Guidelines for Single Laboratory Validation (SLV) of Chemical Methods for Metals in Food

Introduction

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The application of analytical methods within a regulatory analysis or accredited laboratory framework imposes certain requirements on both the analyst and laboratory. Under ISO-17025, accredited laboratories are expected to demonstrate both "fitness for purpose" of the methods for which they are accredited and competency of their assigned analysts in performance of the methods¹. The Codex Alimentarius Commission has issued a general guideline for analytical laboratories involved in the import and export testing of foods which contains four principles²:

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- Such laboratories should demonstrate internal quality control procedures which meet the requirements of the Harmonised Guidelines for Internal Quality Control in Analytical Chemistry³;
- Such laboratories should be regular participants in appropriate proficiency testing schemes which have been designed and conducted as per the requirements of the International Harmonized Protocol for Proficiency Testing of (Chemical) Analytical Laboratories⁴;
- Such laboratories should become accredited for tests routinely performed according to ISO/IEC-17025:1999 General requirements for the competence of calibration and testing laboratories (now ISO/IEC-17025¹); and
- Such laboratories should use methods which have been validated according to the principles laid down by the Codex Alimentarius Commission whenever such methods are available.

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General requirements for validation of analytical methods according to principles laid down by the Codex Alimentarius Commission are provided in the Codex Manual of Procedures, including provision for "single laboratory" validation of analytical methods³. However, there remains considerable misunderstanding among analysts as to precisely what is meant and what is required to demonstrate "method validation". Additional guidance for possible future inclusion in the Manual of Procedures is currently under discussion in the Codex Committee on Methods

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Yi-Tong Ma

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Thin Layer Chromatography in Drug Analysis Lukasz Komsta, Monika Waksmundzka-Hajnos, Joseph Sherma, 2013-12-20 Used routinely in drug control laboratories forensic laboratories and as a research tool thin layer chromatography TLC plays an important role in pharmaceutical drug analyses It requires less complicated or expensive equipment than other techniques and has the ability to be performed under field conditions Filling the need for an up to date Toxicology Ramesh C. Gupta, 2012-03-15 1e dr 2007 Distillers Grains KeShun Liu, Kurt A. Rosentrater, 2016-04-19 This reference provides in depth coverage of the history and current status of the fuel ethanol industry in the United States It examines processing methods scientific principles and innovations for making grain based fuel ethanol physical and chemical properties of distillers dried grains with solubles DDGS assay methodologies for compositional analyses and mycotoxin occurrence in DDGS The contributors also discuss changes during processing and analysis of factors causing variations in compositional nutritional and physical values Additional chapters cover emerging uses for DDGS including feed for livestock feedstocks for bioenergy production ingredients for food and industrial materials Chemical Analysis of Antibiotic Residues in Food Jian Wang, James D. MacNeil, Jack F. Kay, 2011-11-29 An insightful exploration of the key aspects concerning the chemical analysis of antibiotic residues in food The presence of excess residues from frequent antibiotic use in animals is not only illegal but can pose serious health risks by contaminating products for human consumption such as meat and milk Chemical Analysis of Antibiotic Residues in Food is a single source reference for readers interested in the development of analytical methods for analyzing antibiotic residues in food It covers themes that include quality assurance and quality control antibiotic chemical properties pharmacokinetics metabolism distribution food safety regulations and chemical analysis In addition the material presented includes background information valuable for understanding the choice of marker residue and target animal tissue to use for regulatory analysis This comprehensive reference Includes topics on general issues related to screening and confirmatory methods Presents updated information on food safety regulation based on routine screening and confirmatory methods especially LC MS Provides general guidance for method development validation and estimation of measurement uncertainty Chemical Analysis of Antibiotic Residues in Food is written and organized with a balance between practical use and theory to provide laboratories with a solid and reliable reference on antibiotic residue analysis Thorough coverage elicits the latest scientific findings to assist the ongoing efforts toward refining analytical methods for producing safe foods of animal origin **Seafood and Freshwater Toxins** Luis M. Botana, 2008-01-28 The occurrence of marine and freshwater toxins is a rapidly evolving problem due to ever changing circumstances Expanding international commerce is forcing cargo ships into virgin territory deforestation and pollution violate the natural ecological balance and a changing climate holds unknown potential to alter current factors and trigger toxic Improving Import Food Safety Wayne Ellefson, Lorna Zach, Darryl Sullivan, 2012-10-22 Food safety has been a global concern for many years While

