



Expert Panel Determines Virginiamycin and DDGS with Virginiamycin to be Generally Recognized as Safe (GRAS)

According to the Food and Drug Administration, GRAS (Generally Recognized as Safe) designation “requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive. Ordinarily, GRAS is based upon published studies, which may be corroborated by unpublished studies and other data and information¹.”

Phibro sought the most stringent review possible of Lactrol’s virginiamycin by an independent panel of experts.

Expert Panel Review

The Panel consisted of scientists of relevant expertise in animal science, microbiology, pharmacology, toxicology and FDA regulations and policy. The distillers’ products will contain less than 1 ppm residual virginiamycin, as confirmed by analytical data on actual samples of fermentation co-products. The panel reviewed the major studies relevant to virginiamycin on possible transmission of microbial resistance, biotransformation, toxicology studies in laboratory animals and safety, nutritional and residue studies in livestock. In addition, the major regulatory reviews and risk assessments done by FDA and other regulatory bodies around the world were also consulted.

The panel concluded:

- There is a long history of safe use of virginiamycin at higher levels as an animal drug in livestock and the major regulatory agencies agree that virginiamycin is a safe animal drug.
- There are sufficient data in the public domain to judge the safety of virginiamycin.
- It is highly unlikely that resistant pathogens will develop from the use of virginiamycin as a processing aid in fermentation.

¹ U.S. Food and Drug Administration website

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- The presence of a maximum level of 1 ppm in animal feed is not harmful to livestock or other animals.
- The residues expected in meat and other animal products used as human food are negligible and present no risk to consumers.

The Panel agreed, based on these conclusions, that distillers co-products from ethanol production using virginiamycin as a processing aid is Generally Recognized as Safe (GRAS) as defined by the Food Drug and Cosmetic Act as animal feed for all animal species .

Phibro is confident the scientific data secures a path for long-term regulatory compliance for use of Lactrol in ethanol production.

Expert Panel Short Biographies

Dr. Lester Crawford, DVM, PhD, Former Director, FDA Center for Veterinary Medicine



Spanning a distinguished career in both the public and private sector, Dr. Crawford has served as FDA commissioner and as administrator of the Food Safety & Inspection Service at USDA. He has also served as the executive vice-president of the National Food Processors Association and executive director of the Association of American Veterinary Medical Colleges.

Dr. Kristi Smedley, PhD, Nutritionist, is the vice president for the Center for Regulatory Services, Inc, where she oversees the impact of regulatory policy on the animal health industry. She received her bachelor's degree from The Pennsylvania State University and her master's in science and Ph.D. from Virginia Tech. At the Center for Veterinary Medicine for the FDA, she was active in the areas of food additives (nutrients and technical additives), policy and guidance development, and regulations (including the bovine spongiform encephalitis rules).



Dr. Peter Silley, Microbiologist, graduated in Bacteriology from the University of Birmingham. After a period in the pharmaceutical industry with Cyanamid (GB) Limited, he earned his doctorate from the University of Newcastle upon Tyne in rumen microbiology. Silley's tenure with the Glaxo group of companies included the Head of Microbiology for Glaxo Animal Health and subsequently as Senior Research Leader with Glaxo Group Research working on the development of novel anti-infective compounds in human medicine. Since 1990, Dr. Silley has been Research Director at Don Whitley Scientific.



Dr. Richard Kraska, GRAS Associates, Toxicologist, began his career at FDA in food additives and moved on to GRAS Review. At FDA, he participated in safety evaluations on sensitive topics such as aspartame, cyclamate and salt. For the next 22 years, he had numerous assignments with three major chemical companies where he integrated critical toxicology aspects into a wide variety of regulatory matters. Dr. Kraska is currently the CEO of GRAS Associates, LLC, which specializes in technical consulting for the food and allied industries on matters related to the review of food ingredients and chemicals which may be considered "Generally Recognized as Safe" as defined by the Federal Food Drug and Cosmetic Act. He is a member of the Roundtable of Toxicology Consultants, Society of Toxicology, Regulatory Affairs Professionals Society and Society of Tribologists and Lubrication Engineers.



Dr. Jerry Shurson, Professor, Department of Animal Science, University of Minnesota, received his bachelor's degree in Animal Science and Agricultural Economics at the University of Minnesota and continued his college education at Michigan State University in East Lansing where he received his master's and Ph.D. degrees in swine nutrition. During the past 12 years, Shurson has focused on evaluating the nutritional value of distillers dried grains with solubles in swine diets. He has presented these research findings to numerous national and international audiences. He works very closely with the U.S. Grains Council to provide educational programs and assess export market opportunities for DDGs.

