FEDERAL INSTITUTE FOR RISK ASSESSMENT

BfR
Risiken erkennen – Gesundheit schützen

2nd International Workshop on Harmonisation of GMO detection and Analysis

Practical Implementation of ISO standards and Codex guidelines

Hermann Broll

Federal Institute for Risk Assessment (BfR)
Berlin, Germany

From „Health Office“ (Gesundheitsamt) to the BfR

- Kaiserliches Gesundheitsamt (1876-1919)
- Reichsgesundheitsamt (1919-45)
-
-
- Bundesgesundheitsamt (1952-1994)
  „Federal Health Office“
- Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (1994-2002)

“Federal Institute for Health protection of Consumers and Veterinary Medicine”

BfR
Risiken erkennen – Gesundheit schützen

risk assessment

Gesetz zur Neuorganisation des gesundheitlichen Verbraucherschutzes und der Lebensmittelsicherheit

Vom 6. August 2002

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

risk management

Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR)

- Established 1st of November 2002;
- 31st of October 2002: BgVV disappeared by law
- based on an expert opinion asked by the federal government regarding food safety;
- separation of risk assessment and risk management;
- BfR duties:
  - risk identification in advance,
  - preparation of scientific opinions and reports and
  - Communication of those hazards and risks to the public.

Locations

The BfR is located in three areas in

- Berlin-Dahlem (main buildings) and

- Berlin-Marienfelde

Content

- ISO/CEN standards and their relevance
- Codex Alimentarius activites dedicated to GMOs
- Practical Implementation of Codex and ISO requirements
- Developments on international level towards harmonisation of GMO detection

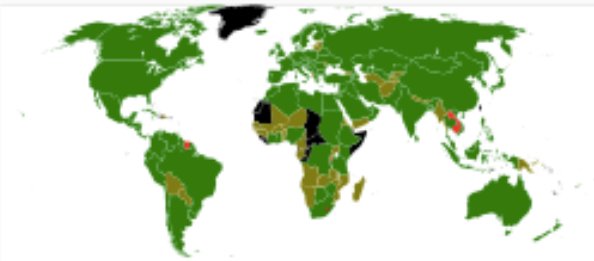
International Organization for Standardization (ISO)

- ✓ The International Organization for Standardization widely known as ISO, is an international-standard-setting body composed of representatives from various national standards organizations;
- ✓ ISO is a non-governmental organization;
- ✓ It is setting standards that often become law, either through treaties or national standards;
- ✓ Therefore it makes it more powerful than most non-governmental organizations.
- ✓ Standards, technical specifications etc are usually developed together with experts from governmental organisations, company representatives and other interested stakeholders.

International Organization for Standardization
Organisation internationale de normalisation
Международная организация по стандартизации [1]

