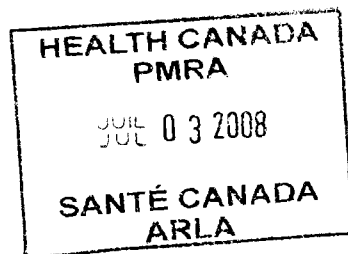
The BC Ministry of Forests and Range is strongly committed to a safe work environment for all our employees and contractors. If there was any scientific evidence to support the use of the PPE equipment recommended within the PACR, we would endorse its use and would seriously reconsider the use of this product in urban environments. However, there is no scientific evidence to support these changes, and in fact the science reinforces the safety of this product for the approved uses in Canada. Based on the scientific evidence that shows no adverse health risk, we recommend that the cautionary notes regarding potential sensitization and the requirement for '-95' NIOSH respirators should be deleted.

We look forward to your response,

Sincerely,



Jennifer Burleigh,  
Provincial Forest Entomologist  
BC Ministry of Forests and Range



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Ministry of Forests  
and Range

Provincial Forest Entomologist

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