



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx ALIMENTARIUS COMMISSION

41st Session

FAO Headquarters, Rome, Italy, 2 - 6 July 2018

COMMUNICATION FROM ISO¹

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.

Any general information regarding the International Organization for Standardization (ISO) can be found on <http://www.iso.org/>. ISO counts more than 22 150 published ISO deliverables, 238 active technical committees and 488 active subcommittees managing some 2431 working groups.

ISO's INTERNATIONAL STATUS

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).

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. ISO methods have been endorsed in the document "*Recommended methods of analysis and sampling*" (CODEX STAN 234-1999) which is updated each year during the CCMAS meeting.

ISO AND STANDARDS FOR THE SDGs

A conference is co-organized by ISO and the United Nations Office at Geneva (UNOG), represented by the United Nations Economic Commission for Europe (UNECE). Taking place during the same week as the 41st ISO General Assembly, it will bring together ISO's members (representatives from the National Standards Bodies of more than 160 countries) with UN agencies, international organizations, NGOs, diplomats and national policymakers to explore how standards can support the achievement of the UN Sustainable Development Goals (SDGs).

Governments, businesses and organizations around the world have committed to help achieve these 17 goals and this conference will explore how voluntary standards can be powerful tools to support their efforts.

Participants will discover case studies demonstrating how standards can further environmental sustainability by supporting the uptake of resource-saving products and equipment; or how they can promote economic development through bringing technological innovations to scale and increasing economic productivity.

The objectives of the conference are:

- strengthening partnerships between standards bodies and UN organizations;
- raising awareness amongst standards bodies of the 2030 Agenda;
- promoting the use of standards as a tool for policymakers, authorities, civil society, businesses, and other stakeholders.

The event provides a unique opportunity to connect the standardization community with representatives of the United Nations agencies, Geneva-based international organizations and NGOs, the diplomatic community, and national policymakers who do not usually have an opportunity to engage with standards-setting bodies.

ISO AND DEVELOPING COUNTRIES – DEVCO

DEVCO, ISO's policy committee on developing country matters, established in 1961, is a unique forum for ISO members from developed and developing countries to discuss standardization and related issues, to exchange experience and best practice, and to identify needs and requirements of developing countries. It is also the role of DEVCO to monitor the implementation of the ISO Action Plan for developing countries. In September

¹ Document prepared by and under the responsibility of the ISO.

2017, DEVCO created working groups tasked at identifying standardization needs of members in developing countries and to consider ways to share resources for the development and use of standards.

Today, 148 out of the 162 ISO members are members of DEVCO. (Find out more about DEVCO on <http://www.iso.org/iso/home/about/iso-and-developing-countries.htm>)

Capacity Building

In 2017, technical assistance and training projects were carried out under the ISO Action Plan for developing countries 2016-2020 to strengthen standardization capacities of ISO members in various areas.

Sponsorships were granted to experts from developing countries to participate in the standardization work of the following committees dealing with food:

- 5th meeting of ISO/TC 34/SC 18 *Cocoa* in June 2017
- 39th meeting of ISO/TC 34/SC 4 *Cereals and pulses* in October 2017
- 8th meeting of ISO/TC 34/SC 17 *Management systems for food safety* in October 2017
- 7th meeting of ISO/TC34/SC 17/WG 8 *Food safety management systems — Requirements* in November 2017

ISO's CONFORMITY ASSESSMENT COMMITTEE – 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). To date, CASCO has 139 members. CASCO maintains liaisons with 23 international organizations and has recently welcomed ISEAL Alliance as a new Liaison to CASCO. The CASCO 33rd plenary meetings and workshop was hosted by the CASCO Mexican Member, Dirección General de Normas (DGN), together with Entidad Mexicana de Acreditación (EMA), from 25-26 April 2018 in Mexico City, Mexico.

CASCO Policy Groups

In December 2017, the Strategic Alliance and Regulatory Group (STAR) supported the CASCO Engagement Strategy for the next 5 years and its commitment to continue engaging with the insurance industry and to initiate the dialogue with the procurement sector in 2018.

Promotion of the CASCO Toolbox and 2017 workshops

Over 2017-2018, CASCO Secretariat has continued the promotion of the CASCO Toolbox and highlighted the importance of implementing well established and recognized conformity assessment practices in different events, among which:

- Workshop and training on CASCO Toolbox, China Certification & Accreditation Association, Shenzhen, September 2017
- BIPM, OIML, ILAC, ISO Quadripartite meeting, Paris, November 2016/March 2017
- IAF-ILAC-ISO meetings, Frankfurt in March/April 2017 and Vancouver in October/November 2017.

