



## Generally Recognized as Safe (GRAS) Determination for:

### **Intentional use of Allpen Special™ as a processing aid in renewable fuel and distillers' grain production**

Lallemand Biofuels & Distilled Spirits has successfully completed a review of **Allpen Special™**, resulting in a GRAS (Generally Recognized as Safe) determination as defined by Section 201(s) of the Federal Food, Drug and Cosmetic Act and corresponding Food and Drug Administration (FDA) guidelines. Penicillin is the active ingredient in **Allpen Special™**, a leading antimicrobial for renewable fuels production.

Lallemand Biofuels & Distilled Spirits has consistently been working on regulatory compliance for all its antimicrobial products with the FDA. A number of years ago, under the guidance of the FDA's Food Additive Petition (FAP) process, Lallemand Biofuels & Distilled Spirits began preparing scientific data and research necessary to secure long-term regulatory compliance for **Allpen Special™**. During this time, Lallemand Biofuels & Distilled Spirits developed a proprietary process for determination of residuals in distillers' grains.

Since its launch, **Allpen Special™** has proven to be a safe product for use in renewable fuels and distillers' grain production. The GRAS determination was made by independent experts and counsel after a comprehensive evaluation of Lallemand Biofuels & Distilled Spirits' validated residual test method and scientific data.

The experts' determination was based upon the publicly available scientific literature pertaining to the safety of the product and the demonstrated absence of residues in the feed ingredient (distillers' grain).

The **Allpen Special™** GRAS determination achieves full regulatory compliance and obviates the need for a Food Additive Petition. However, Lallemand Biofuels & Distilled Spirits is continuing to work with FDA and has submitted its scientific data and research to CVM for the record.