global sourcing of foods and ingredients provides great opportunity for variety and diversity of cultural products there are significant risks Programs that regulate food safety and quality in countries around the world vary in their scope and effectiveness with many being underfunded Rapidly developing countries may lack the expertise laboratory resources for testing and established inspection programs to adequately promote the safety of foods Rather these countries may be more focused on providing enough food for their citizens Lack of documentation or traceability in the exporting country can further exacerbate the situation Of course safety problems in food imported from more developed countries also occur and the source of food borne disease outbreaks are found regularly within the United States Improving Import Food Safety gathers together vital information on the food safety programs of national governments the food industry and the testing industry Chapters have been contributed by authors from the United States Latin America Europe and Asia Readers will learn about a variety of regulatory approaches to food safety at the federal and state levels in the United States as well as in selected countries and within the food industry itself They will also gain insights into the nature and source of safety problems in addition to approaches to food safety around the world The book is divided into three sections Highlighting Key Issues authors illustrate the millions of permutations for the origin of ingredients discussing the difficulty if policing imports providing a unique perspective on the economic situation in China and insight into development of support for small farm producers in Mexico Legal and Regulatory Issues Structures in the USA and Abroad describes the legal and regulatory system in the European Union the United States and China plus a chapter addressing global approaches to fraud Potential Strategies to Improve Import Safety presents strategies to deal with what are ultimately global issues but on multiple levels Perspectives are provided by authors from Industry and industry trade association academia and a recently semi retired global ambassador or food safety Readers will find this book noteworthy because of the diverse topics and perspectives offered on the challenges of keeping food safe in a global economy Authors come from a variety of backgrounds and each has provided a unique perspective on this critical topic The volume is aimed at importers and exporters of food and ingredients food microbiologists food safety and QC QA personnel regulatory and legal personnel in food manufacturing companies food policy makers and regulatory officials and facility and graduate students in food science Nutraceutical and Functional Food Regulations in the United States and Around the World Debasis Bagchi, 2008-07-18 Globalization of the nutraceutical and functional food industries presents significant challenges not the least of which is the regulatory variance between countries active in the marketplace Nutraceutical and Functional Food Regulations in the United States and Around the World has been written by eminent experts in the field with the specific intention of addressing these important considerations Beginning with insights into the scope importance and growing opportunities in these industries the book demonstrates the global scenario on the acceptance and demand for nutraceuticals and functional foods It explores the regulatory hurdles and claim substantiation of these foods and dietary supplements as well as the intricate aspects of

