

OFFICE OF THE TEXAS STATE CHEMIST

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FEED INDUSTRY MEMORANDUM NO. 5-30

Procedure for Reviewing and Approving Feed Ingredients or Drug Definitions, Uses or Products

OBJECTIVE:

Explain procedures for submission and review of new feed ingredient or drug definitions, uses, or products for approval by the Texas State Chemist.

BACKGROUND:

The Texas Commercial Feed Control Act 141.004 and the Commercial Feed Rules 61.22(5)(B)(iii) define the Texas Feed and Fertilizer Control Service (hereafter referred to as Service) authority to approve new products and name of those products and is further explained in Feed Industry Memorandum 5-21. The Service responds to requests by feed manufacturers and consumers of feed to approve new products or ingredients in consultation with the Advisory Committee and experts to ensure the safety of feed and to protect the market place from fraudulent practices. In response to input by stakeholders, including the Office of the Texas State Chemist (OTSC) advisory committee and experts, the Office approves the new feed ingredient or drug definition, uses, or products for manufacture and distribution in Texas.

The purpose of this memorandum is to provide an explanation of the process flow for approval of an ingredient definition. A request for a new ingredient definition is submitted to OTSC, accompanied by a third party risk assessment. The request is first reviewed for completeness, incomplete packets are returned. If the package is complete, the risk assessment is evaluated. Upon satisfactory completion of the review of the individual's qualifications performing the risk assessment, thoroughness of the risk assessment, and the conclusions (end point) of the risk assessment, the packet will be forwarded to the OTSC Registration for a label review. Conditional approval by the State Chemist results in preparation of a draft Feed Industry Memorandum with the proposed definition. The draft definition, accompanied by a presentation of the risk assessment and relevant studies by qualified researchers, are reviewed by the OTSC Advisory Committee for unintended consequences of the new ingredient definition. Based on input by the advisory committee, the State Chemist will grant final

approval of the ingredient and post the new ingredient definition on the OTSC website. These steps are outlined in a process flow in the appendix.

All packets for a new feed ingredient definition or drug must meet criteria outlined in Feed Industry Memorandum 5-21. Only approved ingredients may be manufactured and distributed as commercial feed in Texas.

POLICY:

A. Process for Approval

The Service will approve new feed ingredients and drug definitions, uses, and products following the process approach outlined in this memorandum.

B. Criteria for Approval

Criteria for approval of a new ingredient are outlined in Feed Industry Memorandum 5-21.

C. Cost for Approval

All costs associated with preparing, submitting, and presentation of the proposed new ingredient, use, or product are borne by the applicant.



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Appendix. Process flow for packet review of new ingredient definition.