ISO International Organization for Standardization

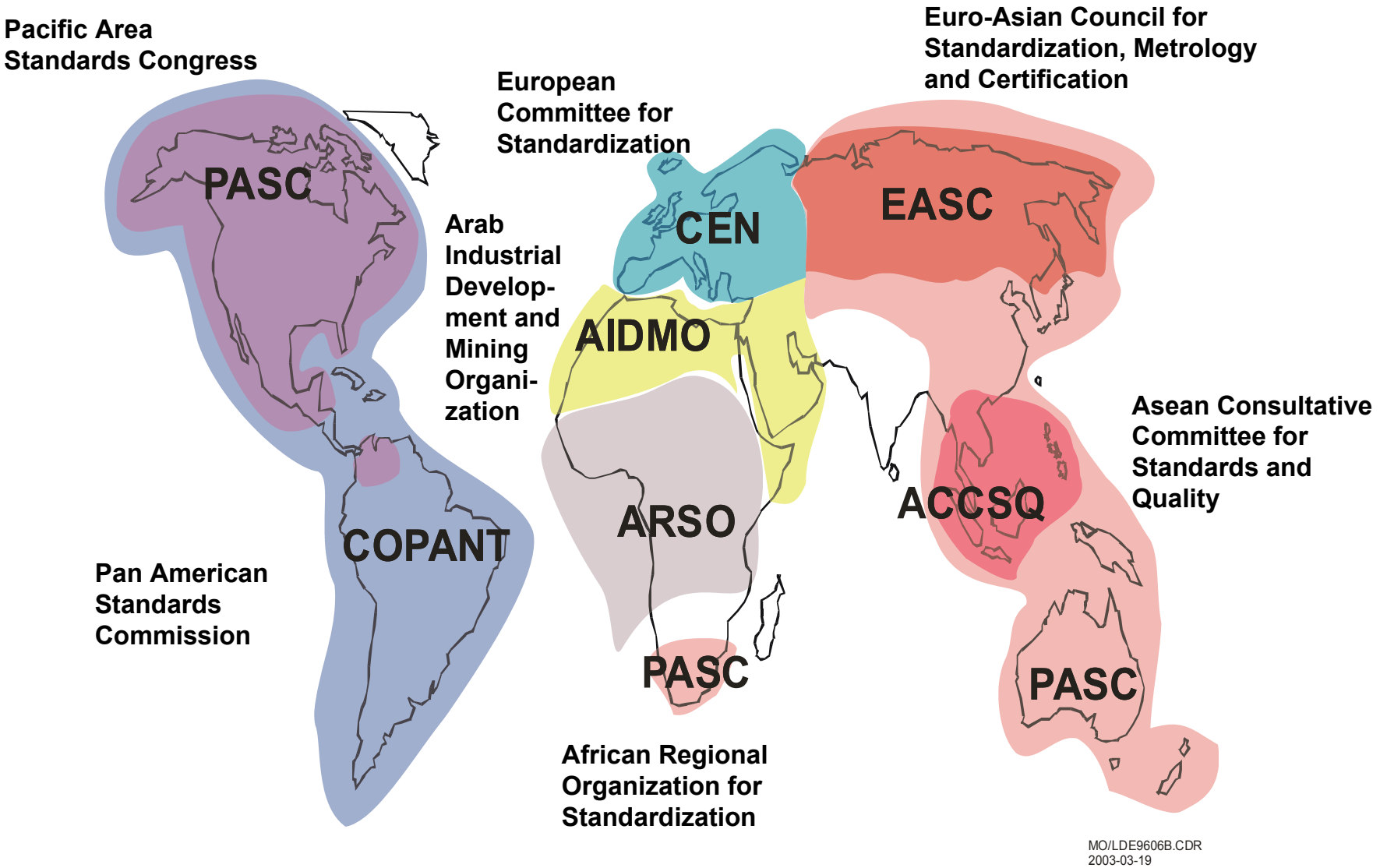
English language logo of the ISO



List of members

Formation	23 February 1947
Type	NGO
Purpose/focus	International standardization
Headquarters	Geneva, Switzerland
Membership	163 members[2]
Official languages	English, French and Russian
Website	www.iso.org

Regional standardization bodies



CEN TC 275 Food analysis - Horizontal methods
WG 11: Genetically modified foodstuffs

Convener: Dr. Marianna Schauzu, Federal Institute for Risk Assessment, Berlin
Secretary: Carola Seiler, DIN, Germany

EN ISO	Topic	Stage	Details
21572	Foodstuffs - Methods for the detection of genetically modified organisms and derived products - **Protein based method**	Standard ratified in November 2003	**Corrigendum to change the status of the Annex from "normative" into "informative" has been published by ISO and is under way in CMC**
21571	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - **Nucleic acid extraction**	Standard ratified in February 2005	
21569	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - **Qualitative nucleic acid based methods**	Standard ratified in June 2005	
24276	Foodstuffs - Nucleic acid based methods of analysis for the detection of genetically modified organisms and derived products - **General requirements and definitions**	Standard ratified in January 2006	
21570	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - **Quantitative nucleic acid based methods**	Standard ratified in October 2005	
21568	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products – **Sampling**	European Technical Standard 2006	**No agreement within ISO**

Sampling prEN TS 21568
consignment → lab sample

DNA based methods

Extraction
EN ISO 21571
test sample→ DNA

GMO detection
DNA→ test result

Screening
EN ISO 21569
Qualitative PCR

Identification
EN ISO 21569
Qualitative PCR

Quantitation
EN ISO 21570
Quantitative PCR

Protein based methods EN ISO 21572

Extraction
test sample→ Protein

GMO detection
Protein → test result

Screening

Identification

Quantitation

General document EN ISO 24276

CEN → ISO

2008

“According to the Vienna Agreement, the secretariat for the future work on those EN/ISO standards concerning GMO, which were elaborated under CEN/TC 275/WG 11 (CEN-Lead), has been transferred to ISO. The responsible expert group is ISO/TC 34/SC 16 which had its first meeting in Chicago from 11th to 13th November 2008.”

