

ISO 22003:2022 Part 1 and Part 2 – Harmonizing Food Safety Certification

June 2022

Webinar Outline

- Two new standards – ISO 22003 Part 1 & ISO 22003 Part 2
- Why two parts to ISO 22003?
- What does ISO 22003-1 add to ISO/IEC 17021-1:2015?
- What does ISO 22003-2 add to ISO/IEC 17065:2012?
- Common normative Annexes A, B, C brings harmonization
- Final Thoughts

ISO sets new requirements for food safety certification bodies

On 7 June 2022, ISO published two standards that will advance food safety globally by harmonizing the requirements for certification bodies (CBs) providing audit and certification of (i) food safety management systems and (ii) product certifications involving food safety systems.

- ISO 22003-1:2022 supplements ISO/IEC 17021-1:2015 and covers food safety management systems (FSMS).
- ISO 22003-2:2022 supplements ISO/IEC 17065:2012 and covers food safety systems (FSS) when implemented alongside a product certification

FSMS & FSS

FSMS certification – a certification, based on ISO's harmonized requirements for management systems, that incorporates food safety requirements based on the internationally accepted principles of food safety (i.e. prerequisite programmes and, as appropriate, control measures that result from either a site-specific or generic hazard analysis).

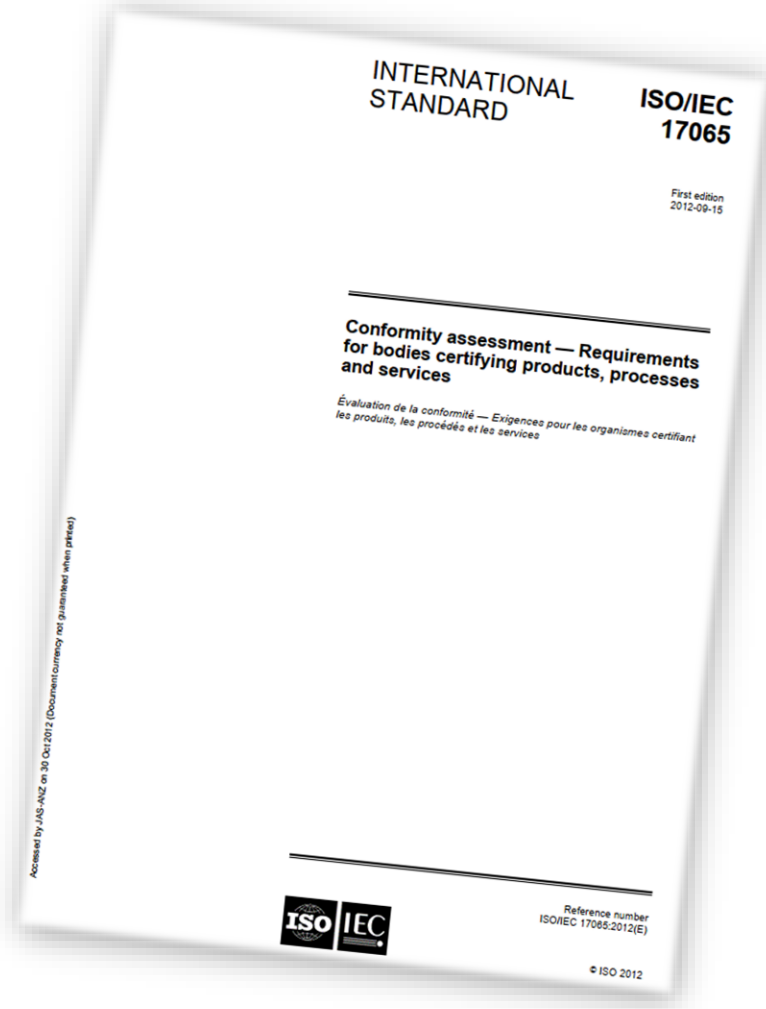
FSS certification – a product certification that incorporates requirements based on the internationally accepted principles of food safety (i.e. prerequisite programmes and, as appropriate, control measures that result from either a site-specific or generic hazard analysis) and management system components (e.g. management commitment, responsibility and review, documented information, internal audit) that support the production of safe food.

Scope ISO 22003 - Part 1



- Revise ISO TS 22003 *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems* originally published in 2007 and 1st revised in 2013
- Supplemental to ISO/IEC 17021-1:2015 *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements* (a generic standard for all types of management system certification)
- 2nd revision initiated in December 2017 with objective of developing it as an International Standard ISO 22003-1

Scope ISO 22003 – Part 2



- Approved as a new work item (NWIP) in 2019, with the objective of developing as an International Standard ISO 22003-2 *Requirements for bodies providing evaluation and certification of products, processes and services, including an audit of the food safety system.*
- Part 2 is supplemental to ISO/IEC 17065:2012 Conformity assessment — Requirements for bodies certifying products, processes and services (a generic standard for all types of product certification)
- It defines the rules applicable for the audit required for the certification of products, processes and services compliance with a certification scheme that includes a *food safety system.*



Expected use of ISO 22003 Parts 1 & 2

- ISO's published standards in the field of conformity assessment have many users. ISO 22003 Parts 1 & 2 are designed to be used as:
 - a criteria documents for the accreditation or peer assessment of certification bodies which seek to be recognized as being competent to certify that an organization's FSMS or FSS comply with the requirements of a standard or certification scheme;
 - regulatory authorities and industry consortia which engage in direct recognition of certification bodies to certify that an organization's FSMS or FSS complies with a standard or certification scheme's requirements;
 - by other parties involved in the conformity assessment of such certification bodies; and
 - in the conformity assessment of bodies that undertake to certify the compliance of a FSMS or FSS with additional criteria.



