

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>

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FEED INDUSTRY MEMORANDUM NO. 5-21

CRITERIA FOR APPROVING NEW INGREDIENT DEFINITIONS, USES OR PRODUCTS

OBJECTIVE:

To provide a set of criteria to approve new ingredients or new use of approved ingredients as authorized by Commercial Feed Rule §61.22(5)(B)(iii). Products containing unapproved ingredients or uses may also be approved under these criteria.

BACKGROUND:

For the benefit of users and producers of agricultural feed products, a mechanism to approve new ingredients has been established. This will allow end-users of approved products to quickly get their product into the marketplace and implement their use than otherwise would be permitted by requiring their approval through customary channels such as AAFCO and/or FDA. The guiding principle of this is that an established science based need is being fulfilled.

POLICY: Clarify the decision making process for approving new ingredients, uses, definitions, and products outlined in the criteria below.

CRITERIA:

1. Creation of new definitions for ingredients, claims or products subject to the Texas Commercial Feed Control Act [Texas Agriculture Code (1981)], Texas Administrative Code Title 4. Agriculture Chapter 61 (Commercial Feed Rules) and Chapter 63 (Pet Food Rules) to determine whether there is an established need for the ingredient, new use or product. A justification establishing a science based need for granting approval will be required.
2. Supporting documentation for proposing the approval of a new ingredient, a new use of an approved ingredient, or product must be accompanied by a complete literature review including search terms used and databases searched.
3. Policy decisions are based on multiple studies. The number of studies is dependent on the scope of the individual studies submitted for review and the Office of the Texas State Chemist will consider inference space of these composite data.
4. The product meets GRAS (generally recognized as safe) criteria.
5. The new product claim is supported by research that defines/explains the mode of action (causality).
6. Analytical procedures to verify the mode of action or functional properties must be provided.

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7. The new ingredient definition includes a common name or description, the scientific name, if any. A standard of identity, i.e., the source of the additive, the purity of the additive, an impurity profile, and analytical procedures to ensure the standard identity is met.
8. There are approved methods for measuring ingredient properties.
9. The OTSC possesses the capability to measure the properties or such measurement is readily available in outside labs.
10. The cost of measuring the ingredient must be commensurate with the benefits derived by the industry for introducing this ingredient.
11. The OTSC must possess the capability to respond to complaints associated with the ingredient or product.
12. Product claims are consistent between national and Texas advertisement including brochures and websites.

ADMINISTRATION:

A firm or individual may seek approval under this procedure. The firm or individual seeking approval under this procedure must provide a notarized statement expressing their understanding that approval by the Office of the Texas State Chemist does not confer GRAS status, AAFCO or FDA approval.

The decision to “approve” or “not approve” will be issued. Products are subject to further review as new data becomes available that may change the product status.



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