Published in 2017 and 2018

- ISO/IEC 17011:2017, *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC 17021-3:2017, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems*
- ISO/IEC TS 17021-10:2018, *Requirements for bodies providing audit and certification of management systems — Part 10: Competence requirements for auditing and certification of OHAS management systems*
- ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*
- ISO/IEC TR 17028:2017, *Conformity assessment — Guidelines and examples of a certification scheme for services*

On-going CASCO technical work

Documents	Stage
Revision of ISO/IEC 17000, <i>Conformity assessment — Vocabulary and general principles</i>	CD ballot started in May 2018

Development of ISO/IEC TS 17021-8, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 8: Competence requirements for auditing and certification of management systems for sustainable development in communities	WD1
Development of ISO/IEC TS 17021-11, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 11: Competence requirements for auditing and certification of Facility Management Systems	DTS ballot started in April 2018
Development of ISO/IEC 17029, General requirements for bodies performing validation and verification activities	CD ballot started in April 2018
Development of ISO/IEC TR 17032, Guidelines and examples of a certification scheme for processes	Project just approved
Development of ISO/TS 17033, Ethical claims — Labels and supporting information — Requirements	WD1
Revision of ISO/TS 22003, Requirements for bodies providing audit and certification of food safety management system (Joint work with ISO/TC 34/SC 17)	WD1 in May 2018

CODEX AND ISO/TC 34, FOOD PRODUCTS

There is a long history of collaboration between the Codex Committees and ISO/TC 34, *Food products*. ISO/TC 34 supports the 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.

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 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.

Since its creation in 1947, ISO/TC 34 has published 830 ISO deliverables (International Standards, Technical Specifications and Technical Reports). Two thirds of these publications are methods of analysis. See Annex or Annex 1 for the structure of ISO/TC 34 and a list of projects/publications of interest to Codex. In 2017, the following can be mentioned as interest for the CAC:

- **Publication of ISO/TS 19657, Definitions and technical criteria for food ingredients to be considered as 'natural'.**

There is a growing amount of food ingredients and food products with natural claims due to the growing demand by consumers and therefore by the food industry. This demand is expected to maintain a sustainable trend. To address those requirements and to provide common understanding, ISO/TC 34/WG 18 has established an ISO technical specification ISO/TS 19657, *Definitions and technical criteria for food ingredients to be considered as natural*. ISO and involved national standards bodies would welcome if Codex Alimentarius, with its objective to protect the health of consumers and ensure fair practices in the food trade, takes this recently developed ISO/TS 19657:2017 in consideration and provides guidance on consumer communication complementary to the ISO/TS 19657.

- Development of methods of analysis for vitamins and nutrients on Infant Formula and Adult Nutritionals, in collaboration with AOAC (SPIFAN project: Stakeholder Panel on Infant Formula and Adult Nutritionals) and IDF.
- Validation of 15 methods of analysis for food microbiology.
- A new subcommittee (SC 19) was created on bee products. (See details in the section for SC 19.)

Concerning the work currently undertaken at the Subcommittees' level, ISO/TC 34/SCs are working on the following main topics:

ISO/TC 34/SC 2, Oleaginous seeds and fruits and oilseed meals

ISO/TC 34/SC 2 covers standardisation in the field of oilseeds and oilseed residues in particular sampling, methods of test and analysis including physical, physical-chemical and biochemical methods.

The main project of interest for CAC is the current revision of ISO 542:1990, *Oilseeds — Sampling*. ISO/TC 34/SC 2 members plan to replace this standard by two ISO standards:

- ISO 21294, *Oilseeds — Manual or automatic discontinuous sampling* has been published in 2017,

- one project on *Oilseeds — Automatic continuous sampling* is still under development.

Moreover, the revision of ISO 17059, *Oilseeds — Extraction of oil and preparation of methyl esters of triglyceride fatty acids for analysis by gas chromatography (Rapid method)*, is under development in order to take into account the replacement of ISO 5509, *Animal and vegetable fats and oils — Preparation of methyl esters of fatty acids*, with ISO 12966, *Animal and vegetable fats and oils — Gas chromatography of fatty acid methyl esters*" (4 parts).