ISO/TC 034/SC 16 "Horizontal methods for molecular biomarker analysis"

ISO/TC 034/SC 16 "Horizontal methods for molecular biomarker analysis"

N-Documents

Zip & Download | Collect

Type	N Number	Title (Description)	Document Type	Document Sub Type	Exp. Action	Due Date	Creation Date
	23	WG 1 Comments on tomato quantitative N16 (replaces N 22)			Info	None	2011-02-18
	22	~~WG 1 Comments on tomato quantitative N16 (replaced by N 23)~~			Info	None	2011-02-17
	21	WG 1 Comments on tomato qualitative N12			Info	None	2011-02-17
	20	WG 1 Comments on duplex screening N10			Info	None	2011-02-17
	19	WG 1 Comments on CTP2-CP4EPSPS N8			Info	None	2011-02-17
	18	WG 1 Comments on Bt63 construct specific N6			Info	None	2011-02-17
	17	WG 1 Comments on bar screening N4			Info	None	2011-02-17
	16	Chinese proposal for tomato LAT52 gene for QN (68B)			Comment	2011-01-31	2010-11-29
	15	Validation report for tomato LAT52 gene (68A)			Comment	2011-01-31	2010-11-29
	14	Validation on tomato LAT52 gene 2008 (68C)			Comment	2011-01-31	2010-11-29
	13	Validation tomato LAT52 2005 (68D)			Comment	2011-01-31	2010-11-29
	12	Chinese proposal for tomato LAT52 gene for QL (68E)			Comment	2011-01-31	2010-11-29
	11	Validation Duplex-Screening-method (72A)			Comment	2011-01-31	2010-11-29
	10	German proposal Duplex-Screening-method (72B)			Comment	2011-01-31	2010-11-29
	9	Validation CTP2-CP4EPSPS (69A)			Comment	2011-01-31	2010-11-29
	8	German proposal CTP2-CP4EPSPS Construct-specific method (69B)			Comment	2011-01-31	2010-11-29
	7	Validation Bt63 construct specific method (071)			Comment	2011-01-31	2010-11-29
	6	German proposal Bt63 construct specific method (71B)			Comment	2011-01-31	2010-11-29
	5	Validation bar screening method (70A)			Comment	2011-01-31	2010-11-29
	4	German proposal - bar-screening-method (70B)			Comment	2011-01-31	2010-11-29
	3	003 Template for comments			Info	None	2010-11-15
	2	SC 16 N 081 Call for WG experts			Info	None	2010-08-19
	1	SC 16 N 080 Resolutions 2nd plenary meeting ISO/TC 34/SC 16			Info	None	2010-08-19

Zip & Download | Collect

Summary of Work Program of ISO/TC 34/SC 16

I.D.	Title	Project Leader	Action required	Action by:
EN ISO 21572	Foodstuffs - Detection of genetically modified organisms and derived products - Protein based methods	Dave Grothaus (US)	Provide revised standard	2009/01/01
EN ISO 21569	Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods	Manuela Schultze (DE)	Provide text for corrigendum or revision	2009/02/01
EN ISO 21570	Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods	Frédéric Bois (FR)	Provide text for corrigendum or revision	2009/02/01
EN ISO 21571	Foodstuffs – Methods of analysis for the detection of genetically modified organisms and derived products – Nucleic acid Extraction	Lutz Grohmann (DE)	Provide text for corrigendum or revision	2009/02/01
EN ISO 24276	Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products – General requirements and definitions	Laurence Amat (FR)	Secretary requests comments	2009/03/01
ISO/TS 21098	Foodstuffs — Nucleic acid based methods of analysis of genetically modified organisms and derived products — Information to be supplied and procedure for the addition of methods to ISO 21569, ISO 21570 or ISO 21571	Ray Shillito (US)	Call for experts	2009/01/15

