

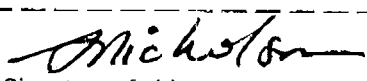


Health Canada Santé Canada
 Pest Management Regulatory Agency Agence de réglementation de la lutte antiparasitaire

Date Received - Date de réception:
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**Notice of Objection to a Registration
 Decision under Subsection 35(1) of
 the Pest Control Products Act**

**Avs 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 VALENT BIOSCIENCES CANADA LTD.			
Postal Address - Adresse postale 2704 ORRER RD, BRIM BURG			
City/Town - Ville ELGIN BURG	Province/State - Province/État ONTARIO	Country - Pays CANADA	Postal Code/ZIP - Code postal/Zip K0H 1M8
Phone - Téléphone 613 576 1070	Fax - Télécopieur 613 576 1069	E-mail - Adresse électronique Stephen.nicholson@valent.com	
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 : NUMBTOOLS - FORAY, DIFEL ETC.			
3. Registration decision to which the objection relates - Décision d'homologation pour laquelle vous déposez un avis d'opposition			
<u>Decisions on application - Décision concernant la demande</u>			
<input type="checkbox"/> Granting registration - Homologation accordée			
<input type="checkbox"/> Denying registration - Homologation rejetée			
<input type="checkbox"/> Granting an amendment of a registration - Modification à l'homologation accordée			
<input type="checkbox"/> Denying an amendment of a registration - Modification à l'homologation rejetée			
<u>Decisions on re-evaluation or special review - Décision concernant la réévaluation ou l'examen spécial</u>			
<input type="checkbox"/> Confirming registration - Homologation confirmée			
<input type="checkbox"/> Cancelling registration - Homologation annulée			
<input checked="" type="checkbox"/> Amending registration - Modification à une homologation			
4. Date the decision statement was made public: Date de la publication de l'énoncé de décision : MAY 6, 2008			
5. Area of scientific evaluation to which the objection relates - Volet de l'évaluation scientifique touché par l'avis d'opposition			
<input checked="" type="checkbox"/> Health risk assessment (toxicology, food residue, occupational exposure) - Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)			
<input checked="" type="checkbox"/> Environmental risk assessment (environmental fate, environmental toxicology) - Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie)			
<input type="checkbox"/> 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 Fondement scientifique de l'opposition		Attachment Included: Pièce jointe incluse :	
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Oui <input type="checkbox"/> Non	
		STEPHEN A. NICHOLSON	
7. Signature of objector or representative - Signature de l'opposant ou de son représentant		Printed Name - Nom en lettres mouluées	
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_info@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_info@hc-sc.gc.ca .			

July 3, 2008

Pest Management Information Service
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, Ontario
K1A 0K9

Via fax @ 613 736 3798

Dear/Sir/Madam

Valent BioSciences Canada Limited: Notice of Objection, RVD2008-18, Re-evaluation Decision, Bacillus thuringiensis, 6 May, 2008.

Please find enclosed my Notice of Objection to the recently issued (May 6, 2008) Bt Re-Evaluation Decision.

I am responding as a Canadian who has been involved in forest protection for over three decades, and as a director of VBC Canada Ltd., and as the manager of our (VBC) forestry business in North America and our public health business here in Canada.

A Notice of Objection from Valent BioSciences corporate headquarters has been submitted under separate cover; there may be some overlap in our correspondence as our responses were not drafted in isolation. We share many of the concerns identified in previous correspondence to PMRA, and while my colleagues are best suited to address the regulatory aspects, I am filing a Notice of Objection to PMRA's Re-evaluation decision on the basis that several of the proposed label language amendments are unacceptable based on the scientific evidence available. It would seem that that PMRA's internal policies and concerns of liability and not science are the primary drivers of the re-evaluation process. This is troubling especially when neither the weight of scientific evidence nor the long history of problem-free use of these microbial products supports some of the conclusions drawn in the Decision Document.

Recent communications between PMRA and several provincial forest health authorities have served to support the position that science-based decisions have not been made, and that PMRA must continue with an open dialogue on several re-evaluation issues with registrants and end-users to develop label language which is acceptable to all parties.

I object to the Re-evaluation Decision document due to my continued concerns about the negative impact of the proposed label language changes on the use of Bt-based products in forest protection programs.

