

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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COMMUNICATION FROM ISO

(report of activities relevant to Codex work)

1. The International Organization for Standardization (ISO) has prepared this information paper following on-going communications between the Codex Alimentarius Commission (CAC) Secretariat and the ISO Central Secretariat. It provides a summary of current work undertaken by ISO that may be of interest to the CAC and has the intent to support and enhance the dialogue and coordination between the two organizations.

International Organization for Standardization (ISO)

2. ISO is the International Organization for Standardization (<http://www.iso.org>). ISO is a non-governmental organization established in 1947 with members consisting of the leading and recognized national standards organizations of 151 countries, on the basis of one member per country.

3. ISO has a Central Secretariat, based in Geneva, Switzerland, that employs approximately 150 staff. However, most of the work in developing and maintaining the portfolio of some 15 000 technical International Standards is shared amongst the membership, with individual national members providing and financing the Chairmanships and Secretariats for one or more of the 191 technical committees and 543 subcommittees managing some 2,200 working groups.

4. Two policy committees of ISO, DEVCO and COPOLCO, identify and monitor actions and programmes to encourage and facilitate the participation, respectively of developing countries and consumer interests, in standardization. A third policy committee of ISO, CASCO, deals with conformity assessment matters and is discussed later in greater detail.

International Standards

5. While the most well known standard in the ISO portfolio is ISO 9001:2000, *Quality management systems — Requirements*, the great majority of ISO standards do not relate to management system requirements. Rather they include terminology, sampling, test and analytical methods, interoperability as well as specifications and performance requirements for industrial and agricultural products, equipment, processes and, to a growing extent, services.

6. Application of the international standards that ISO produces starts out as being voluntary. In a majority of cases these standards are needed and used voluntarily as references within commercial contracts between market players, for example in procurement contracts or as a basis for companies to develop, test and market their products.

7. However, more and more standards are cited by regulators to provide a means of compliance with their technical regulations. This is recommended in the WTO TBT and SPS agreements so as to reduce technical barriers to trade, and, for example, by the United Nations Economic Commission for Europe (UNECE) and the Asia Pacific Economic Cooperation Subcommittee on Standards and Conformance (APEC SCSC), in the context of implementing good regulatory practices.

ISO's international status

8. ISO also has specific status with many UN agencies, including the WHO and FAO, and is an observer to the Codex Alimentarius Commission (CAC). It is also an observer at the WTO Committee on Trade and Environment (CTE), the Committee on Technical Barriers to Trade (WTO TBT), and the Committee on Sanitary and Phytosanitary Measures (SPS). In the area of technical assistance, ISO cooperates regularly with WTO and ITC, and has entered into a Memorandum of Understanding with UNIDO.

9. ISO's observer status to the CAC provides an opportunity for the coordination of issues related to a variety of ISO standards that are adopted and used by Codex in its work. According to the second edition of Volume 13, *Codex Alimentarius Methods of Analysis and Sampling, 1994*, ISO Committees with Standards adopted by Codex include: ISO/TC 34, *Food products* (310 Standards); ISO/TC 147, *Water quality* (19 Standards); ISO/TC 47, *Chemistry* (5 Standards), and 1 Standard in each of ISO/TC 24, *Sieves and other sizing methods*, ISO/TC 61, *Plastics* and ISO/TC 93, *Starch*. This list is also complemented by Codex's adoption of the CASCO Standard ISO/IEC 17025 for testing and calibration laboratories.

10. Although there are many ISO Committees with work affecting Codex, the priority areas of mutual interest on which ISO would like to maintain and expand a dialogue with the CAC are the work of ISO/TC 34 on food products and the generic work of the ISO Committee on conformity assessment (ISO/CASCO).

CODEX and ISO Cooperation

11. There is a long history of collaboration between the Codex Committees and ISO/TC 34, *Food products*. ISO/TC 34 is at present updating a document describing the technical cooperation between ISO/TC 34 and Codex with a view to supporting a sustainable framework for further collaboration between Codex and ISO, in order to enhance the mutual coordination of work and the elimination of duplication and contradictions.

12. Based on feedback from the CAC and its Executive Committee, the scope of the collaboration could also consider broader areas of cooperation between ISO and Codex including, for example, liaison and work with other ISO Committees, conformity assessment standardization (ISO/CASCO), and on-going policy-level exchange and coordination with ISO.