Summary of Work Program of ISO/TC 34/SC 16

I.D.	Title	Project Leader	Action required	Action by:
			project	
Methods previously proposed to be annexed to ISO 21570	Event-specific method for the quantitation of maize line MON863 using real-time PCR. Event-specific method for the quantitation of sugar beet line H7-1 using real-time PCR. Event-specific method for the quantitation of maize line TC1507 using real-time PCR	JRC	JRC to inform Secretariat of any progress	
NWIP	General requirements for molecular biology using analysis for detection and identification of pathogenic and destructive organisms of the plants and derived products	France	NWIP vote in progress	2009/02/27
NWIP	Principles of selection and criteria of validation for the varietal identification methods using specific nucleic acid analysis	France	NWIP vote in progress	2009/02/27
New Annex 21569	Construct-specific method for the qualitative detection of genetically modified DNA sequences in papaya ringspot resistant papaya (Carica papaya)	Andrew Damant (UK)	Nomination of Experts for *ad hoc*	2009/01/15
New Annex 21569	Real-time PCR based screening method for the detection of genetically modified plant DNA	Andrew Damant (UK)	Nomination of Experts for *ad hoc*	2009/01/15

General requirements for the competence of testing and calibration laboratories EN ISO/IEC 17025

- **Scope**

  Specification concerning the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods

- **management requirements**

  Organization, quality system, document control, subcontracting of test + calibrations, complaints, control of records, internal audits, management review, etc.

- **technical requirements**

  Personnel, accommodation + environmental conditions, test + calibration methods, equipment, measurement traceability, sampling, assuring the quality of test + calibration results, reporting results, etc.

Traceability
Requirements of ISO/IEC 17025

- **Measurements must be traceable to SI, where feasible**
- **Where above is not feasible, traceability to other measurement standards must be established**
- **This can be achieved by use of transfer standards, that are themselves traceable to higher level standards**
- **The degree of rigour required depends on the contribution of the calibration uncertainty to the total uncertainty**

EN ISO/IEC 17025

5.4 Test and calibration methods and method validation

5.4.1 General

The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

5.4.2 Selection of methods

The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.

ISO/IEC 17025, 5.9

Quality control

- Regular use of certified reference materials and/or internal quality control using secondary reference materials
- Participation in proficiency-testing programmes
- Replicate tests or calibrations using the same or different methods

What is Codex Alimentarius?

- ✓ Codex Alimentarius (Latin for "food book") is a collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety;
- ✓ Codex Alimentarius was established in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO);
- ✓ In 2006, 99 % of the world's population were represented in Codex Alimentarius Commission through 174 member countries and one Member Organization (European Union);
- ✓ Commission's main aims are stated as being to protect the health of consumers and ensure fair practices in the international food trade;
- ✓ The Codex Alimentarius is recognized by the World Trade Organization (WTO) as an international reference point for the resolution of disputes concerning food safety and consumer protection;
- ✓ Codex Alimentarius covers all foods, whether processed, semi-processed or raw, but far more attention has been given to foods that are marketed directly to consumers;
- ✓ It contains general standards covering matters such as food labeling, food hygiene, food additives and pesticide residues, and procedures for assessing the safety of foods derived from modern biotechnology;
- ✓ It also contains guidelines for the management of official (i.e., governmental) import and export inspection and certification systems for foods;
- ✓ The Codex Alimentarius is published in Arabic, Chinese, English, French and Spanish.

Codex Alimentarius – stepwise procedure

Step 1

The project proposal is reviewed by the Executive Committee and compared against the criteria and priorities established by the Commission.

Steps 2, 3 and 4

A draft text is prepared (Step 2) and circulated to member countries and all interested parties for comment (Step 3). The draft and the comments are reviewed at Committee level (Step 4) and, if necessary, a new draft is prepared.

Step 5

The Commission reviews the progress made and agrees that the draft should go to finalization. After this stage, the draft is also endorsed by the relevant General Subject Committees so that it is consistent with Codex general standards.

Steps 6 and 7

The approved draft is sent again to governments and interested parties for comment and finalized by the relevant Committee. The draft is submitted to the Commission for adoption.

Step 8

Following a final round of comments, the Commission adopts the draft as a formal Codex text. The standard, guideline or other text is then published by the Codex Secretariat.

General Principles of the Codex Alimentarius

“The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.”

