

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

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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 as part of ongoing updates and communication 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 is intended to support and enhance 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 160 countries, on the basis of one member per country.

3. ISO has a Central Secretariat, based in Geneva, Switzerland, that employs 153 staff. However, most of the work in developing and maintaining the portfolio of more than 18 000 International Standards is shared amongst the membership, with individual national members providing and financing the Chairmanships and Secretariats for one or more of the 192 technical committees and 494 subcommittees managing some 2 300 working groups.

4. Two ISO policy committees, 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 ISO policy committee, CASCO, deals with conformity assessment matters; its work is discussed in greater detail further on in this document.

#### International Standards

5. While the most well known standard in the ISO portfolio is ISO 9001:2008, *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. The application of the International Standards that ISO produces starts out as being voluntary. In the 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 as a means to assist compliance with relevant governmental principles and/or technical regulations. This is recommended in the WTO TBT agreement and the SPS agreement (with regards specifically to CAC, OIE and IPPC) 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. In 2007, ISO published a new informative brochure entitled “*Using and referencing ISO and IEC standards for technical regulations*” to

describe certain advantages in using and referencing ISO and IEC standards. It provides examples in different sectors, and national and regional regulatory texts that refer to standards.

#### ISO's international status

8. ISO has a 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 regularly cooperates with the WTO and ITC, and has entered into a Memorandum of Understanding with UNIDO.

9. ISO also regularly participates in WTO SPS meetings and mentions its basic principles.

10. The Joint Committee for Guides in Metrology (JCGM), of which ISO is a Member Organization (BIPM, OIML, IEC, IUPAC, IUPAP, IFCC and ILAC are the other members of JCGM), has adopted a revised version of the International Vocabulary of Metrology (*International Vocabulary of Metrology — Basic and General Concepts and Associated Terms* (VIM). 3rd Edition), replacing the 2nd edition published in 1993. In the new edition, an attempt has been made to meet conceptual needs of measurements in fields such as biochemistry, food science, forensic science and molecular biology. JCGM members may publish the VIM under their own name. ISO and IEC have published the revised VIM as ISO/IEC Guide 99:2007.

#### ISO status in Codex

11. 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 document "*Recommended methods of analysis and sampling*" (CODEX STAN 234-1999), approximately 310 methods refer to ISO/TC 34 standards (*Food products*) (representing approximately 60 different ISO/TC 34 standards); 19 methods refer to ISO/TC 147 standards (*Water quality*); 5 methods refer to ISO/TC 47 standards (*Chemistry*), and 1 standard each refers to 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.

12. The priority areas of mutual interest on which ISO would like to maintain and nurture 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). It should however be noted that other ISO Technical Committees are working in fields that could be of interest for CAC:

- ISO/TC 54, *Essential oils* for which CAC has a liaison;
- ISO/TC 147, *Water quality* for which CAC has a liaison with its SC 2 and SC 4 (more details in point 43) (see [Annex 4](#) for the structure of ISO/TC 147);
- ISO/TC 234, *Fisheries and aquaculture* (which is a new committee created in February 2007) for which CAC has a liaison (more details in point 40) (see [Annex 3](#) for the structure of ISO/TC 234).

#### Codex and ISO/TC 34 Cooperation

13. There is a long history of collaboration between the Codex Committees and ISO/TC 34, *Food products*. ISO/TC 34 supports the establishment of an ongoing and sustainable framework for collaboration between Codex and ISO, in order to enhance the mutual coordination of work and the elimination of duplication and contradictions.

14. 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 in particular 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.

15. Since its creation in 1947, ISO/TC 34 has published 732 ISO deliverables (International Standards, Technical Specifications and Technical Reports). 65 % of these documents are test methods. See Annex 1 for the structure of ISO/TC 34.

16. Remaining unchanged for quite a long time, the structure of ISO/TC 34 was modified in 2008 with the establishment of a dedicated Subcommittee on biomarkers, SC 16 (see [Annex 1](#)).

17. Considering the scope of this new SC and the standards already published in this field by ISO/TC 34 (with the European Committee for Standardization (CEN)), the following standards were moved under the responsibility of SC 16:

- ISO 24276:2006, *Foodstuffs — Nucleic acid based methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions*

- ISO 21571:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction*
- ISO 21569:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods*
- ISO 21570:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods*
- ISO 21572:2004, *Foodstuffs — Methods for the detection of genetically modified organisms and derived products — Protein based methods*

It is to be noted that an ISO Technical Specification (not developed with CEN) was also published by ISO/TC 34 and moved under the responsibility of SC 16:

- ISO/TS 21098:2005, *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*

18. Concerning the current work programme of ISO/TC 34, in addition to dedicated work programmes dealing, for example, with *Fruit and vegetable products* (ISO/TC 34/SC 3), *Cereals and pulses* (ISO/TC 34/SC 4), *Milk and milk products* (ISO/TC 34/SC 5), *Animal and vegetable fats and oils* (ISO/TC 34/SC 11) or *Fresh, dry and dried fruits and vegetables* (ISO/TC 34/SC 14), several work items developed under the direct responsibility of ISO/TC 34 may also be of interest to Codex:

- ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*
- ISO/TS 22003:2007, *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*
- ISO/TS 22004:2005, *Food safety management systems — Guidance on the application of ISO 22000:2005*
- ISO 22005:2007, *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation*
- ISO/FDIS 22006, *Guidelines on the application of ISO 9001 for crop production* (under development)
- ISO/CD 22008, *Food irradiation — Requirements for the development, validation and routine control of the ionizing radiation process used for the treatment of food for human consumption* (under development)
- ISO/DIS 26642, *Food products — Determination of the glycemic index (GI) and relevant classification* (under development)
- ISO/WD 12824, *Royal Jelly — Specifications* (under development)
- ISO/NWIP, *Food services — Good Manufacturing Practices* (under registration vote)

19. WG 8 prepared ISO 22000 and ISO/TS 22004, both published in 2005. The adoption of a food safety management system by an organization involved in the food chain is a useful tool for ensuring compliance with requirements specified by law, statute, regulation and/or customers. The design and implementation of an organization's food safety management system are influenced by varying factors, in particular food safety hazards, the products provided, the processes employed and the size and structure of the organization. ISO/TS 22004 gives generic guidance to small and large enterprises on the use of ISO 22000, which is based on the principles of HACCP as described by the Codex Alimentarius Commission and is designed to be applied together with relevant standards published by that organization.

20. The publication of ISO/TS 22004 followed that of ISO 22000:2005, which is based on a management systems approach (as in ISO 9001:2000), as well as on the Codex hazard analysis and critical control point (HACCP) system. The need for a new ISO International Standard arose from the fact that several national standards (Danish, Dutch, Australian, Irish, etc.) have been developed and from the fact that retailer organizations have prepared documents (BRC, IFS, etc.) for the establishment and auditing of food safety systems, possibly including HACCP requirements. In that context, ISO 22000 should help clarify and harmonize the present situation. Considering the importance of these standards, ISO/TC 34 worked on its organization in order to ensure their long term management and agreed in 2008 to the establishment of a dedicated Subcommittee for the management of the "ISO 22000 family" (i.e. ISO 22000, ISO/TS 22003, ISO/TS 22004 and ISO 22005) in replacement of the current Working Groups (WG 8, WG 9 and JWG 11). This decision is to be ratified by the Technical Management Board of ISO.

21. 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. ISO 22000 underwent a systematic review process in 2008 in order to evaluate whether it should be confirmed, revised/amended or withdrawn. The outcome of this enquiry will be available soon.

22. The Publicly Available Specification BS PAS 220 was published at the end of 2008. This publication sets out the detailed requirements for the prerequisite programmes on food safety for food manufacturing. It is intended to be used to support management systems designed to meet the requirements specified in ISO 22000 in the food manufacturing industry.

23. The need for an international document containing requirements for bodies providing audit and certification of food safety management systems against ISO 22000 arose. However, to develop such a standard, the assistance of ISO/CASCO (Committee on conformity assessment) was needed. A Joint Working Group with ISO/CASCO (JWG 11) was established for the elaboration of ISO/TS 22003:2007, *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*.

24. ISO/TS 22003:2007 is based on the generic standard that covers the area of certification and auditing of management systems, namely, ISO/IEC 17021:2006, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*, and includes specific guidance on certification to ISO 22000. The final version was published in February 2007.

25. The development of ISO 22005, *Traceability in the feed and food chain – General principles and basic requirements for system design and implementation* also involved the European Committee for Standardization (CEN) and Codex in view of complementing the Codex work on traceability by explaining the design of a suitable system to enable organizations to comply with the regulations set by Codex.

A traceability system is a useful tool to assist an organization operating within the feed and food chain to achieve defined objectives in a management system. However, the choice of a traceability system is influenced by regulations, the characteristics of the product and customer expectations.

ISO 22005 will assist feed and food organizations to document the history, application and location of a product or components.

26. WG 10 was established in 2005 and is working on ISO 22008, *Food irradiation — Requirements for the development, validation and routine control of the ionizing radiation process used for the treatment of food for human consumption*. This International Standard specifies requirements for the development, validation and routine control of the ionizing radiation process used for the treatment of food for human consumption. It covers irradiation processes using the radionuclides  $^{60}\text{Co}$  or  $^{137}\text{Cs}$ , electron beams or X-ray generators and does not specify a complete management system for the control of all stages of food production. However, elements of a quality management system that are the minimum necessary to control the food irradiation process are given.

This project is currently at the CD (Committee Draft) stage.

27. In addition to the "ISO 22000 family", it should be noted that WG 12 is developing ISO 22006, *Guidelines on the application of ISO 9001 for crop production*. This International Standard contains the text of ISO 9001 and adds additional elements for agricultural production operators and for documents associated with a Farm Plan. It is currently at the Final Draft International Standard (FDIS) stage.

28. Finally, ISO/TC 34 is developing ISO 26642, *Food products — Determination of the glycemic index (GI) and relevant classification*. The development of this International Standard originated from a recognized need to standardize the determination of the glycemic index (GI) of foods for practice and research purposes, particularly with its increasing use as a nutrition claim. This document sets out a method for the determination of the glycemic index of carbohydrates in foods and the classification of foods into low, medium and high GI. The document was voted on as a Draft International Standard (DIS) in 2009.

