

OFFICE OF THE TEXAS STATE CHEMIST

Texas Feed and Fertilizer Control Service • Agricultural Analytical Service

445 Agronomy Road • College Station, TX 77843-2114

Mailing Address
P. O. Box 3160
College Station, TX 77841-3160

Tel. (979) 845 1121
Fax. (979) 845 1389
<http://otsc.tamu.edu>

Issued Date: September 24, 2008

GENERAL ADMINISTRATIVE MEMORANDUM NO. 5-25

RECALL POLICIES AND PROCEDURES IN TEXAS

OBJECTIVE:

Clarify the policies and procedures used by the Office of the Texas State Chemist in the event of an FDA recall or when, in the interest of protecting consumers, the State Chemist requires product recall.

BACKGROUND:

The Texas Commercial Feed Control Act outlines the Office of the Texas State Chemist Enforcement Remedies in SUBCHAPTER F §141.121-128 that include issuing a stop-sale order, condemnation of feed, warnings, injunctions, suit to recover fees, and prosecutions. Section 141.148 of the Texas Agriculture Code prohibits the distribution of adulterated feed. In some instances, removal of adulterated feed from the market may require implementation of a recall strategy.

The steps used during a recall are outlined by the Food and Drug Administration (FDA) in 21 CFR Part 7 and the Food Safety Inspection Service (FSIS) Directive 8080.1 Revision 4. This policy describes how the Office of the Texas State Chemist will respond to voluntary recalls implemented by FDA and under what circumstances the Office will mandate recalls.

FDA and FSIS have classified recalls based on their public health assessment. For the purposes of the Office of the Texas State Chemist, the FDA will be used as follows:

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death,

Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote,

Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

The FDA recall procedure includes performing a health-hazard evaluation and recall classification based on (1) whether any disease or injury has already occurred from use of the product (2) whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard (3) assessment of hazard to various segments of the population (4) assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed (5) assessment of the likelihood of occurrence of the hazard (6) assessment of the consequences of occurrence of the hazard.

POLICY:

OTSC will initiate a class I recall when death or serious adverse health consequences resulted from the use of the product and the Office concludes that implementing a recall is a more effective method of removing adulterated product from the market than utilizing a stop-sale notice. The Office of the Texas State Chemist possesses the implied authority to issue a recall notice if the Feed and Fertilizer Control Service has reasonable cause to believe that the product is being distributed in violation of the Texas Commercial Feed Control Act and represents the best risk management strategy to protect animal and human health.

A handwritten signature in black ink, appearing to read "Timothy J. Herrman". The signature is fluid and cursive, written in a professional style.

Dr. Timothy J. Herrman
State Chemist and Director
Office of the Texas State Chemist