The following projects might also be of interest to CAC:

- Project ISO 9167, *Rapeseed and rapeseed meals — Determination of glucosinolates — Method using high performance liquid chromatography*" in order to simplify the existing methods, replace a potential toxic chemical (methanol) and group rapeseed and rapeseed meals in only one standard.
- Preliminary project ISO 21296, *Oilseeds and oilseed meal — Randall extraction method*, in order to develop an automatic fast method for extraction of oil.

ISO/TC 34/SC 4, Cereals and pulses

ISO/TC 34/SC 4 covers standardization in the field of cereals and pulses as well as their products, in particular terminology, sampling, methods of test and analysis, product specifications and requirements for packaging, storage and transportation.

The following projects under development might be of interest to CAC:

- Revision of ISO 7301, *Rice — Specification*

The purpose is to generally improve the consistency of some definitions and add two new terms of "Entire kernel" and "Stress crack" which have an extensive use in trade.

- ISO/FDIS 19942, *Maize (Zea mays L.) — Specification* (published in July 2018)

This document specifies minimum specifications for maize (*Zea mays L.*) intended for human consumption and which is the subject of international trade.

- Revision of ISO 15141, *Cereal and cereal products — Determination of ochratoxin A — High performance liquid chromatographic method with immunoaffinity column cleanup and fluorescence detection* (published in July 2018)

The purpose is to apply the up to date technology and provide precision data derived from international ring test.

- Revision of ISO 6540:1980, *Maize — Determination of moisture content (on milled grains and on whole grains)*

The purpose is to update the method and provide fidelity data derived from international ring test.

- Revision of ISO 11050, *Wheat flour and durum wheat semolina — Determination of impurities of animal origin*

The purpose is to update the method.

- Revision of ISO 9648, *Sorghum — Determination of tannin content*

The purpose is to update the method and provide precision data.

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

The field of activity of ISO/TC 34/SC 5 covers standardization of methods of analysis and sampling for milk and milk products. ISO/TC 34/SC 5 has a close cooperation with the International Dairy Federation (IDF) since 1961 in preparing standards which are published jointly as ISO-IDF International Standards by ISO since 2001.

Where appropriate, input is provided for ISO/TC 34 and/or IDF/ISO comments to Codex documents:

- Codex Committee on Methods of Analysis and Sampling – receiving documents and attending Inter Agency Meeting, Working Group meetings and CCMAS meetings, providing updates for *CODEX STAN 234-1999* on Recommended Methods of Analysis and Sampling in the area of milk and dairy products
- Codex Committee on Milk and Milk Products (CCMMP)
- Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)
- Codex Committee on Pesticide Residues (CCPR)

Infant formulas need to provide essential nutrients (including vitamins and minerals) for the adequate growth and development of babies and young children. This is why the nutritional quality of infant formula is laid down in international Codex Alimentarius standards, such as *CODEX STAN 72-1981*, and national regulations. To verify that infant formulas contain all necessary nutrients, accurate analytical test methods are required. Although some methods are listed in *CODEX-STAN 234-1999* and are referenced in *CODEX STAN 72-1981*, part of these methods is outdated, not validated for infant formula specifically, or not globally harmonized. A cooperation between ISO (TC 34/WG 14 and SC 5), IDF and AOAC in the SPIFAN project is addressing these issues. The first eight standards (fatty acids composition, total iodine, chromium/selenium/molybdenum, vitamin A and E, B₁₂, inositol, nucleotides and pantothenic acid) were published end of 2015 and have meanwhile been endorsement as international dispute resolution methods following a Codex procedure involving CCFSDU, CCMAS and finally CAC.

Method standards for other nutrients in infant formula are presently in preparation for submission to Codex endorsement:

- ISO/DIS 21422 | IDF 242 (chloride);
- ISO/DIS 15151 | IDF 229 (minerals and trace elements by ICP-AES);
- ISO/DIS 21424 | IDF 243 (minerals and trace elements by ICP-MS);
- ISO 20635 (vitamin C) (publication July 2018)
- ISO 20636 (vitamin D) (publication July 2018);
- ISO/NP 23305 (biotin);

In an ongoing effort to keep the *CODEX STAN 234-1999* list of recommended methods up-to-date, IDF and ISO/TC 34/SC 5, in cooperation with AOAC, have reviewed all methods related to milk and milk products, and have identified some issues that require attention from CCMAS. Furthermore, they have prepared some recommendations on the rules for determining when a defining method should be Type I or Type IV and on the process to be followed to determine whether or not to include such provision in STAN 234 (e.g. iron in milk products, lead in edible casein products and MSNF in cream) when a provision is not specifically listed in the Commodity Standard.