Furthermore, some of the conclusions drawn in the Decision Document would indicate PMRA's deficiencies in operational expertise with respect to current forest protection practices. On numerous occasions, PMRA staff has been invited to view provincial forest protection programs to gain a better understanding of the true nature of these activities, but to no avail. Consequently it would seem that if PMRA is unable to develop a true understanding of the protection technology currently used and the real-world issues faced by program managers, it would be well advised to welcome and accept direction from provincial and federal agencies and registrants intimately involved in such programs.

I recognize that there are both real and perceived issues concerning the application of Bt-based pesticides; it is my hope that PMRA relies upon science and the 'real' issues in addressing concerns about the unsuitability of some of the conclusions drawn in the Bt Re-evaluation Decision document.

Regards,

Stephen Nicholson
Sales Manager,
Forestry and Public Health

stephen.nicholson@valent.com

(enclosure)

Notice of Objection: RVD2008-18, Re-evaluation Decision, Bacillus thuringiensis

1) Aquatic Habitats:

The proposed label language wording is unacceptable and if applied, will result in severely limiting the ability of protection managers to protect the nation's forested lands. The proposed wording is not supported by fact and ignores over 30+ years of successful aerial applications to North American forests.

Research work conducted by Charles Buckner, Peter Kingsbury, Steve Holmes, and David Kreuzweiser amongst others has shown that impact to aquatic habitats is negligible. (Numerous references available)

Operational assessments conducted in Quebec by the provincial Ministry of Resources, and in Ontario by the provincial Ministry of Natural Resources in the 1980's support the conclusions drawn by these researchers.

Additionally reference texts such as by Glare and O'Callaghan, (2000) and the World Health Organization (1999) would indicate that PMRA's proposed wording regarding aquatic habitats is not supported by science.

As indicated in the PACR document, since health risks associated with drinking water and Bt are negligible, and aquatic habitat impacts are minimal or non-existent, the statement as proposed is unjustified and not based on fact or in science.

Additionally, PMRA's misuse of GPS/GIS terminology in identifying aquatic habitats underscores its lack of understanding of current forest protection technology.

Proposed Wording:

Delete all references to 'lotic' and 'lentic' as this adds a degree of complexity and interpretation not required for label purposes. In layman terms, water is either standing, running, or frozen; do not complicate the issue.

Amend first sentence of current wording as follows:

“Avoid direct application to sensitive aquatic habitats... ..estuaries or marine habitats.”

2) Personal Protective Equipment:

Again, the proposed label language is not supported by fact. Research conducted regarding exposure levels of agricultural workers to microbial compounds is not applicable to forestry applications. It also misrepresents the risks involved to the public, especially regarding the use of Btk to protect forested residential areas.

Protection program managers are placed in an awkward situation with this proposed requirement; all studies show, and PMRA agrees that Btk is of minimal risk to people, yet PMRA is mandating the use of significantly more stringent PPE. This sends a definite mixed message that will only make a program manager's duties more difficult.

Forestry applications use fully formulated products, handled through closed-loop loading systems. In a typical forestry season, ground workers loading aircraft etc are exposed to the products in a liquid form, and only for a brief time when opening tank hatches etc. There is no particulate matter and no reason for a NIOSH -95 series type respirator.

Contrary to PMRA's statement, NIOSH-approved respirators ARE more intrusive and threatening in appearance.

This requirement will only serve to increase anxiety of residents and bystanders living in residential forested areas that are being sprayed with Btk.

Proposed Wording:

Delete in entirety all references to NIOSH-95 respiratory equipment. Current label language is acceptable.

3) Sensitization:

This is being fully addressed by my regulatory colleagues. My concern is that the approach taken by PMRA to add 'boiler plate' language to all pesticide labels is not flexible enough to be responsive to individual products. All registered pesticides do not pose the same risks, so blanket language is unacceptable and ignores product-specific research. Furthermore, if PMRA does not accept the science supporting this issue, again the risks of using such products will be, in the public's eye, unacceptable.

Proposed Wording:

As per Valent BioSciences Corporation submission.

4) Resistance Management:

Again, a broad brush approach by PMRA that it not supported by fact. Resistance is NOT an issue in forest applications, and there are few alternate products available if a program manager wished to follow PMRA's recommendations.

In reviewing the original PACR Re-evaluation Document, there is no indication of any concerns re resistance management. It can also be argued that in consideration of 30+ years of application to forests, resistance has never occurred. Resistance has been noted twice, and in isolated conditions (once on an island, and once in a storage silo); a quick scan of the literature would indicate the fallacy of such a recommendation.

Proposed Wording:

Delete this section as it is non-applicable.

Stephen Nicholson
July 3, 2008