Codex Alimentarius – scientific sounds

- *"The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis …";*
- *Codex Alimentarius work is dedicated to member countries;*
- *However, since its beginning, the Commission has welcomed the participation of consumers, whose organizations have been represented at its sessions;*
- *Decisions are made based on consensus; there is normally no voting procedure established;*
- *Member countries are encouraged to adopted Codex standards, guidelines etc in national regulations.*

Codex Alimentarius is quoted in trade agreements

World Trade Organization (WTO)

- ✓**WTO is an organization that intends to supervise and liberalize international trade.**
- ✓**Existing since 1995 (before GATT)**
- ✓**The organization deals with regulation of trade between participating countries**
- ✓**The WTO has 153 members, representing more than 97% of total world trade**
- ✓**Decision making process is generally by consensus, and relative market size is the primary source of bargaining power**

World Trade Organization (English)
Organisation mondiale du commerce (French)
Organización Mundial del Comercio (Spanish)

WORLD TRADE ORGANIZATION

WTO founder members (January 1, 1995)
WTO subsequent members

Formation	January 1, 1995
Headquarters	Centre William Rappard, Geneva, Switzerland
Membership	153 member states
Official languages	English, French, Spanish[1]
Director-General	Pascal Lamy
Budget	189 million Swiss francs (approx. 182 million USD) in 2009.[2]
Staff	625[3]
Website	www.wto.org

wikipedia

Relevance of Codex Alimentarius – Fostering consumer protection worldwide

In 1985 United Nations General Assembly

Guidelines for consumer protection

Stated that:

"When formulating national policies and plans with regard to food, Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards from the Food and Agriculture Organization's ... and the World Health Organization's Codex Alimentarius ...".

In 1995 Agreement on the Application of Sanitary and Phytosanitary Measures (SPSS) and Agreement on Technical Barriers to Trade (TBT) of the World Trade Organization (WTO).

Formally recognized:

International standards, guidelines and recommendations, including the Codex Alimentarius, as reference points for facilitating international trade and resolving trade disputes in international law.

Codex Alimentarius is quoted in trade agreements (WTO)

SPS Agreement:

Agreement on the Application of Sanitary and Phytosanitary Measures

Article 2.2 of the SPS Agreement states:

“Members shall ensure that any sanitary and phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence ...”.

“The SPS Agreement has identified and chosen the standards, guidelines and recommendations established by the Codex Alimentarius Commission for food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. This means that Codex standards are considered scientifically justified and are accepted as the benchmarks against which national measures and regulations are evaluated.”

Codex Alimentarius is quoted in trade agreements (WTO)

TBT Agreement: Agreement on Technical Barriers to Trade

- ✓ **It exists to ensure that technical regulations, standards, testing, and certification procedures do not create unnecessary obstacles to trade;**
- ✓ **The TBT agreement strongly encourages countries to recognize the results of other countries' conformity assessment tests – the tests that determine whether a product conforms to a given standard;**
- ✓ **It also promotes the development of international standards and provides governments and inter-governmental bodies with guidance on how to best develop such standards. TBT members are strongly encouraged to adopt international standards as their technical requirements whenever possible.**

Article 2.6 of the TBT Agreement states:

"With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they have either adopted, or expect to adopt, technical regulations."

Codex Alimentarius is quoted in trade agreements

Codex and its work have been quoted in many bilateral and multilateral trade agreements

The North American Free Trade Agreement (NAFTA) between Canada, Mexico and the United States of America is such an agreement.

- It includes two ancillary agreements dealing with sanitary and phytosanitary measures and technical barriers to trade. With regard to food safety measures, Codex standards are cited as basic requirements to be met by the three member countries in terms of the health and safety aspects of food products.

Argentina, Brazil, Paraguay and Uruguay have signed the Treaty of Asunción, establishing the Southern Common Market (MERCOSUR).

- MERCOSUR's Food Commission has recommended a range of Codex standards for adoption by member countries and is using other Codex standards as points of reference in continuing deliberations.

In Asia and the Pacific area, economic cooperation arrangements have been formalized under Asia-Pacific Economic Cooperation (APEC).

- APEC has drafted a Mutual Recognition Arrangement on Conformity Assessment of Foods and Food Products. This calls for consistency with the requirements of the SPS and TBT Agreements as well as with Codex standards, including the recommendations of the Codex Committee on Food Import and Export Inspection and Certification Systems.