ISO/TC 34/SC 9, Microbiology

The field of activity of ISO/TC 34/SC 9 covers standardization of microbiological analysis of the food chain: from primary production to animal feed and food as end products, including the environment of food production and handling.

The link between TC 34/SC 9 and Codex Alimentarius is made via Codex Committee on Food Hygiene. The secretary of CCFH is invited at each SC 9 plenary meeting (in 2018: 19-23 June, Lausanne, Switzerland) and encouraged to report CCFH activities.

Some experts from ISO/TC 34/SC 9 community are nominated in CCFH working groups (e.g. CCFH50 e-WG on histamine guidance).

In 2017, 15 standards of interest for CCFH were published, which was communicated to CCFH for its plenary meeting. These standards are all describing reference methods, fully validated with performance characteristics derived from collaborative studies:

- detection of *Salmonella* spp. (ISO 6579-1), of *E. coli* O157 (ISO 16654), of *Cronobacter* spp. (ISO 22964), of enteropathogenic *Vibrio* (ISO 21872-1) and of *Yersinia enterocolitica* (ISO 10273);
- detection and enumeration of *Enterobacteriaceae* (ISO 21528-1 & -2), of *Listeria* spp./*monocytogenes* (ISO 11290-1 & -2), and of *Campylobacter* (ISO 10272-1 & -2);
- quantification of *Bacillus cereus* cereulide toxin (ISO 18465), detection of staphylococcal enterotoxins (ISO 19020), detection and quantification of histamine (ISO 19343);
- quantification of noroviruses and hepatitis A viruses (ISO 15216-1);

In 2018, standardization works continue on a protocol for the validation of alternative methods for microbiological confirmation, for the validation of in-house methods and for the verification of validated methods.

New projects are started on:

- whole-genome sequencing for food microbial typing and genomic characterization of foodborne microorganisms (link ensured with the FAO works (“Impact of WGS on food safety management within a One Health framework”));
- detection of *Anisakidae* larvae in fish.

ISO/TC 34/SC 11, Animal and vegetable fats and oils

This sub-committee is involved with standards concerning animal and vegetable fats and oils, and many member bodies of SC 11 are very active within the Codex Committee on Fats and Oils (CCFO).

The scope of SC 11 has been changed to clearly state that the standards developed by the Committee exclude methods of analysis developed specifically for milk and milk products.

SC 11 has several standards which apply exclusively to Olive and Olive Pomace Oil and is working to ensure that SC 11 methods are exactly the same as those of the International Olive Council.

Related to the work of CCFO, SC 11 is in the process of developing standards for the determination of additives such as antioxidants, and now also sterols in food products (the sterols project may be the subject of a horizontal method within ISO/TC 34).

In relation to the development, in the Codex Committee on Contaminants in Food (CCCF), of a Code of Practice (COP) for the Reduction of 3-Monochloropropane-1,2-Diol Esters and Glycidyl Esters in refined oils and products made with refined oils, especially infant formula, it can be noted that SC 11 had published two methods (ISO 18363-1 and -3) for the determination of fatty-acid-bound chloropropanediols (MCPDs) and glycidols and the third (ISO 18363-2, *Part 2: Method using slow alkaline transesterification and measurement for 2-MCPD, 3-MCPD and glycidol*) will be published in August 2018.

ISOTC 34/SC 15, Coffee

ISO 18794, *Coffee — Sensory analysis — Vocabulary* was published in January 2018. It covers definitions applicable to green, roasted and ground coffee, coffee extracts and soluble coffee. The terms are given under the following sections: basic terms in sensory analysis; generic terms in sensory assessment of coffee; terminology relating to coffee-specific odors and tastes; and terms commonly used in sensory assessment of coffee by practitioners.

Before this publication, there were different documents concerning sensory analysis vocabulary for coffee, developed by expert associations in different regions of the world. These documents may be compatible in some concepts, however, there was no common vocabulary that could be used as internationally-shared terminology. ISO 5492 is a general vocabulary standard for sensory analysis, concerning food, but does not address the specific needs of coffee industry sector.

ISO 18794 provides a common terminology for the entire coffee production chain around the world, and surely it will become a tool for international coffee trade. This International Standard will facilitate communication and trade between different regions and countries, allowing to meet one of the objectives set by the ISO/TC 34, *Food products*, about fair trade practice. The entire chain of coffee, including growers, producers, buyers and sellers, small, medium and large companies, will be benefited from having a common language for coffee sensory analysis.