During the last year, after a general review of its Business Plan, the following 4 main objectives were identified:

- Safety of food products
- Fair practices in trade
- Quality of products
- Sustainable development

ISO/TC 34 and its subcommittees initiated new projects. As examples :

- ISO/WD 12824, *Royal Jelly — Specifications* (under development under the responsibility of ISO/TC 34)
- ISO/CD 12779, *Lactose — Determination of water content — Karl Fischer method* (under development under the responsibility of SC 5)
- ISO/WD 3720, *Black tea — Definition and basic requirements* (under development under the responsibility of SC 8)
- ISO/WD 24114, *Instant coffee — Criteria for authenticity* (under development under the responsibility of SC 15)

- ISO/NP 5526, *Cereals, pulses and other food grains — Nomenclature* (under development under the responsibility of SC 4)
- ISO/NWIP, *Food services — Good Manufacturing Practices* (under registration vote)

29. In order to increase the coordination of the work done within all its structures, ISO/TC 34 decided to establish a Chairman Advisory Group (CAG) that first met in 2007. It has the task of assisting the Chairs and Secretaries of the Technical Committee and Subcommittees in the coordination, consistency, planning and steering of the ISO/TC 34 work or other specific tasks of an advisory nature. It also has the task of advising the Chairs and Secretaries of the Technical Committee and Subcommittees of ISO/TC 34 on: strategic and critical issues; newly identified development activities that may impact the topics of interest within the subject area; gaps between those developments and Committee's outcome.

The CAG held a second meeting in conjunction with the last plenary meeting of ISO/TC 34 (October 16-17 2008, France). This was the first plenary since France and Brazil took over the responsibility of the secretariat of ISO/TC 34. Attended by representatives from more than 20 countries, this meeting was the occasion for:

- A discussion of the Business Plan and the scope of ISO/TC 34
- A presentation of the current work of the TC and its SCs
- A presentation of the work done by some of the liaison organizations of ISO/TC 34, namely Codex Alimentarius and Global Food Safety Initiative (GFSI)

Concerning the work currently undertaken at the SC level, ISO/TC 34/SCs are working on the following main topics.

#### 30. ISO/TC 34/SC 4, *Cereals and pulses*

The field of activity of ISO/TC 34/SC 4 covers standardization of cereals, pulses and their products in particular terminology, sampling, methods of test and analysis, product specifications and requirements for packaging, storage and transportation. There are 65 members in the Subcommittee: 17 Participating countries, 36 Observing countries and 12 international liaisons. Among these, CAC is the liaison that has most common interests with SC 4.

SC 4 has published 58 International Standards and has 16 ongoing projects.

The following projects might be of interest for CAC:

- ISO/FDIS 24333, *Cereals and cereal products — Sampling*
- Revision of ISO 7301:2002, *Rice — Specification*
- Revision of ISO 7970:2000, *Wheat — Specification*

By developing closer relations and increasing cooperation with CAC, SC 4 members sincerely hope to promote the level of International Standards of cereals and pulses.

#### 31. ISO/TC 34/SC 5, *Milk and milk products*

The field of activity of ISO/TC 34/SC 5 covers standardization of methods of sampling and analysis in the field of milk and milk products.

With regard to analytical and test methods, 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 Committee on Milk and Milk Products and are endorsed by the Codex Committee on Methods of Analysis and Sampling.

An important document is ISO/TS 22964:2006, *Milk and milk products — Detection of *Enterobacter sakazakii**. This bacterium has been found to exist in some infant formulations. The bacterium is thermotolerant and can remain after sterilization. After publication of the TS in 2006, the project was handed over to ISO/TC 34/SC 9 to prepare a horizontal International Standard for food products for the detection of *Enterobacter sakazakii*.

#### 32. ISO/TC 34/SC 9, *Microbiology*

The field of activity of ISO/TC 34/SC 9 covers standardization of horizontal microbiological analysis methods for all food and animal feeding stuffs.

- Number of published ISO standards under the direct responsibility of TC 34/SC 9: 57
- Participating countries: 30
- Observing countries: 25

ISO/TC 34/SC 9 develops horizontal methods, applicable to all foods, feeds, samples from primary production and from processing environment, for the detection and/or enumeration of such food-borne pathogens as *Salmonella*, *Listeria monocytogenes*, *Bacillus cereus*, *Staphylococcus aureus*, thermotolerant *Campylobacter* and pathogenic *Vibrio*. A set of standards also deals with the use of polymerase chain reaction (PCR) for the detection of food-borne pathogens. Another set

of standards is being developed on the validation of microbiological methods. AOAC International is in liaison with SC 9, in particular, has formally recognized the ISO *Salmonella* test method as being equivalent to the corresponding AOAC Official Method of Analysis.

### 33. ISO/TC 34/SC 11, *Animal and vegetable fats and oils*

The field of activity of ISO/TC 34/SC 11 covers standardization of methods of sampling and analysis of animal, marine and vegetable fats and oils.

ISO/TC 34/SC 11 has had a most satisfactory relationship with the Codex Committee on Fats and Oils (CCFO) for many years. ISO has observer status at the meetings and has usually been represented by the Chairman and the Secretary of SC 11, generally in dual capacities as their national delegates. This attendance is useful as there is usually a meeting on methods of analysis held during the meeting.

It is to be noted that ISO Standards are the first choice for methodology within the CCFO Specifications. Participation also helps to keep the focus of methodology development on the requirements of international trade.

