



ACVM Alert Notification 16-001

For manufacturers and registrants of Agricultural Compounds and Veterinary Medicines

Tianjin explosion and contamination risks to raw materials

The ACVM Group wish to advise NZ manufacturers and registrants of an alert issued by the US Food and Drug Administration (FDA) on 22 Dec 2015 to notify that shipments from Tianjin, China may be at risk of chemical contamination.

The FDA reported they had increased surveillance of pharmaceutical shipments after the August 2015 explosions at Tianjin Dongjiang Port Ruihai International Logistics Co., a chemical warehouse. Two shipments from Tianjin Tianyao Pharmaceuticals intended for the USA were found to have been contaminated with hydrogen cyanide and were stopped. This manufacturer was approximately 30 km from the explosion site. Two subsequent shipments from the same company were released after no contamination was found.

The FDA are working with the Chinese Food and Drug Administration on this issue. It should also be noted that while information related to the incident is limited, more than 40 different types of chemicals were discovered at the blast site.

The ACVM Group would like to remind manufacturers and registrants that they must know the source and quality of the ingredients they are purchasing and using. It is advised that companies contact the manufacturers of the ingredients or materials they order or receive, particularly from the Tianjin City area, to ensure the ingredients are of the appropriate quality and are free from contamination associated with the explosion and not contaminated in any way.

It is the responsibility of companies that obtain finished products, active ingredients and excipients - from the Tianjin City region to take appropriate precautions to ensure the quality of these products before they are distributed and/or used in manufacturing.

Contact details

Ministry for Primary Industries (MPI)
Regulation and Assurance Branch
Agricultural Compounds and Veterinary Medicines
PO Box 2526
Wellington 6140
Email: approvals@mpi.govt.nzbradburyg

ISSUED BY:

Glen Bradbury
Manager Agricultural Compounds and Veterinary Medicines
System Audit, Assurance and Monitoring Directorate

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