ISO/TC 34/SC 17, Management systems for food safety

The working group responsible for the revision of ISO 22000 Food safety management system — *Requirements*, ISO/TC 34/SC 17/WG 8, met in Schiphol, The Netherlands in October/November 2017. It was the 7th and last meeting in the revision process of the standard.

2017 has been a crucial year in the revision process, as the draft standard has been out for the public enquiry procedure, and the experts have discussed and solved the last technical comments in this process.

The publication date for the new version of ISO 22000 is set to 19 June 2018.

The revision process has been very comprehensive, as the working group has worked thoroughly to cover several extensive concepts:

- Firstly, the new High Level Structure (HLS) developed by ISO, which is mandatory when drafting or revising management system standards, had to be incorporated into the standard. The HLS sets a framework for the management system standards, which makes it very easy for businesses to conform to more than one management system standard.
- Secondly, WG 8 decided to provide the users of ISO 22000 with a new understanding of the different approaches to the notion RISK. As a concept, risk is used in various ways and it is very important for food businesses to distinguish between the well-known hazard assessment on the operational level (HACCP), and the concept of business risk where opportunities also form part of the concept.
- Thirdly, WG 8 also decided to further clarify how the Plan-Do-Check- Act (PDCA) circle works by having two separate circles in the standard. The two PDCA circles will operate one inside the other; one covering the management system and the other, within it, the operations described in Clause 8, which simultaneously cover the principles of HACCP defined by Codex.
- Finally, the users of the current standard have asked for a clear description of the differences between CCPs, OPRPs and PRPs, while maintaining alignment with Codex definitions as much as possible. WG 8 has worked very dedicated developing this clear distinction to benefit the users of the standard.

The experts of the working group have dedicated lots of time and brainpower in the process, to discuss how to communicate these concepts to the users in a clear and concise manner. The aim has been to draft the standard comprehensible and easy to understand and implement in all sizes of businesses throughout the food chain.

Following the publication of the new version of ISO 22000, SC 17 will

- Initiate the revisions of the sector specific prerequisite programs (the ISO 22002 series) to ensure consistency in the ISO 22000 family of standards.
- Develop a revised guide.
- Work with CASCO on the revision of ISO/TS 22003, *Requirements for bodies providing audit and certification of food safety management system* (Joint work with ISO/CASCO/JWG 36)

The next ISO/TC 34/SC 17 plenary meeting will be in October 2018 in Bordeaux, France.

ISO/TC 34/SC 19, Bee products

A new subcommittee was established in September 2017 on bee products. This Subcommittee had its 1st meeting on 24/25 May 2018 in Nanjing, China. The following scope has been agreed for their future discussions and work: Standardization of the whole process and circulation of all forms of bee products (honey, beeswax, royal jelly, pollen, propolis, bee larvae, etc.) including but not limited to the following: definitions, beekeeping practices, specifications, transportation, basic processing, requirements for testing methods and testing methods, storage, quality, etc. Food safety standards are excluded from the scope of this new committee. It was also decided during this first meeting to create a working group dealing with honey, and that the work developed in this committee will not contradict with the Codex definition and description of honey.