In particular, SC 11 is working on some of the key analytical parameters for the analysis of environmental food contaminants. Some of these, such as polycyclic aromatic hydrocarbons (PAH), can be reduced by changing the agricultural procedures which are used to dry the product. Others, such as dioxins, are almost entirely absorbed from industrial waste products which have not been disposed of to a satisfactory level. In summary, the relationship between Codex and SC 11 is both fruitful and complementary.

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

### Food safety — ISO publication

35. ISO and ITC have jointly published “*ISO 22000, Food safety management system, An easy-to-use checklist for small business, Are you ready?*”. This handbook on ISO 22000 will be of benefit to small businesses, especially in developing countries and transition economies, in their effort to improve their market share of food and agricultural products in the global market. French and Spanish versions of the publication are also available. ISO has used this publication in various workshops it has conducted for developing countries.

36. This publication is a checklist consisting of questions covering various aspects of the setting-up, implementation and certification of a food safety management system according to ISO 22000:2005. It is aimed at small and medium enterprises both in developed and developing countries, and gives an overview of the requirements of ISO 22000. Working through the questions in a step-by-step manner will enable managers of an enterprise to determine the present status of their business and will help them identify main areas for improvement. It will therefore be of value even if the ultimate aim is not full certification of that enterprise.

### ISO/DEVCO and food safety

37. Since 1960, ISO has had a policy development committee – DEVCO – that deals specifically with the needs of developing countries in standardization. Developing countries need to focus both on acquiring world-class technological competence and on achieving a good understanding of the technical requirements underlying global trade. For over 40 years, ISO has been assisting in both these areas through ISO/DEVCO, the ISO Committee on developing country matters. DEVCO's membership comprises over 133 national standards institutes from industrialized as well as developing countries.

38. The committee has four main objectives:

- to identify the needs and requirements of developing countries in the fields of standardization and related activities (i.e. conformity assessment including accreditation, quality and metrology) and to assist the developing countries, as necessary, in defining these needs and requirements;
- having established these needs and requirements, to recommend actions to assist the developing countries in meeting them;
- to monitor the implementation of *the ISO Action Plan for developing countries*;
- to provide a forum for the discussion of all aspects of standardization and related activities, and for the exchange of experience among developed and developing countries.

39. In 2008, ISO/DEVCO carried out 14 projects in relation to ISO 22000 technical assistance and has already planned 3 for 2009 (see [Annex 2](#)). The main objective is to improve awareness of key stakeholders in developing countries of the role of such standards in economic growth, world trade and their contribution to sustainable development. In addition, 7 sponsorships were provided in 2008 to individuals from developing countries to attend the Plenary Meeting of ISO/TC 34 on 16 – 17 October 2008, Paris, France.

### Codex and ISO/TC 234 (see structure in [Annex 3](#))

40. The increasing importance of seafood as a protein source for the world population, and the increasing internationalization of both seafood production and trade, have led to a need for international standards to enable sustainable development and environmental compatibility of the fisheries and aquaculture sectors.

41. In the process leading to the establishment of ISO/TC 234, it was stressed that the work of the committee should be complementary to and not in competition with ongoing standardization under the auspices of other non-governmental or governmental organizations.

42. ISO/TC 234 held its second plenary meeting in Madrid, Spain in November 2008 and the following two working groups have started their work:

- WG 1 Traceability of fish products
- WG 2 Environmental monitoring of the seabed impacts from marine finfish farms

In addition other areas are under consideration for future work.

### Codex and ISO/TC 147 (See structure in [Annex 4](#))

43. ISO has an observer status in CAC, and CAC maintains a category A liaison with ISO/TC 147 "Water quality", and especially with sub-committee SC 2 "Physical, chemical and biochemical methods" and sub-committee SC 4 "Microbiological methods".

As water plays an important role in food processing (for all kinds of cleaning purposes, preparation of half-finished food products, production of beverages like beer and lemonades), many International Standards elaborated in ISO/TC 147/SC 2 and SC 4 are, or should be, taken into account.

44. Topics covered by ISO/TC 147/SC 2 range from metal determinations (single or multicomponent methods), anions, cations, to methods for organic substances such as plant treatment agents, or methods for ubiquitous pollutants like phthalates or polycyclic hydrocarbons, PAH.

In the investigations on the quality of food products, International Standards from ISO/TC 147 may be used as basic standards because water is – compared with all food products – the less difficult matrix to be investigated.

It should be stressed as well that all methods from ISO/TC 147/SC 2 have been validated by interlaboratory trials and are only accepted as standards if the results have been found satisfactory.

In addition, standards on analytical quality control are available.

45. In respect to microbiological methods (ISO/TC 147/SC 4), special importance is given to existing standards on the determination of *salmonella*, *coliforms* (*E.coli* and other substances), or e.g. methods on the investigation of microorganisms by culture. Special emphasis is laid on the preparatory work for a standard on the estimation of uncertainty in microbiological analysis.

It is important to note that ISO/TC 147/SC 4 is in liaison with ISO/TC 34/SC 9 (*Microbiology*): There is a Joint Working Group between ISO/TC 34/SC 9 and ISO/TC 147/SC 4 preparing ISO 11133 for quality criteria for media used for microbiological analysis of food and water samples.

The scope of all standards from ISO/TC 147/SC 4 does not exclude bottled water, so all standards can, in principle, be applied to analysis of bottled water.

Besides the fact that tap water is used for preparation of food and rinsing purposes in food production the exact interface where responsibility for water quality changes from water to food regulations may be different in different regions of the world. At some appliances the exact responsibility lies somewhat "in between" (e.g. automatic vending machines for beverages which are connected to tap water). This makes cooperation and harmonization between food and water microbiology necessary.

ISO/TC 147/SC 4 has recently worked on basic standards for enumeration (ISO 8199:2005) and for sampling for microbiological analysis (ISO 19458:2006). These standards have some overlaps with the food sector.

Other work has dealt with *Salmonella* (ISO/DIS 19250: 2007), *Legionella* (ISO 11731-2:2004), *Cryptosporidium* and *Giardia* (ISO 15553:2006), *Campylobacter* (ISO 17995:2005) and comparison of different microbiological methods for water analysis (ISO 17994:2004).

### Codex and ISO/TC 54

46. The ISO Technical Committee on "Essential Oils" (ISO/TC 54) works continuously on the characterization and authentication of essential oils used as raw material for food flavour compounding. All physicochemical, odour, obtention, etc. properties have been discussed and agreed within the ISO committee P-members prior to their inclusion in the standard.

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

47. ISO is an International Standards developer and does not itself undertake assessments of conformity of products, management systems, processes or services against the requirements of the standards it produces.

48. ISO does however produce International Standards and Guides 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).

49. 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 5](#) gives a list of documents and ongoing work.

50. Since its last session in June-July 2008 in Geneva, the Codex Alimentarius Commission (CAC) has obtained the status of A-liaison.

This new status allows Codex to participate in all ISO/CASCO working groups. To date, Codex has the following memberships:

- CASCO STAR (Strategic Alliance and Regulatory Group);
- CASCO WG 28 (General requirements for proficiency testing);
- CASCO WG 29 (Requirements for certification bodies certifying products (including services) and processes, revision of ISO/IEC Guide 65).

Apart from its participation in ISO technical work (WG's 28 and 29), Codex attended four important ISO/CASCO meetings:

- a CASCO workshop entitled "Conformity Assessment Standards in Support of Market Surveillance" (29 October 2008);
- the 2<sup>nd</sup> and 3<sup>rd</sup> CASCO STAR meetings (29 October 2008 and 02 April 2009);
- the 24<sup>th</sup> CASCO plenary meeting (30-31 October 2008).

#### 51. CASCO plenary meeting

Codex is one of the 14 A-liaisons that were present at the 24<sup>th</sup> ISO/CASCO plenary meeting.

The CAC Secretary (Mr. Kazuaki Miyagishima) gave an update on Codex work. He indicated that Codex standards recognize ISO standards (cooperation between Codex and ISO/TC 34) and that Codex and ISO standards are complementary (Codex standards are generally used by governments, and ISO standards are much welcomed by the market). The CAC Secretary stressed the importance of the exchange of information between Codex and ISO at general and technical levels.

#### 52. CASCO STAR meeting

CASCO STAR provides a mechanism for industry sectors and regulators to interact with CASCO (keeping abreast of activities in conformity assessment, promotion of CASCO toolbox, forum to discuss conformity assessment needs and concerns). The 2<sup>nd</sup> STAR meeting was attended by the CAC Secretary Mr. Kazuaki Miyagishima and the 3<sup>rd</sup> STAR meeting attended by the CAC Chair Dr. Karen Hulebak. The CAC seeks to increase collaboration with ISO to participate in the production of international standards and although the CAC currently did not have a process enabling it to actively participate in the development of ISO standards it was developing a procedure to facilitate its participation in ISO work. The STAR group welcomed this and stressed that cooperation in identification of real concerns between the members of CASCO STAR should be sought. It was vital that all can contribute to providing confidence and quality to the consumer.

Dr. Karen Hulebak informed the 3<sup>rd</sup> STAR meeting that CAC is the interface between national and international entities. Dr. Hulebak indicated that CAC together with the World Health Organization are working on guidance on risk assessment for industry and governments.

Codex through the STAR group raised issues for possible future discussion within ISO/CASCO:

- methods for analysis of sampling (current CAC project);
- food inspection and certification system (current CAC project);
- food (and product) traceability is a growing concern and although Codex does not see a need for an ISO standard at this stage, it should be monitored;
- Codex and ISO/CASCO should initiate a dialogue in order to determine how both ISO/IEC 17065 (product certification) and ISO/IEC 17020 (Inspection bodies) can be used for food safety.

- Dr. Hulebak indicated that the CAC would be interested in participating in the ISO/CASCO 2009 workshop on the "Role of standards in managing global supply chains". A session of the workshop would be devoted to food and food traceability.

### Conclusion

53. 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.

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

55. 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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## Annex 1

Structure of ISO/TC 34, *Food products*

ISO/TC 34 comprises 51 Participating countries and 55 Observing countries. ISO/TC 34 secretariat is held jointly by France and Brazil (twinning arrangement). ISO/TC 34 has established several substructures [active structures are: 14 Subcommittees (SC) and 5 Working Groups (WG)]; the development of important horizontal standards being under the responsibility of Working Groups directly reporting to ISO/TC 34. These substructures are the following:

- WG 8, *Food safety management systems (FSMS)* [with DS (Denmark) having the convenorship]
- WG 10, *Food irradiation* [with IRAM (Argentina) having the convenorship]
- JWG 11, *Requirements for bodies providing audit and certification of FSMS* [with DS (Denmark) having the convenorship] (Joint CASCO – TC 34 Working Group)
- WG 12, *Application of ISO 9001 in the agriculture* [with ANSI (USA) having the convenorship]
- WG 13, *Royal jelly* [with SAC (China) having the convenorship]
- ISO/TC 34/SC 2, *Oleaginous seeds and fruits and oilseed meals* (secretariat held by France)
- ISO/TC 34/SC 3, *Fruit and vegetable products* (secretariat held by Poland)
- ISO/TC 34/SC 4, *Cereals and pulses* (secretariat held by China)
- ISO/TC 34/SC 5, *Milk and milk products* (secretariat held by The Netherlands)
- ISO/TC 34/SC 6, *Meat, poultry, fish, eggs and their products* (secretariat held by Botswana)
- ISO/TC 34/SC 7, *Spices, culinary herbs and condiments* (secretariat held by India)
- ISO/TC 34/SC 8, *Tea* [(secretariat held jointly by UK and China (twinning arrangement))]
- ISO/TC 34/SC 9, *Microbiology* (secretariat held by France)
- ISO/TC 34/SC 10, *Animal feeding stuffs* (secretariat held by The Netherlands)
- ISO/TC 34/SC 11, *Animal and vegetable fats and oils* (secretariat held by UK)
- ISO/TC 34/SC 12, *Sensory analysis* (secretariat held by Argentina)
- ISO/TC 34/SC 14, *Fresh, dry and dried fruits and vegetables* (secretariat held by Turkey)
- ISO/TC 34/SC 15, *Coffee* (secretariat held by Brazil)
- ISO/TC 34/SC 16, *Horizontal methods for molecular biomarker analysis* (secretariat held by USA)

It can be noted that out of these 14 Subcommittees, only 3 are horizontal in scope (ISO/TC 34/SC 9, ISO/TC 34/SC 12 and ISO/TC 34/SC 16).

## Selected ISO/TC 34 work items and publications of interest to Codex

(as of March 2009)

Project number	Title	Status
ISO 22000:2005	<i>Food safety management systems — Requirements for any organization in the food chain</i>	Published in September 2005. Systematic review enquiry in 2008 (decision to be taken in 2009).
ISO/TS 22003:2007	<i>Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems</i>	Published in February 2007.

ISO/TS 22004:2005	<i>Food safety management systems — Guidance on the application of ISO 22000:2005</i>	Published in November 2005. Systematic review enquiry in 2008 (decision to be taken in 2009).
ISO 22005:2007	<i>Traceability in the feed and food chain — General principles and basic requirements for system design and implementation</i>	Published in July 2007.
ISO/FDIS 22006	<i>Guidelines on the application of ISO 9001 for crop production</i>	Final Draft International Standard under FDIS vote in 2009.
ISO/CD 22008	<i>Food irradiation — Requirements for the development, validation and routine control of the ionizing radiation process used for the treatment of food for human consumption</i>	Committee Draft under vote in 2009.
ISO/DIS 26642	<i>Food products — Determination of the glycemic index (GI) and relevant classification</i>	Final Draft International Standard to be received in 2009.
ISO/TS 22964:2006	<i>Milk and milk products — Detection of Enterobacter sakazakii</i>	Published in January 2006. Note that a horizontal International Standard for food products for the detection of <i>Enterobacter sakazakii</i> is presently under development in ISO/TC 34/SC 9.

## Annex 2

**Overview of ISO 22000 technical assistance projects carried out in 2008  
and those planned for 2009**

*ISO 22000 events carried out in 2008*

**Objective 1: Improve awareness of key stakeholders in developing countries of the role of standardization in economic growth, world trade and sustainable development**

<b>Title</b>	<b>Venue/Host</b>	<b>Dates</b>	<b>Total participants</b>	<b>Sponsored participants</b>	<b>Beneficiary countries</b>
Awareness raising national seminar on ISO 22000 - Food safety management systems	Aden, Yemen	20-21 January 2008	48	0	Yemen
Awareness raising national seminar on ISO 22000 - Food safety management systems	Accra, Ghana	22- 24 January 2008	35	0	Ghana
Awareness raising regional seminar on ISO 22000 - Food safety management systems	Amman, Jordan	1 – 4 April 2008	40	9	Algeria, Egypt, Jordan, Lebanon, Libyan Arab Jamahiriya, Morocco, Palestine, Syrian Arab Rep., Tunisia, Yemen
Awareness raising national seminar on ISO 22000 - Food safety management systems	Yerevan, Armenia	3 – 5 June 2008	45	0	Armenia
Awareness raising national seminar on ISO 22000 - Food safety management systems	Tashkent, Uzbekistan	24-26 June 2008	50	0	Uzbekistan
Awareness raising regional workshop on ISO 22000 - Food safety management systems	Lusaka Zambia	28 – 30 July 2008	40	15	Burundi, Congo, Egypt, Eritrea, Ethiopia, Kenya, Libya, Malawi, Mauritius, Rwanda, Seychelles, Sudan, Swaziland, Uganda, Zambia, Zimbabwe
Awareness raising national seminar on ISO 22000 - Food safety management systems	Manila, Philippines	15 – 16 September 2008	107	0	Philippines
Awareness raising national seminar on ISO 22000 - Food safety management systems with Training of Trainers	Manila, Philippines	17-19 September 2008	15	6	Philippines

