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Use of standardized enzyme safety evaluation methodology in the GRAS process - a model for other food ingredients and jurisdictions

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Enzymes are used as processing aids in various food applications including baking, brewing, protein processing and manufacture of dairy products. In the US, any ingredients added to food, even if only as processing aids, require premarket approval unless they are generally recognized as safe (GRAS). The enzyme industry has effectively pursued GRAS exemption claims for its products as described recently. A thorough enzyme safety evaluation considers aspects of the enzyme itself, its production organism (including genetic engineering aspects), the manufacture process, and the exposure in the intended use, in addition to safety studies. The success in pursuing and notifying FDA of GRAS status for enzymes in an expedited manner was based on extensive collaboration within industry and with academia to summarize available toxicological studies for enzymes produced with genetically engineered microbes, made available for publication in review papers by Pariza and Johnson and; Pariza and Cook, all pointing at no adverse effects for microbial food enzymes. The Pariza papers also elaborated the concept of Safe Strain Lineage (SSL) as part of a safety evaluation decision tree methodology, which allows extrapolation of existing toxicological data to evaluate new products. The SSL concept builds on the repeated use of common production organisms such as *Bacillus* subtilis, B. licheniformis, and Trichoderma reesei and the repeated assessment of these production organisms using the decision tree. These efforts resulted in a standardized, generally recognized safety evaluation methodology, and a high success rate in US FDA's GRAS notification program. Other food safety professionals have commented that the concerted effort by the enzyme industry make clear the value in developing such processes. Indeed, this approach may serve as a model to other food ingredient categories for a scientifically sound, rigorous, and transparent application of the GRAS process and as inspiration to other jurisdictions involved in safety oversight of microbial products.

Recent Publications

1. Pariza M W and Cook M (2010) Determining the safety of enzymes used in animal feed. Regulatory Toxicology and Pharmacology 56:332–342.
2. Pariza M W and Johnson E A (2001) Evaluating the safety of microbial enzyme preparations used in food processing: Update for a new century. Regulatory Toxicology and Pharmacology 33:173-86.
3. Sewalt V (2017) Performance enzymes for food ingredients at the BIO world congress-enabling biotechnologies and supporting capabilities join in a model for successful commercialization of food ingredients. Industrial Biotechnology 13:219-220.
4. Sewalt V, La Marta J, Shanahan D, Gregg L and Carrillo R (2017) Letter to the editor regarding GRAS from the ground up: review of the interim pilot program for GRAS notification by. Food and Chemical Toxicology 107:520–521.
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Biography

Vincent J Sewalt has over 20 years' of experience in managing biotechnology innovation, safety and regulatory compliance, of which the last 10 years in the fermentation biotechnology industry. He is passionate about sharing food enzyme safety and biotechnology risk assessment expertise to enhance capabilities in governments, non-profits and industry globally. He is a frequent speaker on proactive approaches in safety, regulatory and technology communication at biotechnology conferences and has addressed the National Academy of Sciences on managing risks associated with future biotechnology products.

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