CONCLUSION

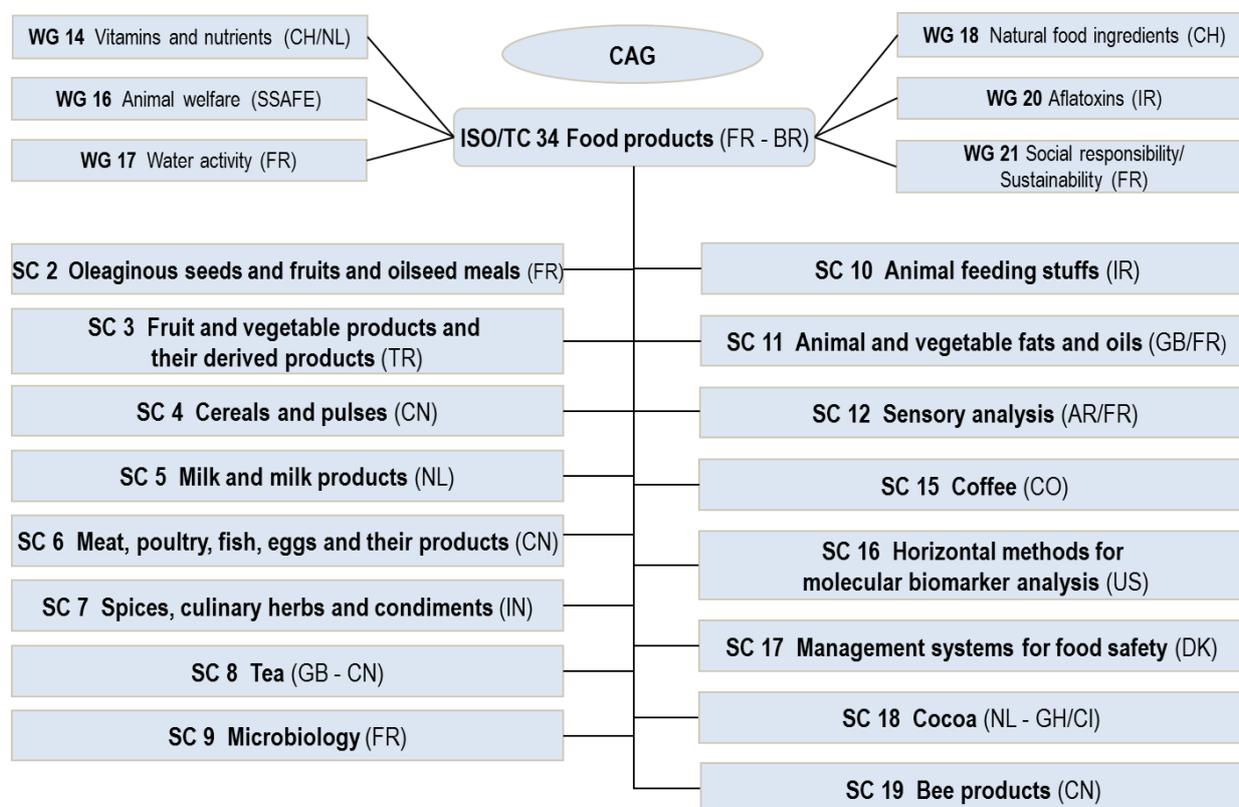
It is recognized that the Commission's members, as governments, have the authority to regulate at the national level and that ISO, as a producer of voluntary International Standards, does not. In the framework of good regulatory practice, as promoted at international and regional levels, International 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.

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.

For any further information on technical developments within ISO that have been reported in this paper, please do not hesitate to contact Mrs. Marie-Noëlle Bourquin at ISO Central Secretariat (bourquin@iso.org).

ANNEX 1**Structure of ISO/TC 34, Food products**

ISO/TC 34 comprises 73 Participating countries and 65 Observing countries. ISO/TC 34 secretariat is held jointly by France and Brazil (twinning arrangement). ISO/TC 34 has established several substructures as follows:

**Selected ISO/TC 34 projects having changed status during the past twelve months (as of May 2018)**

Project number	Title	Status
ISO 18787	<i>Foodstuffs — Determination of water activity</i>	Published in 2017
ISO 2451	<i>Cocoa beans — Specification and quality requirements</i>	Published in 2017
ISO 2292	<i>Cocoa beans — Sampling</i>	Published in 2017
ISO 22000	<i>Food safety management systems — Requirements for any organization in the food chain</i>	Published in June 2018
ISO/TS 19657	<i>Definitions and technical criteria for food ingredients to be considered as natural</i>	Published in 2017
ISO 20635	<i>Infant formula and adult nutritionals — Determination of vitamin C by (ultra) high performance liquid chromatography with ultraviolet detection ((U)HPLC-UV)</i>	Published in July 2018
ISO 20636	<i>Fortified milk powders, infant formula and adult nutritionals — Determination of vitamin D by liquid chromatography-mass spectrometry</i>	Published in July 2018
ISO/DIS 21446	<i>Infant formula and adult nutritionals — Determination of trans vitamin K1 content by normal phase high performance liquid chromatography (HPLC)</i>	Under development
ISO/CD 21468	<i>Infant formula and adult nutritionals — Determination of total choline and carnitine content by Liquid chromatography and tandem mass spectrometry (LC-MS/MS)</i>	Under development
ISO/CD 21470	<i>Infant formula and adult nutritionals — Determination of vitamin B1, B2, B3 and B6 content by liquid chromatography and tandem mass spectrometry (LC-MS/MS)</i>	Under development