Codex Alimentarius is quoted in trade agreements

Codex and its work have been quoted in many bilateral and multilateral trade agreements, including:

- Mexico–Bolivia, 1995
- Baltic Area Free Trade Agreement, 1996
- Chile–Mexico, 1997
- Bulgaria–Turkey, 1998
- Central America–Chile, 1999
- Association of Southeast Asian Nations (ASEAN), 2000
- Turkey–Bosnia and Herzegovina, 2002
- Australia–Thailand, 2005
- United States of America–Australia, 2005

Developments within Codex Alimentarius regarding genetically modified foods

1999 Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology established at the 23rd Session of the CAC in Rome in June/July 1999 for a 4 years' period under the chairmanship of Japan

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology were developed on the basis of a pre-market safety evaluation of these foods on a case-by-case basis and Principles provide for post-market monitoring of potential consumer health effects and nutritional effects, as appropriate.

- Two detailed guidelines on the conduct of safety assessments, one for foods from DNA-modified plants and the other for foods from DNA-modified micro-organisms, include consideration of both intended and unintended effects of the genetic modification and an assessment of possible allergenicity have been developed.

- List of available analytical methods including those for the detection or identification of foods derived from biotechnology

Ad hoc Working Group on Analytical Methods

- established at the 1st meeting of the Codex *Ad Hoc* Intergovernmental Task Force on Food Derived from Biotechnology in Chiba, Japan, in March 2000, under the chairmanship of Germany

Methods reported by Member Countries and International Organisations

24 Reporting Countries / Organisations

26 GMOs detectable

235 Detection methods

- 177 DNA-based GM-specific methods
- 46 DNA-based GM-screening methods
- 12 Protein-based GM-specific methods

58 Quantitative methods (DNA + protein)

34 Validated methods

In 2004 the list has been sent to CCMAS for their consideration

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA AND VALIDATION OF METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS IN FOODS*

Starting point was the Codex Intergovernmental Task Force on foods derived from Biotechnology hosted by Japan 2000 - 2003

- **Establishment of a list of methods to identify those foods;**
- **WG lead by Germany;**
- **In 2004 the list have been sent to CCMAS for consideration;**
- **CCMAS felt unable to evaluate those methods based on PCR and immunological detection;**
- **Establishment of a WG lead by Germany and UK;**
- **In 2009 electronic working group was established lead by Argentina, UK and Germany;**
- **Consensus has been reached in last meeting in March 2010.**

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA AND VALIDATION OF METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS IN FOODS*

ALINORM 10/33/REP
JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Thirty-Third Session
International Conference Centre, Geneva, Switzerland, 5 - 9 July 2010
Report

Methods of Analysis and Sampling
Proposed Draft Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods 13
37. Several delegations expressed their support for this important document which reflected the wide applications of the methodologies concerned and their appreciation for the constructive contribution of all participants, noting that the electronic platform used by Argentina had been very useful and would be made available for use in other electronic working groups. The Commission adopted the Guidelines as proposed.

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA AND VALIDATION OF METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS IN FOODS*

- ✓ **Criteria are applicable to protein and DNA-based methods;**
- ✓ **Criteria approach, it is foreseen not to endorse individual methods;**
- ✓ **Scope includes applications such as 'food derived from modern biotechnology', food authentication, food speciation and other purposes;**
- ✓ **Contains the reference to 'food derived from modern biotechnology' twice;**
- ✓ **Title was modified to reflect the scope; 'foods derived from modern biotechnology' is still in the footnote to the title;**
- ✓ **Text was modified extensively during the sessions, however major parts are derived from the ENGL document 'Definition of minimum performance requirements for analytical methods of GMO testing';**
- ✓ **Modular Approach to Method Validation is included;**
- ✓ **On several places thresholds are indicated.**

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA AND VALIDATION OF METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS IN FOODS*

Requirements with defined thresholds in the document I:

Repeatability standard deviation (RSDr)

21. The relative repeatability standard deviation for the PCR step should **be ≤25%** over the whole dynamic range of the method.

Reproducibility standard deviation (RSDR)

22. The relative reproducibility standard deviation for the PCR step should be **below 35%** over the majority of the dynamic range, except at the limit of quantification, where the RSDR could be higher.

Robustness

23. Robustness is a measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage. Examples of such variations include: reaction volumes (e.g., 29 vs. 30µl), annealing temperature (e.g., +/- 1oC) and/or other relevant variations. The experiments need to be performed at least in triplicate. The response of an assay with respect to these small changes **should not deviate more than ±35%** in reproducibility experiments from the response obtained under the original conditions.

