

Presentation
to
Analytical Environmental Immunochemical Consortium

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ILSI

International Life Sciences Institute

A public, non-profit foundation established in 1978, with branches worldwide

Brings together scientists from academic, government and industry to resolve scientific issues of mutual interest

Works in the areas of nutrition, food safety, toxicology and environmental health

Recognized as a non-governmental organization by WHO and FAO

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Biotechnology Efforts

Interest in food biotechnology beginning in the late 1980's

Provided a home for industry effort which led to the development of published guidelines for the safety evaluation of foods/ food ingredients produced by genetic modification

ILSI North America included biotechnology as the focus of a scientific session in conjunction with its 1989 annual meeting

ILSI Japan sponsored scientific programs in 1989 and again in 1993

ILSI addressed the issue of allergenicity of genetically modified foods/food ingredients in a comprehensive report published in 1996

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ILSI International Food Biotechnology Committee

Background

Established during 1997 in response to recognition by ILSI members that scientific issues related to the development, distribution, safety, and public acceptance of foods and food products produced by modern biotechnology are global in scope.

Committee can provide an important forum to work collectively to address the many scientific questions and issues

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ILSI International Food Biotechnology Committee

Objectives

Serve as a focal point for gathering information on scientific and regulatory developments around the world as they relate to food biotechnology

Serve as a resource for all ILSI branches and institutes by developing programs to address scientific issues in food biotechnology

Collaborate with ILSI branches and other ILSI entities to ensure that scientific information about food biotechnology is available to the scientific and regulatory communities throughout the world

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ILSI International Food Biotechnology Committee

Program Examples

Assisted many ILSI branches and entities in presenting scientific meetings on the topic of food biotechnology, including Argentina, Southeast Asia, Thailand, Korea, China, India, Brazil, North Africa & Gulf Region, Australia, and Mexico

Collaborated with ILSI Europe to organize and support the Workshop on Detection Methods for Novel Foods Derived from Genetically Modified Organisms in June 1998

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WORKSHOP ON DETECTION METHODS FOR NOVEL FOODS
DERIVED FROM GENETICALLY MODIFIED ORGANISMS
June 3-5, 1998, Brussels, Belgium

sponsored by

ILSI Europe

ILSI International Food Biotechnology Committee

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1998 Detection Methods Workshop

Purpose: to explore the attributes and limitations associated with analytical procedures for detecting the presence of genetically modified foods and food ingredients

Participants: nearly 100 government, industry, academic and public sector scientists

Format: Plenary presentations and working group discussions

Publication: *Food Control*, Vol 10, No 6, December 1999

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1998 Detection Methods Workshop

Objectives:

Examine sampling strategies and sample preparation

Evaluate the state-of-the-science relative to both DNA and protein detection methods

Identify validation and performance criteria for assessing the sensitivity, specificity, reproducibility, and reliability of existing methods

Discuss the approaches to developing standards and reference materials

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1998 Detection Methods Workshop

Session 1	General Introduction
Session 2	Detection of Modified Protein
Session 3	Detection of DNA
Session 4	Validation Criteria for Compliance Working Groups Sampling Standards and Reference Materials DNA - Qualitative Analysis DNA - Quantitative Analysis Protein
Session 5	Plenary Discussion

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1998 Detection Methods Workshop

Recommendations and Conclusions

- The production of appropriate reference materials as the basis for the validation of analytical detection methods and for the assessment of method performance should be regulated and *not* the methods for detection.
- Protein immunoassays (e.g. ELISA) appear to be the methods of choice for screening raw materials and basic ingredients when the presence of modified proteins can be expected.
- PCR methods are available for qualitative screening and quantitation of DNA in virtually all DNA-containing food matrices. Quantitation is possible using internal or external calibration standards.
- Both DNA or protein detection methods can be expected to yield false-positive findings.

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1998 Detection Methods Workshop

Recommendations and Conclusions (cont.)

- There is an urgent need for internally validated detection methods that fulfill certain performance criteria, rather than for standardized methods, given the relatively slow process of standardization.
- Further development and validation of methods will be contingent upon the establishment, in Europe, of thresholds for labeling and for GM-free declarations.
- There is value to establishing a list (“negative list”) of ingredients that would not need to be analyzed for GM content.
- A database should be created to provide information on the types of genetic modifications, target and marker gene sequences, target organisms, etc.
- Further research is needed to facilitate the development, evaluation, and validation of DNA and protein detection methods.

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Proposed Followup Workshop

Working Title: Methodological Developments in Relation to Regulatory Requirements Concerning GM foods

Sponsors: ILSI Europe and ILSI International Food Biotechnology Committee in collaboration with EC Joint Research Centre

Date/Place: December 2000, Brussels, Belgium

Focus: Further exploration of sampling and detection methods as applied to different food matrices, e.g., seed, feed, foods and their validation

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Proposed Followup Workshop

Areas of interest:

- Sampling
- Reference materials / control materials / standards materials
- DNA detection methods
- Protein detection methods
- Traceability/identity preservation
- Validation

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Proposed Followup Workshop

Sampling

- Distinguishing between GM, non-GM, and GM-free foods
- Agricultural sampling plans, e.g., different plant varieties; different events
- Definition of GMO-free
- Identity preservation
- Influence of the sampling plan on the levels of confidence in test results
- Relationships between processing stage and sampling, e.g., raw agricultural commodity, ingredient, food product

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Proposed Followup Workshop

Reference materials / control materials / standards materials

- Definitions of each
- Relationship between degree of processing and reference materials / control materials / standards materials
- Clarification of stage of enforcement, where in the food processing chain does compliance testing occur
- Production and certification of standards
- Appropriate materials for testing of products with stacked traits
- Establishing criteria for defining standards, i.e., purified DNA, purified protein
- Influence of method on the selection of reference materials, etc., e.g., line-specific, product-specific

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Proposed Followup Workshop

DNA methods

- Comparative evaluation of available quantitative methods
- Criteria for determining amplicon length
- Criteria for method selection
- Prescribed vs performance-based methods
- Method sensitivity and specificity
- Criteria for method validation
- Defining precision and accuracy; confidence levels

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Proposed Followup Workshop

Protein Methods

- Same as those noted under DNA methods
- Relevance of method for related proteins
- Variations in protein expression in different products