

Guidelines for the Validation and Use of Immunoassays for Determination of Introduced Proteins in Biotechnology Enhanced Crops and Derived Food Ingredients

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Recent advancements in agricultural biotechnology have created a need for analytical techniques to determine introduced proteins in crops enhanced through modern biotechnology techniques. These proteins are expressed in plant tissues and may be present in food ingredients. Immunoassays are ideally suited for protein detection and may be used as both quantitative and threshold methods. Microplate ELISA and lateral flow devices are two of the most commonly used immunoassay formats for agricultural biotechnology applications. This paper provides general background information and a discussion of criteria for the validation and application of immunochemical methods to the analysis of proteins introduced into plants and food ingredients using biotechnology methods. It is the result of a collaborative effort of members of the Analytical Environmental Immunochemical Consortium. This collaborative effort represents the combined expertise of several organizations to reach consensus on establishing guidelines for the validation and use of immunoassays. Further, the paper offers developers and users a consistent approach to adopting the technology as well as aid in producing accurate and meaningful results.

Keywords: Immunoassay, ELISA, introduced proteins, transgenic crops, genetically modified crops, GM food testing, analytical method validation, Analytical Environmental Immunochemical Consortium, AEIC, agricultural biotechnology

INTRODUCTION

Agricultural biotechnology (ag biotech) is a new technology influencing the agriculture and food industries. A large proportion of major crops currently grown in the USA have been

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