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA AND VALIDATION OF METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS IN FOODS*

Requirements with defined thresholds in the document II:

Sensitivity

25. For a quantitative PCR method, a linear relationship of the Ct as a function of the logarithm of the template concentration should be obtained across the range of the method. The correlation coefficient, y-intercept and slope of the regression line should be reported. **The % of residual for each of the calibrators should preferably be ≤30%.**

30. For assays selective for the target DNA. Experimental evidence of selectivity for the target DNA should include:

Two replicates should be analyzed for each DNA sample, which shall **give results within a Ct-value of 0.5.**

32. For assays on taxon-specific DNA sequences. Experimental evidence of taxon selectivity should include:

Two replicates should be analyzed for each DNA sample, which shall **give results within a Ct-value of 0.5.**

Trueness

35. A trueness value of **± 25%, in regards to the PCR step**, should be acceptable over the whole dynamic range.

Codex Alimentarius
JOINT FAO/WHO FOOD STANDARDS PROGRAMME

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 10/33/23

http://www.codexalimentarius.net/download/report/738/al33_23e.pdf

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-third Session
Geneva, Switzerland, 5-9 July 2010

REPORT OF THE THIRTY-FIRST SESSION OF THE
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Budapest, Hungary
8-12 March 2010

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA AND VALIDATION OF METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS IN FOODS*

If validated methods are available they might be submitted to CCMAS for endorsement as Codex standards?!

Either via:

- National contact points
- Standardization bodies in individual countries

Developments within Codex Alimentarius regarding genetically modified foods

Codex Committee for Food Labelling (CCFL)

- **In 1999 a WG was established to draft a text regarding GMO labelling**
- **WG comprised Japan, Thailand, India, Brazil, USA, Canada, European Community**
- **Text was drafted «Proposed draft recommendations for the Labelling of Food and Food Ingredients derived from Biotechnology»**
- **Options were given for method of production labelling as well as labelling only for significant changes in composition incl. nutrition**

Detection methods were mentioned for the first time in Codex system

Developments within Codex Alimentarius regarding genetically modified foods

Codex Committee for Food Labeling (CCFL)
Proposed draft Recommendations for the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering (at Step 3)

From „**Mandatory Labelling Provisions“**

From „**Voluntary Labelling Provisions “**

There is still no consensus reached; consequently no global standard for gm food labelling is existing

Developments within Codex Alimentarius also dedicated to genetically modified foods

Draft Revised Guidelines on Measurement Uncertainty

At step 6 of the Codex procedure
To be included as an Annex to the Guidelines on Measurement Uncertainty (CAC/GL 54-2004)

Explanatory Notes to the Codex Guidelines on Measurement Uncertainty

Users of validation data should note that sources of uncertainty that are not covered by validation studies include:
- Sampling
- Pre-treatment
- Method bias
- Variation in conditions
-Changes in sample matrix

4 different scenarios are described in the guideline (above maximum level incl. MU up to incl. MU less than maximum level)

Useful References

Developments within Codex Alimentarius also dedicated to genetically modified foods

GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS (CAC/GL 70-2009)

1. SCOPE

These guidelines provide guidance to governments on the procedures to resolve disputes which arise between food control authorities about the status of a food consignment, when the assessment based on test results made in the importing country disagrees with the assessment made by the exporting country on the same lot.

These guidelines only address disputes related to methods of analysis or laboratory performance and do **not** address questions of **sampling**. The procedure examines only the validity of the importing country's results on which non-compliance is alleged. It is recognised that disputes may arise from other cause(s), which should also be investigated.

These guidelines do not cover microbiological test results!

Developments within Codex Alimentarius also dedicated to genetically modified foods

GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS (CAC/GL 70-2009)

PREREQUISITES/ASSUMPTIONS for a applying these guidelines are:

- both countries agree on using this guideline;
- laboratories comply with quality assurance provisions;
- at least one representative sample5 from the same food lot has been taken;
- laboratories report quantitative analytical results in the form of “a ± 2u” or “a ± U”
- laboratories use specific methods of analysis, which have been endorsed by the Codex Alimentarius

THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED

ANALYSING RESERVE SAMPLE

ANALYSIS OF REMAINING RESERVE SAMPLE by third party (importing country can select a laboratory

The Commission adopted the Draft Guidelines in *Thirty-Second Session in 2009*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Thank you for your attention

Hermann Broll

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