Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices

Abstract:
This document provides supplement guidance on specifications for the development and implementation of studies to validate the performance characteristics of quantitative ELISA methods for the determination of food allergens. It is intended as a companion document to the "AOAC Official Methods of Analysis Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis" [1]. The guidance is divided into two sections: information to be provided by the method developer on various characteristics of the method, and implementation of a multi-laboratory validation study. Certain criteria included in the guidance are allergen-specific. Two food allergens: egg and milk are used to demonstrate the criteria guidance. These recommendations will be the basis of the harmonized validation protocol for any food allergen ELISA method, whether proprietary or nonproprietary, that will be submitted to AOAC and/or regulatory authorities or other bodies for status recognition. It should be noted that regulatory authorities may have their own particular requirements for data packages in addition to the guidance in this document. Future work is planned for the implementation and validation of this guidance. This future work will also include guidance specific to other priority allergens.

URI:
Authors:
ABBOTT Michael
HAYWARD Stephen
ROSS William
GODEFROY Samuel Benrejeb
ULBERTH Franz
VAN HENGEL Arjon
ROBERTS James
AKIYAMA Hiroshi
POPPING Bert
YEUNG Jupiter M.
WEHLING Paul
TAYLOR S.L.
POMS Roland Ernest
DELAHAUT Philippe
Publication Year: