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ODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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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

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 (<u>http://www.iso.org/</u>). ISO is a non-governmental organization established in 1947 with members consisting of the leading and recognized national standards organizations of 159 countries, on the basis of one member per country.

3. ISO has a Central Secretariat, based in Geneva, Switzerland, that employs 155 staff. However, most of the work in developing and maintaining the portfolio of more than 18 100 International Standards is shared amongst the membership, with individual national members providing and financing the Chairmanships and Secretariats for one or more of the 196 technical committees and 485 subcommittees managing some 2 340 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. In 2010, ISO published an informative brochure entitled <u>International standards and "private standards"</u> to outline the important role that ISO's international standards play in fostering trade while supporting the implementation of public policy and allowing good regulatory practice through performance- based, as opposed to prescriptive, technical regulations. It also makes the important distinction between standards that are developed using the core WTO TBT principles of transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and addressing the concerns of developing countries – and standards that do not follow these principles. This complements the ISO informative brochure entitled "<u>Using and referencing ISO and IEC standards for technical regulations</u>", published in 2007, to describe certain advantages in using and referencing

¹ Document prepared by and under responsibility of ISO.

ISO and IEC standards. This document provided examples in different sectors, including national and regional regulatory texts that refer to standards.

ISO's international status

7. ISO has a specific status with many UN agencies, including the WHO and FAO. 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.

8. 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 the JCGM), has prepared the following publications. Draft Guide ballots closed in November 2009.

- ISO/IEC Guide 98-3/Draft Suppl.2, Uncertainty of measurement Part 3: Guide to the expression of uncertainty in measurement (GUM:1995) Supplement 2: Models with any number of output quantities (= JCGM 102).
- ISO/IEC Draft Guide 98-4, Uncertainty of measurement Part 4: Role of measurement uncertainty in conformity assessment (= JCGM 106).

This document provides guidance and procedures for assessing the conformity of an item (entity, object or system) with specified requirements. The item might be, for example, a gauge block, a grocery scale or a blood sample. Examples are provided to illustrate the guidance provided, including one for a food toxin.

9. The Codex Alimentarius Commission places an emphasis on the acceptance of methods of analysis which have been validated through a collaborative trial conforming to an internationally accepted protocol according to ISO 5725:1994 or the AOAC/IUPAC Harmonized Protocol: It is therefore important to note that ISO 5725:1994, Accuracy (trueness and precision) of measurement methods and results is being completely revised and the future document will contain four parts (instead of the current 6 parts).

ISO status in Codex

10. 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); 21 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 CCMAS recent endorsement of methods for the detection of 21 different commodities (representing 28 different standards developped by ISO/TC 147) and Codex's adoption of the CASCO standard ISO/IEC 17025 for testing and calibration laboratories.

11. 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 <u>41</u>) (see <u>Annex 4</u> for the structure of ISO/TC 147);
- ISO/TC 234, *Fisheries and aquaculture* (created in February 2007) for which CAC has a liaison (more details in point <u>37</u>) (see <u>Annex 3</u> for the structure of ISO/TC 234).

Codex and ISO/TC 34 Cooperation

12. 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. This also includes interest to support any joint or collaborative communication on each others' work.

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 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.

14. Since its creation in 1947, ISO/TC 34 has published 756 ISO deliverables (International Standards, Technical Specifications and Technical Reports). 65 % of these documents are test methods. See <u>Annex 1</u> for the structure of ISO/TC 34 and a list of projects/publications of interest to Codex.

Remaining unchanged for quite a long time, the structure of ISO/TC 34 was modified in 2008 and 2009 with the establishments of dedicated Subcommittees on biomarkers, SC 16, and on Management systems for food safety, SC 17 (see <u>Annex 1</u>).

15. 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 published standards and on-going work items under the direct responsibility of ISO/TC 34 may also be of interest to Codex:

- ISO/DIS 14170, 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/FDIS 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 development)

16. The standard ISO 1871:2009, *Food and feed products* — *General guidelines for the determination of nitrogen by the Kjeldahl method* was published in June 2009. This International Standard provides general guidelines for the determination of nitrogen by the Kjeldahl method. It applies to food and feed products containing nitrogenous compounds that can be directly determined by the Kjeldahl method.

17. The standard ISO 16634-1:2008, Food products — Determination of the total nitrogen content by combustion according to the Dumas principle and calculation of the crude protein content — Part 1: Oilseeds and animal feeding stuffs, specifies a method for the determination of the total nitrogen content and the calculation of crude protein content of oilseeds and animal feeding stuffs. This method is not applicable to milk and milk products for which a method is specified in ISO 14891 | IDF 185.

A part 2 on cereals, pulses and milled cereal products was published in 2009: ISO/TS 16634-2:2009, *Food products* — *Determination of the total nitrogen content by combustion according to the Dumas principle and calculation of the crude protein content* — *Part 2: cereals, pulses and milled cereal products.*

18. WG 10 was established in 2005 and is working on ISO 14470, *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 $_{60}$ Co or $_{137}$ 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 DIS (Draft international Standard) stage.

19. Finally, ISO/TC 34 is developing ISO 26642, *Food products* — *Determination of the glycaemic index (GI)* and recommendation for food 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 will be under Final Draft International Standard (FDIS) in July 2010.

20. 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:

- Microbiology of food and animal feeding stuffs Horizontal method for detection of hepatitis A virus and norovirus in food using real-time RT-PCR Part 1: Method for quantitative determination
- Vegetable fats and oils Determination of triacylglycerols Method by high performance liquid chromatographie (HPLC)
- Soya meals soluble protein content
- *Milk, milk products and infant formulae Guideline for the quantitative determination of melamine and cyanuric acid by LC-MS/MS*

21. 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 third meeting in order to prepare the 2010 plenary meeting of ISO/TC 34 (April 28-29 2010, Brazil). This will be the second 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:

- Model for the presentation of analytical standards;
- Standards on vitamins in Food products;
- Correlation list between the Subcommittees of ISO/TC 34 and the Committees of Codex Alimentarius;
- Sampling;
- Pesticides;
- Action plan for Developing Countries...

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

22. 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 11 active projects. In the year 2009, there are 7 standards published under the direct responsibility of SC4:

- ISO 712:2009, Cereals and cereal products Determination of moisture content Reference method
- ISO 3093:2009, Wheat, rye and their flours, durum wheat and durum wheat semolina Determination of the falling number according to Hagberg-Perten
- ISO 24333:2009, Cereals and cereal products Sampling
- ISO 24557:2009, Pulses Determination of moisture content Air-oven method

- ISO 7971-3:2009, Cereals Determination of bulk density, called mass per hectolitre Part 3: Routine method
- ISO 7971-2:2009, Cereals Determination of bulk density, called mass Cereals Part 1: Reference method instruments through reference to the international standard instrument
- ISO 7971-1:2009, Cereals Determination of bulk density, called mass per hectolitre Part 1: Reference method

The following active projects might be of interest for CAC:

- ISO/DIS 520, Cereals and pulses Determination of the mass of 1000 grains
- ISO/CD 5526, Cereals, pulses and other food grains Nomenclature
- ISO/CD 5527, Cereals Vocabulary
- ISO/CD 5530-1, Wheat flour Physical characteristics of doughs Part 1: Determination of water absorption and rheological properties using a farinograph
- ISO/CD 5530-2, Wheat flour Physical characteristics of doughs Part 2: Determination of rheological properties using an extensograph
- ISO/CD 6646, Rice Determination of the potential milling yield from paddy and from husked rice
- ISO/DIS 7301, Rice Specification
- ISO/CD 7970, Wheat (Triticum aestivum L.) Specification
- ISO/CD 11746, Rice Determination of biometric characteristics of kernels
- ISO/CD 11747, Rice Determination of cooked rice kernel hardness index
- ISO/CDTR 29263, Cereals and cereal products Sampling studies

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.

23. ISO/TC 34/SC 5, Milk and milk products

The objectives of ISO/TC 34/SC 5 are to develop and standardize methods of analysis and sampling for milk and milk products. In achieving its objectives and based on a request of the FAO/WHO Joint Committee of Government Experts on the Code of Principles concerning Milk and Milk Products in 1961, ISO/TC 34/SC 5 has a close co-operation with the International Dairy Federation (IDF) since 1962 in preparing their standards which are published jointly as ISO-IDF International Standards by ISO since 2001.

Nearly all ISO-IDF International Standards are also adopted by the Codex Committee on Milk and Milk Products (CCMMP) and, thereafter, were also endorsed by the Codex Committee on Methods of Analysis and Sampling (CCMAS).

Presently, ISO/TC 34/SC 5 and IDF are preparing an important document, namely a technical specification; ISO/TS 15495 | IDF/RM 230, providing guidelines for the quantitative determination of melamine and cyanuric acid by LC-MS/MS for Milk, milk products and infant formulae. The Dairy Industry has a strong demand for such a guidance due to the, regrettable still ongoing, adulteration of milk problems in China. The publication of ISO/TS 15495 | IDF/RM 230 is foreseen in the course of 2010. Thereafter ISO/TC 34/SC 5 and IDF will focus on preparing a real International Standard taking the technical specification as basis.

24. 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 foodborne pathogens. Another set of standards is being developed on the validation of microbiological methods.

ISO/TC 34/SC 9 would like to have a direct liaison with CCFH (Codex Committee on Food Hygiene).

25. 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 enjoyed a most satisfactory relationship with the Codex Committee on Fats and Oils (CCFO) for many years. ISO has observer status at the meetings and is usually 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 CCFO meeting. It should 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 processes 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.

The International Olive Council has recently joined SC 11 as a Liaison Member and is introducing standards which are useful to CCFO in determining the international specifications for olive oil. In summary, the relationship between Codex and SC 11 is both fruitful and complementary.

26. ISO/TC 34/SC 14, Fresh, Dry and Dried Fruits and Vegetables

The scope of ISO/TC 34/SC 14 is the Standardization in the field of fresh, dry and dried fruits and vegetables, in particular, terminology, sampling, product specifications, requirements for packaging, storage, transportation, methods of tests and analysis. ISO/TC 34/SC 14 has a liaison with CAC (Codex Alimentarius Commission),

The aims of SC 14 are:

- To provide validated methods and analysis;
- To facilitate international trade of fresh, dry and dried fruits and vegetables;
- To satisfy consumers' requirements from the point of view of human nutrition;
- To provide guidance and common terminology for the product specifications, storage and transportation of fruits and vegetables.
- 27. ISO/TC 34/SC 16, Horizontal methods for molecular biomarker analysis

Considering the scope of the new SC 16 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
- 28. ISO/TC 34/SC 17, Management systems for food safety

The ISO 22000 series are now under responsibility of the new SC 17. These documents of particular interest to the CAC are:

- ISO 22000:2005, Food safety management systems Requirements for any organization in the food chain
- ISO/TS 22004:2005, Food safety management systems Guidance on the application of ISO 22000:2005
- ISO/TS 22002-1:2009 Prerequisite programmes on food safety Part 1: Food manufacturing
- ISO/TS 22003:2007, Food safety management systems Requirements for bodies providing audit and certification of food safety management systems
- ISO 22005:2007, Traceability in the feed and food chain General principles and basic requirements for system design and implementation
- ISO 22006:, Guidelines on the application of ISO 9001 for crop production

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 and was confirmed.

29. New work was published at the end of 2009: ISO/TS 22002-1:2009, Prerequisite programmes on food safety — Part 1: Food manufacturing.

This document specifies requirements for establishing, implementing and maintaining prerequisite programmes (PRP) to assist in controlling food safety hazards. ISO/TS 22002-1:2009 is applicable to all organizations, regardless of size or complexity, which are involved in the manufacturing step of the food chain and wish to implement PRP in such a way as to address the requirements specified in ISO 22000:2005, Clause 7.

ISO/TS 22002-1:2009 specifies detailed requirements to be specifically considered in relation to ISO 22000:2005, 7.2.3: a) construction and layout of buildings and associated utilities; b) layout of premises, including workspace and employee facilities; c) supplies of air, water, energy, and other utilities; d) supporting services, including waste and sewage disposal; e) suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance; f) management of purchased materials; g) measures for the prevention of cross-contamination; h) cleaning and sanitizing; i) pest control; j) personnel hygiene.

In addition, ISO/TS 22002-1:2009 adds other aspects which are considered relevant to manufacturing operations: 1) rework; 2) product recall procedures; 3) warehousing; 4) product information and consumer awareness; 5) food defence, biovigilance, and bioterrorism.

30. In addition to the "ISO 22000 family", it should be noted that the ISO standard ISO 22006, *Guidelines on the application of ISO 9001 for crop production* was developed. 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 was published in December 2009.

31. 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

32. 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.

33. 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

34. 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 133 national standards institutes from industrialized as well as developing countries.

35. 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.

36. In 2009, ISO/DEVCO carried out 3 projects in relation to ISO 22000 technical assistance and planned 4 events for 2010 (see <u>Annex 2</u>). 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. Two events were organized with the further objective of building capacity by using a training of trainers module. In addition, 4 sponsorships were provided in 2009 to individuals from developing countries to attend the Meeting of ISO/TC 34/SC 17 on Management Systems for Food Safety on 17–18 September 2009, Charlottenlund, Denmark.

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

37. 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.

38. 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.

39. ISO/TC 234 held its third plenary meeting in Nanaimo, Canada in October 2009. The new structure is in Annex 3)

40. ISO/TC 34/SC 17 and ISO/TC 234 work closely on aquaculture food safety issues and on traceability issues in order to be efficient, use the knowledge available and not duplicate work.

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

41. 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.

42. 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 ubiquitary 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.

43. 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.

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.

44. 28 ISO methods for natural mineral waters were endorsed during the last CCMAS meeting in March 2010 for the detection of different commodities in mineral waters (Codex stan 108-1981) like Antimony, Arsenic, Barium, Borate, Cadmium, Chromium, Copper, Cyanide, Fluoride, Lead, Manganese, Mercury, Nickel, Nitrate, Nitrite, Selenium, Surface active agents, Mineral oil (hydrocarbon index), PCB, Pesticides, PAH.

Codex and ISO/TC 54

45. 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

46. 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.

47. 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 (<u>ISO/CASCO</u>).

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).

48. In relation to ISO/CASCO, most of the conformity assessment Guides have been, or are in the process of being, turned into International Standards. <u>Annex 5</u> gives a list of documents and ongoing work.

49. Since its 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 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 29), Codex attended four important ISO/CASCO meetings:

- a CASCO workshop entitled ""The role of International Standards in managing the global supply chain and traceability" (11 November 2009);
- the 4th CASCO STAR meeting (9 November 2009);
- the 25th CASCO plenary meeting (12-13 November 2009).

50. CASCO plenary meeting

Codex is one of the 15 A-liaisons that were present at the 25th ISO/CASCO plenary meeting. The CAC Secretary (Dr. Selma Doyran) gave an update on Codex work.

51. 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). At the 4th CASCO/STAR meeting (9 November 2009 in Geneva), the Secretary of CAC, Dr. Selma Doyran, gave an update of CAC work. There are discussion at the CAC level on how to improve the participation of developing countries in the work of CAC and on the use of the CAC Trust Fund.

There are ongoing discussions within CAC on industry standards (so-called private standards) versus government/intergovernmental standards.

Taking into account the importance of inspection in the food safety sector, it was suggested that CAC should seek member status to CASCO WG 31 (revision of ISO/IEC 17020:1998).

Conclusion

52. 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.

53. 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.

54. 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 any ISO Technical Committee	For matters related to certification, inspection and conformity assessment:
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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: 15 Subcommittees (SC) and 3 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 10, Food irradiation (with Argentina having the convenorship)
- WG 12, Application of ISO 9001 in the agriculture (with USA having the convenorship)
- WG 13, *Royal jelly* (with 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 Turkey)
- 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 Iran)
- 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)
- ISO/TC 34/SC 17, Horizontal methods for Food Safety Management System Standards (secretariat held by Denmark)

It can be noted that out of these 15 Subcommittees, only 4 are horizontal in scope (ISO/TC 34/SC 9, ISO/TC 34/SC 12, ISO/TC 34/SC 16 and ISO/TC 34/SC 17).

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

(as of March 2010)

Project number	Title	Status
ISO 22000:2005	Food safety management systems —	Published in September 2005.
	Requirements for any organization in the food chain	Confirmed in 2009.
ISO/TS 22002-1	Prerequisite programmes on food safety — Part 1: Food manufacturing	Published in 2009.
ISO/TS 22003:2007	Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems	Published in February 2007.
ISO/TS 22004:2005	Food safety management systems —	Published in November 2005.
	ISO 22000:2005	Confirmed in 2009.
ISO 22005:2007	Traceability in the feed and food chain — General principles and basic requirements for system design and implementation	Published in July 2007.
ISO 22006:2009	<i>Guidelines on the application of ISO 9001</i> <i>for crop production</i>	Published in 2009.
ISO/DIS 14470	Food irradiation — Food irradiation — Requirements for the development, validation and routine control of the ionizing radiation process used for the treatment of food	Draft International Standards under vote until August 2010.
ISO/FDIS 26642	Food products — Determination of the glycemic index (GI) and relevant classification	Final Draft International Standard to be launched in June 2010.
ISO/TS 22964:2006	Milk and milk products — Detection of	Published in January 2006.
	Enterobacter sakazaku	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.
ISO/TS 15495 IDF/RM 230	Guidelines for the quantitative determination of melamine and cyanuric acid by LC- MS/MS for Milk, milk products and infant formulae	Under development. Publication planned for Autumn 2010.

Overview of ISO 22000 technical assistance projects carried out in 2009 and those planned for 2010

ISO 22000 events carried out in 2009 - 1st quarter 2010

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

Title	Venue/Host	Dates	Total participants	Sponsored participants	Beneficiary countries
National seminar on ISO 22000 - Food safety management systems	Luanda, Angola	29 June – 1 July 2009	60	0	Angola
National seminar on ISO 22000 - Food safety management systems	Skopje, The FYR of Macedonia	14-15 September 2009	29	0	The FYR of Macedonia

Objective 2: Build capacity of ISO members and stakeholders involved in developing the standardization infrastructure and participating in international standardization work

Title	Venue/Host	Dates	Total participants	Sponsored participants	Beneficiary countries
Regional awareness raising seminar and Training of trainers on ISO 22000 - Food Safety Management Systems	Hanoi, Viet Nam	20-24 April 2009	89	12	Brunei Darussalam, Cambodia, China, Indonesia, Lao People's D. Rep., Malaysia, Mongolia, Myanmar, Papua New Guinea, Philippines, Singapore, Thailand and Viet Nam
Regional awareness raising seminar and Training of trainers on ISO 22000 - Food Safety Management Systems	Windhoek, Namibia	15-19 March 2010	16	14	Botswana, Congo, the DR of, Ethiopia, Kenya, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe

ISO 22000 events also planned for 2010

Title	Region	Country
National seminar on ISO 22000 Food Safety Management Systems	Eastern and Southern Africa	Botswana*
National seminar on ISO 22000 Food Safety Management Systems	Eastern and Southern Africa	Malawi*
National seminar on ISO 22000 Food Safety Management Systems	Caribbean and Central America	Cuba

(* to be confirmed)

Annex 3

Structure of ISO/TC 234, Fisheries and aquaculture

ISO/TC 234, Fisheries and aquaculture, was established in February 2007. The current list of member countries comprises 19 participating members and 17 observing members.

In addition to Codex Alimentarius Commission (CAC), three international organizations are in liaison: the Food and Agriculture Organisation of the United Nations (FAO), the International Union for the Conservation of Nature and Natural Resources (IUCN) and the Federation of European Aquaculture Producers (FEAP).

The following working groups are established:

ISO/TC 234/AG 1	Aquaculture advisory group
ISO/TC 234/WG 1	Traceability of fish products
ISO/TC 234/WG 2	Environmental monitoring of the seabed impacts from marine finfish farms
ISO/TC 234/WG 3	Aquaculture technology
ISO/TC 234/WG 4	Food safety for aquaculture farms
ISO/TC 234/WG 5	Methodology for sea lice counts
ISO/TC 234/WG 6	Calculation of FIFO (fish in fish out) and FCR (feed conversion ratio)

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.

More information on the scope of work is in the business plan for ISO/TC 234:

http://www.iso.org/iso/standards_development/technical_committees.htm

Work Items of interest to CAC:

- ISO/CD 12875, Traceability of finfish products Specification on the information to be recorded in captured finfish distribution chains
- ISO/CD 12877, Traceability of finfish products Specification on the information to be recorded in farmed finfish distribution chains

Annex 4

Structure of ISO/TC 147, Water quality

ISO/TC 147 comprises 35 Participating countries and 51 Observing countries

ISO/TC 147 consists of the following active groups:

- WG 4, Radiological measurements (with France having the convenorship)
- SC 1, Terminology (secretariat held by South Africa)
- <u>SC 2, Physical, chemical and biochemical methods</u> (secretariat held by Germany)
 - WG 19 Polycyclic aromatic hydrocarbons (PAH) (with The Netherlands having the convenorship)
 - WG 33 Ion chromatography methods (with Germany having the convenorship)
 - WG 38 Flow analysis methods (with Germany having the convenorship)
 - WG 48 Precision and accuracy (with Germany having the convenorship)
 - WG 52 Antimony, arsenic and selenium (with UK having the convenorship)
 - WG 53 GC-MS for groups of non-polar substances (with The Netherlands having the convenorship)
 - WG 55 *Glyphosate and AMPA* (with France having the convenorship)
 - WG 56 PFOS and PFOA (with Japan having the convenorship)
 - WG 57 *SPME* (with Germany having the convenorship)
 - WG 59 *Chloroalkanes* (with Germany having the convenorship)
 - WG 60 *Colour determination* (with Norway having the convenorship)
 - WG 61 Mercury determination (with Germany having the convenorship)
 - WG 62 Dissolved oxygen determination (with Germany having the convenorship)
 - WG 63 *Discrete analysis* (with UK having the convenorship)
- <u>SC 4, *Microbiological methods*</u> (secretariat held by Germany)
 - WG 2 Coliforms (E. coli and other coliforms) (with Germany having the convenorship)
 - WG 5 Sulfite reducing clostridium (with Austria having the convenorship)
 - WG 7 *Salmonella* (with UK having the convenorship)
 - WG 10 *Legionella* (with The Netherlands having the convenorship)
 - WG 12 Analytical quality control of microbiological media (with France having the convenorship)
 - WG 13 Cryptosporidium/Giardia (with UK having the convenorship)
 - WG 15 Uncertainity of measurement (with Finland having the convenorship)
 - WG 17 Legionella by PCR (with France having the convenorship)
 - WG 18 E. coli/coliforms with liquid enrichment (with USA having the convenorship)
- SC 5, *Biological methods* (secretariat held by Germany)
- SC 6, *Sampling* (general methods) (secretariat held by UK)

List of CASCO Guides and Standards by field of application

Vocabulary, principles and	ISO/IEC 17000:2004	Conformity assessment - Vocabulary and general principles
conformity assessment	ISO/PAS 17001:2005	Conformity assessment - Impartiality - Principles and requirements
	ISO/PAS 17002:2004	Conformity assessment - Confidentiality - Principles and requirements
	ISO/PAS 17003:2004	Conformity assessment - Complaints and appeals - Principles and requirements
	ISO/PAS 17004:2005	Conformity assessment - Disclosure of information - Principles and requirements
	ISO/PAS 17005:2008	Conformity assessment - Use of management systems - Principles and requirements
Product certification	ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems
	ISO/IEC Guide 28:2004	Conformity assessment - Guidance on a third-party certification system for products
	ISO/IEC Guide 53:2005	Conformity assessment - Guidance on the use of an organization's quality management system in product certification
	ISO/IEC Guide 65:1996	General requirements for bodies operating product certification systems
	ISO/IEC Guide 67:2004	Conformity assessment - Fundamentals of product certification
Code of good practice for conformity assessment	ISO/IEC Guide 60:2004	Conformity assessment - Code of good practice
Mutual Recognition Arrangements (MRAs)	ISO/IEC Guide 68:2002	Arrangements for the recognition and acceptance of conformity assessment results
Writing specifications for use in conformity assessment	ISO/IEC 17007:2009	Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment
Accreditation	ISO/IEC 17011:2004	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
Inspection	ISO/IEC 17020:1998	General criteria for the operation of various types of bodies performing inspection
System certification	ISO/IEC 17021:2006	Conformity assessment - General requirements for bodies providing audit and certification of management systems
Certification of persons	ISO/IEC 17024:2003	Conformity assessment - General requirements for bodies operating certification of persons

Testing/calibration	ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
	ISO/IEC 17043:2010	Conformity assessment - General requirements for proficiency testing
Marks of conformity	ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
	ISO/IEC 17030:2003	Conformity assessment - General requirements for third-party marks of conformity
Peer assessment	ISO/IEC 17040:2005	Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies
Supplier's Declaration of Conformity (SDoC)	ISO/IEC 17050-1:2004	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements
	ISO/IEC 17050-2:2004	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation

LIST OF CASCO PROJECTS UNDER WAY

Inspection	ISO/IEC 17020 [CASCO WG 31] Revision of ISO/IEC 17020:1998 Working Draft in process. Next WG meeting in May 2010.	Conformity assessment – General criteria for the operation of various type of bodies performing inspection
Auditing competence	ISO/IEC 17021 Part 2 [CASCO WG 21] DIS ballot closing in February. Next WG meeting in April 2010.	Conformity assessment – Requirements for third party certification auditing of management systems
Audit reports	ISO/IEC TS 17022 [CASCO WG 33] NP approved. 1 st WG meeting in February 2010.	Conformity assessment – Minimum requirement and additional recommendations for content of third party audit report on management systems
Certification of persons	ISO/IEC 17024 [CASCO WG 30] Revision of ISO/IEC 17024:2003 Working Draft in process. Next WG meeting in February 2010.	Conformity assessment – General requirements for bodies operating certifications of persons
Product certification	ISO/IEC 17065 [CASCO WG 29] Revision of ISO/IEC Guide 65:1996 CD ballot closing in February 2010. Next WG meeting in April 2010.	Conformity assessment – Requirements for certification bodies certifying products, processes and services
Product certification	ISO/IEC 17067 [CASCO WG 32] Revision of ISO/IEC Guide 67 including Guides 23, 27, 28 and 53. 1 st WG meeting in February 2010.	Conformity assessment – Fundamentals of product certification