manufacturing procedures Including regulations from South America Canada European Union Australia New Zealand Africa Japan Korea China India and Southeast Asia as well as the United States Nutraceutical and Functional Food Regulations in the United States and Around the World provides a valuable resource for understanding the key considerations of operating in this rapidly expanding area Overview of nutraceutical and functional food regulations around the world Discusses the important of GRAS status and DSHEA regulations Provides insight on quality manufacturing techniques cGMP and standardized analytical techniques Includes salient features on overcoming regulatory hurdles Addresses the importance of safety efficacy and human clinical studies for worldwide acceptance Highlights anti terrorism safety assurance through traceability Explores the significance of intellectual property trademark and branding on marketing Toxins and Toxicants, 2 Volume Set Yiu-Chung Wong, Richard J. Lewis, Sr., 2017-09-25 Analysis of Food Toxins and Toxicants consists of five sections providing up to date descriptions of the analytical approaches used to detect a range of food toxins Part I reviews the recent developments in analytical technology including sample pre treatment and food additives Part II covers the novel analysis of microbial and plant toxins including plant pyrrolizidine alkaloids Part III focuses on marine toxins in fish and shellfish Part IV discusses biogenic amines and common food toxicants such as pesticides and heavy metals Part V summarizes quality assurance and the recent developments in regulatory limits for toxins toxicants and allergens including discussions on laboratory accreditation and reference materials Botanicals Kurt Revnertson, Khalid Mahmood, 2015-01-13 The international trade in plants is growing steadily as the worldwide demand for natural and botanical raw materials increases Customers value natural products and botanicals as green alternatives safer ingredients for their families which also represent an environmentally and socially responsible choice for the planet In order to build Harmful Algal Blooms Sandra E. Shumway, JoAnn M. Burkholder, Steven L. Morton, 2018-08-06 Harmful Algal assura Blooms A Compendium Desk Reference erl utert die Grundlagen der sch dlichen Algenbl te HAB und bietet die notwendigen technischen Informationen wenn es um unerwartete oder unbekannte sch dliche Ereignisse in Zusammenhang mit Algen geht Dieses Fachbuch behandelt die Gr nde fr die sch dliche Algenbl te erfolgreiche Management und Monitoring Programme Kontroll Pr ventions und Minderungsstrategien die wirtschaftlichen Folgen Gesundheitsrisiken sowie die Folgen fr die Nahrungskette und kosysteme Dar ber hinaus bietet es ausf hrliche Informationen zu den hufigsten HAB Arten Harmful Algal Blooms A Compendium Desk Reference ist ein unsch tzbares Referenzwerk fr Manager Einsteiger in das Fachgebiet Praktiker mit eingeschr nkten Zugang zu wissenschaftlicher Literatur und alle die schnell Zugriff auf Informationen ben tigen insbesondere vor dem Hintergrund neuartiger oder unerwarteter HAB Ereignisse Die drei Herausgeber geh ren zu den weltweit f hrenden Forschern auf dem Fachgebiet F hrende Experten haben ebenfalls zu diesem Fachbuch beigetragen das sich zu einem wichtigen Referenzwerk des Fachgebiets entwickeln wird zumal das Thema immer mehr an Bedeutung gewinnt <u>Light Metals—Advances in Research and Application: 2012 Edition</u>, 2012-12-26 Light Metals

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sign checks and describes some flight experiences which called for design updates The book is unique for its strong practical flavour and is directly useful to the working engineers in the field and post graduate students in Aerospace Engineering

StarBriefs Plus Andre Heck,2004-03-31 With about 200 000 entries StarBriefs Plus represents the most comprehensive and accurately validated collection of abbreviations acronyms contractions and symbols within astronomy related space sciences and other related fields As such this invaluable reference source and its companion volume StarGuides Plus should be on the reference shelf of every library organization or individual with any interest in these areas Besides astronomy and associated space sciences related fields such as aeronautics aeronomy astronautics atmospheric sciences chemistry communications computer sciences data processing education electronics engineering energetics environment geodesy geophysics information handling management mathematics meteorology optics physics remote sensing and so on are also covered when justified Terms in common use and or of general interest have also been included where appropriate

Principles and Practices of Method Validation A Fajgelj, A Ambrus, 2007-10-31 Principles and Practices of Method Validation is an overview of the most recent approaches used for method validation in cases when a large number of analytes are determined from a single aliquot and where a large number of samples are to be analysed Much of the content relates to the validation of new methods for pesticide residue analysis in foodstuffs and water but the principles can be applied to other similar fields of analysis Different chromatographic methods are discussed including estimation of various effects eg matrix induced effects and the influence of the equipment set up The methods used for routine purposes and the validation of analytical data in the research and development environment are documented The legislation covering the EU Guidance on residue analytical methods an extensive review of the existing in house method validation documentation and guidelines for single laboratory validation of analytical methods for trace level concentrations of organic chemicals are also included With contributions from experts in the field any practising analyst dealing with method validation will find the examples presented in this book a useful source of technical information **Electrical & Electronics Abstracts**, 1989 **Acronyms in Aerospace and Defense** Peter B. Landecker, Fernando B. Morinigo, 2002 **Government Reports Annual Index**, 1990

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