<b>Title</b>	<b>Venue/Host</b>	<b>Dates</b>	<b>Total participants</b>	<b>Sponsored participants</b>	<b>Beneficiary countries</b>
Awareness raising national seminar on ISO 22000 - Food safety management systems	Cebu, Philippines	20 – 21 October 2008	34	0	Philippines
Awareness raising national seminar on ISO 22000 - Food safety management systems	Davao, Philippines	23 – 24 October 2008	34	0	Philippines
Awareness raising regional seminar on ISO 22000 - Food safety management systems	Caracas, Venezuela	15 – 17 October 2008	48	9	Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, Venezuela
Awareness raising regional seminar on ISO 22000 - Food safety management systems	Santo Domingo, Dominican Rep.	19 -21 November 2008	43	12	Antigua & Barbuda, Barbados, Costa Rica, Cuba, Dominica, Dominican Rep. , El Salvador, Honduras, Jamaica, St. Lucia, St. Vincent & Grenadines, Suriname, and Trinidad & Tobago
Awareness raising national seminar on ISO 22000 - Food safety management systems	Dar-es-Salaam, Tanzania	1 – 3 December 2008	30	0	Tanzania
Awareness raising national seminar on ISO 22000 - Food safety management systems	Yaoundé Cameroun	17 – 19 December 2008	60	0	Cameroun

*ISO 22000 events planned for 2009*

<b>Title</b>	<b>Region</b>	<b>Country</b>
Regional awareness raising seminar and ToT on ISO 22000	East and South East Asia	Hanoi, Vietnam
National workshop on ISO 22000	Africa	Angola
National workshop on ISO 22000	Eastern & Central Europe	Macedonia

### Structure of ISO/TC 234, *Fisheries and aquaculture*

ISO/TC 234, *Fisheries and aquaculture*, was established in 2007. The current list of member countries comprises 17 participating members and 17 observing members.

#### Participating members

Norway, (SN), secretariat	Iceland (IST)	Spain (AENOR)
Belgium (NBN)	India (BIS)	Thailand (TISI)
Canada (SCC)	Malaysia (DSM)	USA (ANSI)
Denmark (DS)	Mauritius (MSB)	United Kingdom (BSI)
Fiji (FTSQCO)	New Zealand (SNZ)	Viet Nam (STAMEQ)
France (AFNOR)	South Africa (SABS)	

#### Observing members

Argentina (IRAM)	Indonesia (BSN)	Netherlands (NEN)
Brazil (ABNT)	Israel (SII)	Poland (PKN)
Croatia (HZN)	Italy (UNI)	Sweden (SIS)
Cyprus (CYS)	Japan (JISC)	Ukraine (DSSU)
Finland (SFS)	Malta (MSA)	
Germany (DIN)	Montenegro (ISME)	

#### Scope of the work of ISO/TC 234:

Standardization in the field of fisheries and aquaculture, including, but not limited to, terminology, technical specifications for equipment and for their operation, characterization of aquaculture sites and maintenance of appropriate physical, chemical and biological conditions, environmental monitoring, data reporting, traceability and waste disposal.

Excluded:

- methods of analysis of food products and traceability covered by ISO/TC 34;
- personal protective clothing covered by ISO/TC 94;
- environmental monitoring covered by ISO/TC 207.

The work of this committee should be complementary to and not in competition with ongoing standardization under the auspices of other non-governmental or governmental organizations.

### Structure of ISO/TC 147, *Water quality*

ISO/TC 147 comprises 33 Participating countries and 53 Observing countries

ISO/TC 147 consists of the following active groups:

- WG 4, *Radiological measurements* [with AFNOR (France) having the convenorship]
- SC 1, *Terminology* (secretariat held by South Africa)
- SC 2, *Physical, chemical and biochemical methods* (secretariat held by Germany)
  - WG 17 *Phenols* [with DIN (Germany) having the convenorship]
  - WG 19 *Polycyclic aromatic hydrocarbons (PAH)* [with NEN (The Netherlands) having the convenorship]
  - WG 33 *Ion chromatography methods* [with DIN (Germany) having the convenorship]
  - WG 38 *Flow analysis methods* [with DIN (Germany) having the convenorship]
  - WG 48 *Precision and accuracy* [with DIN (Germany) having the convenorship]
  - WG 52 *Antimony, arsenic and selenium* [with BSI (UK) having the convenorship]
  - WG 53 *GC-MS for groups of non-polar substances* [with NEN (The Netherlands) having the convenorship]
  - WG 55 *Glyphosate and AMPA* [with AFNOR (France) having the convenorship]
  - WG 56 *PFOS and PFOA* [with JISC (Japan) having the convenorship]
  - WG 57 *SPME* [with DIN (Germany) having the convenorship]
  - WG 59 *Chloroalkanes* [with DIN (Germany) having the convenorship]
  - WG 60 *Colour determination* [with SN (Norway) having the convenorship]
  - WG 61 *Mercury determination* [with DIN (Germany) having the convenorship]
  - WG 62 *Dissolved oxygen determination* [with DIN (Germany) having the convenorship]
- SC 4, *Microbiological methods* (secretariat held by Germany)
  - WG 2 *Coliforms (E. coli and other coliforms)* [with DIN (Germany) having the convenorship]
  - WG 7 *Salmonella* [with BSI (UK) having the convenorship]
  - WG 10 *Legionella* [with NEN (The Netherlands) having the convenorship]
  - WG 12 *Analytical quality control of microbiological media* [with AFNOR (France) having the convenorship]
  - WG 13 *Cryptosporidium/Giardia* [with BSI (UK) having the convenorship]
  - WG 15 *Uncertainty of measurement* [with SFS (Finland) having the convenorship]
  - WG 16 *Sampling for microbiological analysis* [with AFNOR (France) having the convenorship]
  - WG 17 *Legionella by PCR* [with AFNOR (France) having the convenorship]
- SC 5, *Biological methods* (secretariat held by Germany)
- SC 6, *Sampling (general methods)* (secretariat held by UK)

