

Consumer Product Safety

Evaluation of Pesticide Incident Reports 2010-2575, 2010-2681, 2010-2682, and 2010-2820

Background

Pest control products are registered by Health Canada's Pest Management Regulatory Agency (PMRA) for use only if there is reasonable certainty that no harm to human health or the environment will result from exposure to, or use of, the product as directed on the label. The PMRA collects incident reporting data under the authority of the Pest Control Products Act. If a pesticide manufacturer receives information about an incident involving one of their products, they are required by law to submit that information to the PMRA. It is important to note that the information presented in incident reports reflects the observations and opinion of the person reporting it, and does not include any assessment by Health Canada, nor does it confirm an association between the pesticide and the effects reported.

Health Canada considers the reported information to determine if there are potential health or environmental risks associated with a pesticide and, if necessary, takes corrective action. Such action could range from minor label changes to discontinuation of the product.

Incident Reports 2010-2575, 2010-2681, 2010-2682, and 2010-2820

Valent BioSciences Corporation received information about four incidents related to the aerial spraying of Foray 48B (PCP Reg. No. 24977) in the area of Richmond, British Columbia in April and May of 2010. Foray 48B contains the active ingredient *Bacillus thuringiensis* sub-species *kurstaki* (Btk) strain HD-1. It was sprayed to control an infestation of European Gypsy Moth. Four individuals living within or near the spray area were reported to experience symptoms around the time of application of Foray 48B. These symptoms included coughing up of blood (two individuals), worsening of asthma symptoms (one individual), asthmatic reaction (one individual), and malaise and muscle weakness (one individual).

In accordance with the Incident Reporting Regulations classification system, one of these incidents was classified as Human Minor while the other three were classified as Human Moderate. These incident reports are posted on the PMRA electronic [Public Registry](#) on the Health Canada website.

Health Canada Evaluation

When evaluating the level of association between reported effects and a pesticide, Health Canada considers several factors, including the likelihood of exposure to the pesticide, the degree of plausibility that the effects were caused by the alleged exposure, and repetition of the effect in various incident reports. Aside from these four incident reports, the PMRA has received one other report of an individual with a history of asthma who experienced difficulty breathing following a spray program in another community in 2008. Despite the long history of use of Btk in Canada (approximately 40 years), these five instances are the only times such effects have been reported.

Although there was no evidence provided to the PMRA confirming exposure to Btk, there is some likelihood that exposure to the pesticide occurred in three of the incidents given the location of the individuals' residences in relation to the spray area. These three individuals reported respiratory effects (coughing up of blood, asthmatic reaction and/or worsening of asthma symptoms), and were also reported to have underlying medical issues (history of asthma or respiratory issues, Addison's disease). Respiratory effects have been reported in animals and humans following exposure to Btk, but usually under conditions of exposure to

high concentrations. There is some evidence that individuals with medical issues similar to those reported in these incidents may be more susceptible to the effects of Btk. However, it should be noted that there are several other potential causes of these symptoms. In particular, allergic reactions to pollens can lead to episodes of asthma, and applications of Btk spray often coincide with peak allergy season.

The fourth individual lived further outside the 2010 spray area, and experienced malaise and muscle weakness, which are general symptoms that are not typical signs of exposure to Btk.

Health Canada Conclusion

Based on the information available, Health Canada concluded that it was **unlikely** that the effects in one case (malaise and muscle weakness) were related to the spraying of Foray 48B as the person lived too far outside of the spray zone for exposure to have occurred. In the other three cases, it was determined that it was **possible** that the respiratory effects could be related to the spraying of Foray 48B, as the individuals lived within or near the spray area. However, the results of this assessment by Health Canada are inconclusive given that the reported symptoms can be caused by several other factors and that these three individuals had underlying medical issues.

The information as noted in the incidents will remain in the database and will be routinely re-examined in conjunction with any new data that is received. More information about the [Pesticide Incident Reporting Program](#) is available on Health Canada's website. Should you require further information please contact the [Pesticide Incident Reporting Program](#).

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