13. Codex and ISO activities are complementary. Codex, as a governmental organization, prepares documents to assist governments in their statutory and regulatory work to protect their citizens from health hazards caused by food consumption. ISO, as a non-governmental organization, prepares standards on test methods to assist stakeholders along the whole food chain to fulfil both the statutory and regulatory requirements, as well as the requirements of consumers of these products. ISO looks forward to receiving feedback from Codex and its members on areas of cooperation that need to be maintained and strengthened and to jointly working on practical modalities for implementing such coordination in a sustained and programmed manner.

14. ISO/TC 34 (the Chairmanship and Secretariat being held by the ISO member body for Hungary (MSZT)) comprises the following Subcommittees, held by secretariats from all round the world:

- SC 2 *Oleaginous seeds and fruits and oilseed meals* (AFNOR, France)
- SC 3 *Fruit and vegetable products* (PKN, Poland)
- SC 4 *Cereals and pulses* (MSTZ, Hungary)
- SC 5 *Milk and milk products* (NEN, Netherlands)
- SC 6 *Meat, poultry, fish, eggs and their products* (BOBS, Botswana)
- SC 7 *Spices and condiments* (BIS, India)
- SC 8 *Tea* (BSI, United Kingdom)

- SC 9 *Microbiology* (AFNOR, France)
- SC 10 *Animal feeding stuffs* (NEN, Netherlands)
- SC 11 *Animal and vegetable fats and oils* (BSI, United Kingdom)
- SC 12 *Sensory analysis* (AFNOR, France)
- SC 14 *Fresh, dry and dried fruits and vegetables* (TSE, Turkey)
- SC 15 *Coffee* (ABNT, Brazil)

15. ISO/TC 34 is preparing a new international standard based on a management systems approach as in ISO 9001:2000 as well as the principles of the hazard analysis and critical control point (HACCP) system. This new standard, ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*, was circulated for ISO member body voting on 5 May 2005 as a Final Draft International Standard (FDIS). The requirements are applicable to operators along the whole food chain wishing to design and implement an effective food safety management system. Codex has developed the general principles of food hygiene as well as the HACCP system and guidelines for its application. These documents help governments to establish suitable food safety regulations, and assist the relevant authorities to control the enforcement of these regulations.

16. The necessity for a new ISO International Standard was justified by the fact that a diversity of national standards (Danish, Dutch, Australian, Irish, etc.) has been developed and several retailer organizations have prepared documents (BRC, EFSIS, IFS, etc.) for the establishment and auditing of food safety systems, possibly including HACCP requirements. ISO 22000 should become an internationally accepted standard on a management system to address food safety requirements and may thus help to clarify and harmonize the present situation.

Members of the CAC may contact the ISO Central Secretariat contact person for ISO/TC 34 indicated below to obtain a copy of ISO/FDIS 22000.

17. ISO 22000, and its associated conformity assessment, should have a positive impact on the harmonization and proper implementation of voluntary and mandatory food import and export requirements, inspection and certification systems.

18. ISO/TC 34 is also working on two Technical Specifications to assist in the implementation of ISO 22000. ISO/TS 22003 will give specific requirements for bodies providing audit and certification of food safety management systems according to ISO 22000. It is based on the generic standard that covers the area of certification and auditing of management systems, namely, ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*. In this project, TC 34 is working closely with the ISO Committee on Conformity Assessment (CASCO). Another document, ISO/TS 22004, will give guidance on the application of ISO 22000 including guidance for small and medium-sized enterprises (SMEs) and developing countries. It is hoped that this will be published at the same time as ISO 22000 in the last quarter of 2005.

19. Work is also being undertaken in ISO/TC 34 on a new international standard entitled: ISO 22005, *Traceability in the feed and food chain — General principles and guidance for system design and development*. This will soon be at the Draft International Standard (DIS) stage. It will provide recommendations for the implementation of a traceability system both within and among organizations in the food chain.

20. The USA member body to ISO/TC 34 has also recently proposed the development of an ISO standard on *Guidance on the application of ISO 9001 for crop production*. If accepted, this would also be part of the ISO 22000 series.

21. ISO/TC 34 is also working with the European Committee for Standardization (CEN) TC 275 on a series of standards on methods to qualitatively detect genetically modified organisms (GMOs) and derived products by analysing the nucleic acids extracted from the sample under study. The main focus is on polymerase chain reaction (PCR) based amplification methods. The following standards are published or under vote.