## Annex 5

## List of CASCO Guides and Standards by field of application

<i>Vocabulary, principles and common elements of conformity assessment</i>	<b>ISO/IEC 17000:</b> 2004	Conformity assessment - Vocabulary and general principles
	<b>ISO PAS 17001:</b> 2005	Conformity assessment - Impartiality - Principles and requirements
	<b>ISO PAS 17002:</b> 2004	Conformity assessment - Confidentiality - Principles and requirements
	<b>ISO PAS 17003:</b> 2004	Conformity assessment - Complaints and appeals - Principles and requirements
	<b>ISO PAS 17004:</b> 2005	Conformity assessment - Disclosure of information - Principles and requirements
	<b>ISO PAS 17005:</b> 2008	Conformity assessment - Use of management systems - Principles and requirements
<i>Product certification</i>	<b>ISO/IEC Guide 23:</b> 1982 Reconfirmed in 2003	Methods of indicating conformity with standards for third-party certification systems
	<b>ISO/IEC Guide 28:</b> 2004	Conformity assessment - Guidance on a third-party certification system for products
	<b>ISO/IEC Guide 53:</b> 2005	Conformity assessment - Guidance on the use of an organization's quality management system in product certification
	<b>ISO/IEC Guide 65:</b> 1996	General requirements for bodies operating product certification systems
	<b>ISO/IEC Guide 67:</b> 2004	Conformity assessment - Fundamentals of product certification
<i>Code of good practice for conformity assessment</i>	<b>ISO/IEC Guide 60:</b> 2004	Conformity assessment - Code of good practice
<i>Mutual Recognition Arrangements (MRAs)</i>	<b>ISO/IEC Guide 68:</b> 2002	Arrangements for the recognition and acceptance of conformity assessment results
<i>Accreditation</i>	<b>ISO/IEC 17011:</b> 2004	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
<i>Inspection</i>	<b>ISO/IEC 17020:</b> 1998 Reconfirmed in 2002	General criteria for the operation of various types of bodies performing inspection
<i>System certification</i>	<b>ISO/IEC 17021:2006</b>	Conformity assessment - General requirements for bodies providing audit and certification of management systems
<i>Certification of persons</i>	<b>ISO/IEC 17024:</b> 2003	Conformity assessment - General requirements for bodies operating certification of persons
<i>Testing/calibration</i>	<b>ISO/IEC 17025:</b> 2005	General requirements for the competence of testing and calibration laboratories
	<b>ISO/IEC Guide 43-1:</b> 1997	Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes
	<b>ISO/IEC Guide 43-2:</b> 1997	Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies
<i>Marks of conformity</i>	<b>ISO Guide 27:</b> 1983 Reconfirmed in 2003	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity

	<b>ISO/IEC 17030: 2003</b>	Conformity assessment - General requirements for third-party marks of conformity
<i>Peer assessment</i>	<b>ISO/IEC 17040: 2005</b>	Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies
<i>Supplier's Declaration of Conformity (SDoC)</i>	<b>ISO/IEC 17050-1: 2004</b>	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements
	<b>ISO/IEC 17050-2: 2004</b>	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation

#### List of CASCO projects underway

<i>Writing specifications for use in conformity assessment</i>	<b>ISO/IEC 17007</b> [CASCO WG 27] Revision of ISO/IEC Guide 7:1994 DIS ballot closed on 2008-11-20.	Conformity assessment – Guidelines for drafting normative documents suitable for use for conformity assessment
<i>Inspection</i>	<b>ISO/IEC 17020</b> [CASCO WG 31] Revision of ISO/IEC 17020:1998 1 <sup>st</sup> WG meeting planned in Q1 2009.	Conformity assessment – Requirements for the operation of bodies performing inspection
<i>Auditing competence</i>	<b>ISO/IEC 17021 Part 2</b> [CASCO WG 21] CD2 ballot in progress and closing on 2009-02-25.	Conformity assessment – Requirements for third party certification auditing of management systems
<i>Certification of persons</i>	<b>ISO/IEC 17024</b> [CASCO WG 30] Revision of ISO/IEC 17024:2003 1 <sup>st</sup> meeting on 9-10 February 2009.	Conformity assessment – General requirements for bodies operating certifications of persons
<i>Proficiency testing</i>	<b>ISO/IEC 17043</b> [CASCO WG 28] Revision of ISO/IEC Guide 43:1997 DIS ballot in progress and closing on 2009-04-13.	Conformity assessment – General requirements for proficiency testing
<i>Product certification</i>	<b>ISO/IEC 17065</b> [CASCO WG 29] Revision of ISO/IEC Guide 65:1996 Working Draft in progress.	Conformity assessment – Requirements for certification bodies certifying products (including services) and processes