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Issued: November 29, 2007
Revised: March 26, 2008

FEED INDUSTRY MEMORANDUM NO. 5-22

Definition of Crude Glycerin from Biodiesel Production

OBJECTIVE:

To define Crude Glycerin from Biodiesel Production including acceptable methanol levels consistent with 21 CFR 573.460, 21 CFR 573.480, and 21 CFR 573.640 and provide a mechanism for obtaining approval by the Office of the Texas State Chemist (OTSC) to market crude glycerin from biodiesel production in Texas.

BACKGROUND:

The Texas Commercial Feed Control Act §141.004 and Commercial Feed Rules §61.22(5) (B) (iii) define the Office of the Texas State Chemist's authority to approve new ingredients. The OTSC policy applies only to glycerin produced as a by-product during biodiesel production and represents the OTSC interpretation of FDA regulations contained in 21 CFR 573.460, 21 CFR 573.480, and 21 CFR 573.640. Additionally, because methanol production is part of the normal digestive process in ruminants, these animals can tolerate methanol levels higher than those outlined in FDA policy.

Methanol is metabolized in non-ruminant animals to formaldehyde and to formic acid. Formic acid is responsible for the toxic effects. Formaldehyde in accord with 21 CFR 573.460 can be used at levels of approximately 1% of protein meals. These meals can then be fed at levels which may reach 25% of animals' diets, thus providing 0.25% formaldehyde in feeds. Formic acid and its' salts have been researched extensively in monogastrics as a dietary acidifier at levels of approximately 1% (air dry basis). Formic acid has specific approval for use as a hay crop preservative in amounts not to exceed 2.25% on dry weight basis (21 CFR 573.480). These materials may reasonably represent 50% of dry matter content of ruminant animal diets. Methyl esters of higher fatty acids are described for use in all animal feeds under 21 CFR 573.640 as a source of dietary fat. When acted upon by digestive enzymes methanol is released for absorption. The methanol yield from this process represents approximately 11.85% of the weight of the methyl ester itself. The Office of the Texas State Chemist interprets 21 CFR 573.640 to limit methanol levels to 150 ppm when found in combination with methyl esters of higher fatty acids. The OTSC policy precludes the use of crude glycerin in combination with methyl esters of higher fatty acids, formaldehyde, and formic acid.

The use of crude glycerin defined by the OTSC policy would be well tolerated by all species as outline in 21 CFR 573.460, 21 CFR 573.480, and 21 CFR 573.640 and are supported by scientific literature.

POLICY:

(a) **Crude Glycerin From Bio-diesel Production** is a co-product obtained in the production of biodiesel. It must be labeled with guarantees for minimum glycerin, maximum moisture, maximum ash and maximum methanol. The methanol level shall not exceed 1% in the Crude Glycerin targeted for ruminants. Crude Glycerin targeted for other classes of livestock may not exceed 1% methanol with inclusion levels not to exceed 10%. Crude glycerin shall not be used in feeds to which formaldehyde, formic acid or methyl esters have been added and feed manufactured with crude glycerin shall not contain methanol levels that yield toxic metabolites in excess of those specified in 21 CFR 573.460 and 21 CFR 573.480. The words "From Biodiesel Production" are not required when listing as an ingredient in a manufactured feed.

(b) This policy applies to Texas and is viewed by the Office as consistent with federal regulations 21 CFR 573.460, 21 CFR 573.480, and 21 CFR 573.640.

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