ISO/DIS 21568, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Sampling*

ISO 21569:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods*

ISO/FDIS 21570, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods*

ISO 21571:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction*

ISO/DIS 24276, *Foodstuffs — Nucleic acid based methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions*

22. ISO/TC 34 is also currently considering a standard on *Good processing practices for the irradiation of foods intended for human consumption*. The item was recently accepted into the work programme of ISO/TC 34 as a Committee Draft (CD) 22810, following a proposal from Argentina (IRAM). Due to the increase in international trade of irradiated food, such a standard would address the need for a harmonized approach and help to increase the diffusion and application of this technology. Provisions of this standard could be used by an irradiation processor for the application of HACCP and the draft is based on existing Codex documents in this field.

23. With regard to analytical and test methods, in the field of milk and milk products, ISO/TC 34/SC 5 and the International Dairy Federation (IDF) work together to prepare analysis methods that are published jointly. Most of these analysis methods are taken into account by the Codex Commodity Committee on Milk and Milk Products and are endorsed by the Codex Committee on Methods of Analysis and Sampling. Important new work has started on a Technical Specification for the detection of *Enterobacter sakazakii* in milk and milk products. This bacterium has been found to exist in some infant formulations. The bacterium is thermotolerant and can remain after sterilization. Technical Specification (TS) 22964 is currently being discussed at the Joint Meeting of the IDF and ISO/TC 34/SC 5, and it is hoped that it will be published before the end of 2005.

24. ISO/TC 34/SC 9 develops horizontal methods for the enumeration of such contaminants as *Salmonella*, *Escherichia coli*, *Bacillus cereus*, thermotolerant *Campylobacter* and pathogenic *Vibrio*, and the use of polymerase chain reaction (PCR) for the detection of food-borne pathogens. AOAC International has accepted the ISO *Salmonella* test method as an AOAC Official Method of Analysis.

25. ISO/TC 34 will continue to offer its full support and cooperation to the Commission with a view to avoiding duplication of work and it will adopt, for its own documents, the conclusions of the Commission on all matters concerning food hygiene requirements.

ISO's conformity assessment standards and their use in food safety

26. ISO is an international documentary standards writer. It does not undertake assessments of conformity of products, management systems, processes or services against the requirements of the documentary standards it produces. It is true that some individual ISO national members do offer these services, but ISO as an entity does not.

27. ISO does however produce documentary standards on how assessment of conformity should take place - this is the role of the ISO Policy Committee on Conformity Assessment ([ISO/CASCO](#)). It is this body within ISO that is closest to covering the same subject matter as the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

28. As a consequence, ISO can be viewed as providing both international standards that relate to the characteristics of specific products, as well as providing generic horizontal standards that document agreed procedures for the assessment of conformity (e.g. testing, inspection and certification) of products and processes.

29. In relation to ISO/CASCO, most of the conformity assessment Guides have been or are in the process of being turned into International Standards. Annex 1 gives a list of recently completed, or nearly completed documents.

Conclusion

30. It is recognized that the Commission's members, as governments, have the authority to regulate at the national level and that ISO, as a producer of voluntary international standards, does not. In the framework of good regulatory practice, as promoted at international and regional levels, international standards and guides may be considered useful by regulators as effective and efficient tools to achieve important regulatory mandates, manage risk and address market confidence.

31. ISO considers that by using its international standards, regulatory authorities will achieve their aims in public health and safety at less cost to manufacturers, consumers and the taxpayer. Using international standards also assists countries to meet their WTO TBT and SPS Agreement obligations.

32. For any further information on technical developments within ISO that have been reported in this paper, please do not hesitate to contact the following individuals:

For matters related to ISO/TC 34, *Food products*:

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Recent ISO/IEC International Standards and Guides on Conformity Assessment

In relation to ISO/CASCO, most of the conformity assessment Guides have been or are in the process of being turned into International Standards. In particular, the following recently completed, or nearly completed documents may be of interest to the Commission:

- ISO/IEC 17000:2004, *Conformity assessment - Vocabulary and general principles*
- ISO/IEC Guide 60:2004, *Conformity assessment - Code of Good Practice*
- ISO/IEC Guide 68:2002, *Arrangements for the recognition and acceptance of conformity assessment results*
- ISO/IEC Guide 67:2004, *Conformity assessment - Fundamentals of product certification*
- ISO/IEC Guide 28:2004, *Conformity assessment - Guidance on a third-party certification system for products*
- ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*
- ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection* (Reconfirmed in 2002)
- ISO/IEC 17024:2003, *Conformity assessment - General requirements for bodies operating certification of persons*
- ISO/IEC DIS 17021, *Conformity assessment -- Requirements for bodies providing audit and certification of management systems*
- ISO/IEC 17011:2004, *Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC 17040:2005, *Conformity assessment -- General requirements for peer assessment of conformity assessment bodies and accreditation bodies*