Development Process

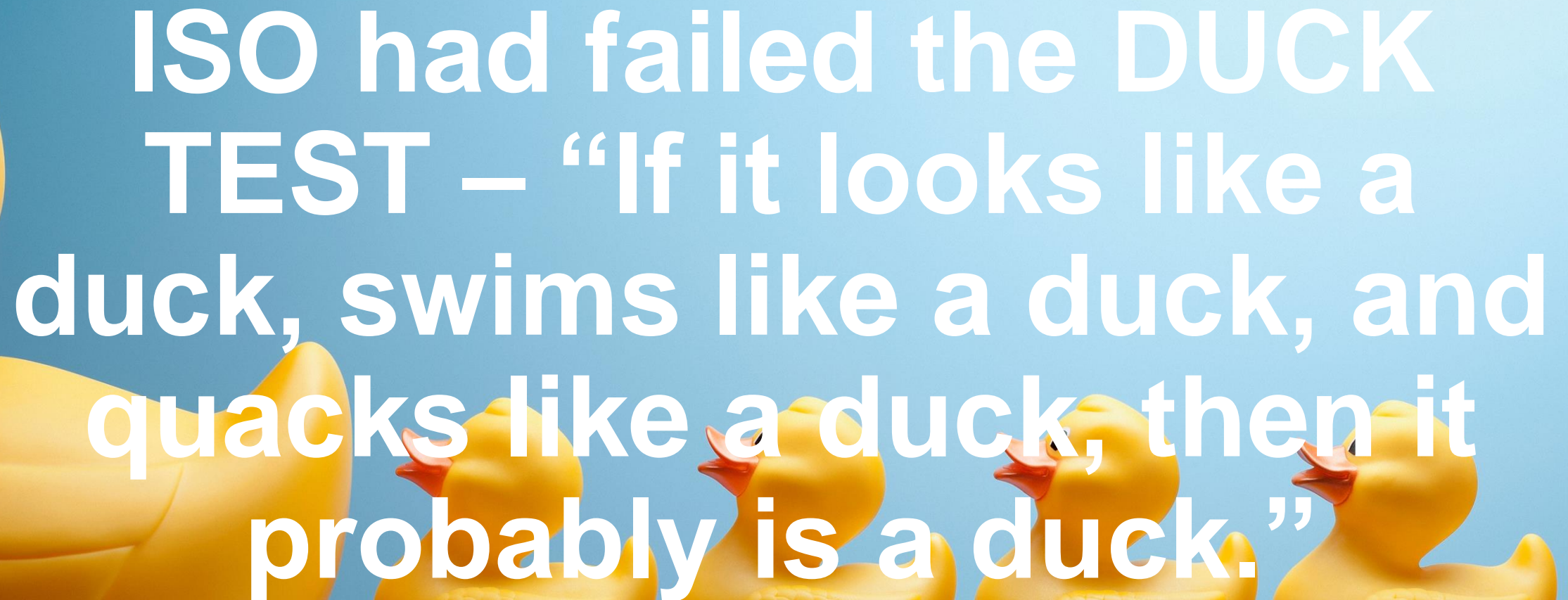
- Project was a collaboration between two ISO committees
 - ISO/TC34/SC17 – the committee responsible for the ISO 22000 family of food safety standards
 - ISO/CASCO – the committee responsible for conformity assessment standards
- SC17 & CASCO formed a joint working group (JWG36) which
 - Involved more than 100 experts on food safety, product and management system certification & accreditation
 - Met 12 times between December 2017 & December 2021
 - Reviewed more than 1741 formal comments
 - Conducted five ballots of ISO members

**Publication coincided with
World Food Safety day
7 June 2022**

Why two parts?

Background – ISO 22003 Part 2 - Rationale

- By 2017, customers of organizations with food safety certifications were increasingly confused by the differences in the certification approaches based on ISO/IEC 17021-1/ISO/TS 22003 (FSMS) and on ISO/IEC 17065 (product/process/service plus food safety) which lacks requirements on audit process, categories, audit duration, competence because of the broad application of the document.
- Many food safety certification schemes, including those recognized by the Global Food Safety Initiative (GFSI) were incorporating most of the basic requirements of a food safety system (Codex General Principles of Food Hygiene) and management system elements
- One of the key requirements of ISO/IEC 17065:2012 contained in clause 6.2 was not always consistently implemented – i.e. default to ISO/IEC 17021-1/ISO 22003 for competence and other requirements when “management systems requirements” were present in product certification schemes with food safety elements



ISO had failed the DUCK TEST – “If it looks like a duck, swims like a duck, and quacks like a duck, then it probably is a duck.”

ISO 22003-2 - NWIP

- In May 2019, after much discussion in ISO/TC34/SC17, in JWG36, and in the CASCO Chairman's Policy Committee (CPC) – a NWIP was circulated for the development of ISO 22003-2.

- Proposed Scope:

“ ... a defined set of common elements for bodies providing auditing and certification of food safety systems supplemental to ISO/IEC 17065:2012 and that includes:

1) Internationally accepted food safety principles (e.g. GHP's/PRP's and CODEX HACCP), and

2) Management system elements (e.g. objectives, internal audit, corrective actions, management review, competence).

This standard would not apply to certifications that are solely based on product testing or inspection.”

Simplification from...

ISO/TS 22003

Audit and competence requirements (current sub-set of ISO/IEC 17021-1)

ISO/IEC 17021-1

Variable individual Scheme Owner requirements

Scheme 3 requirements

Scheme 1 Requirements

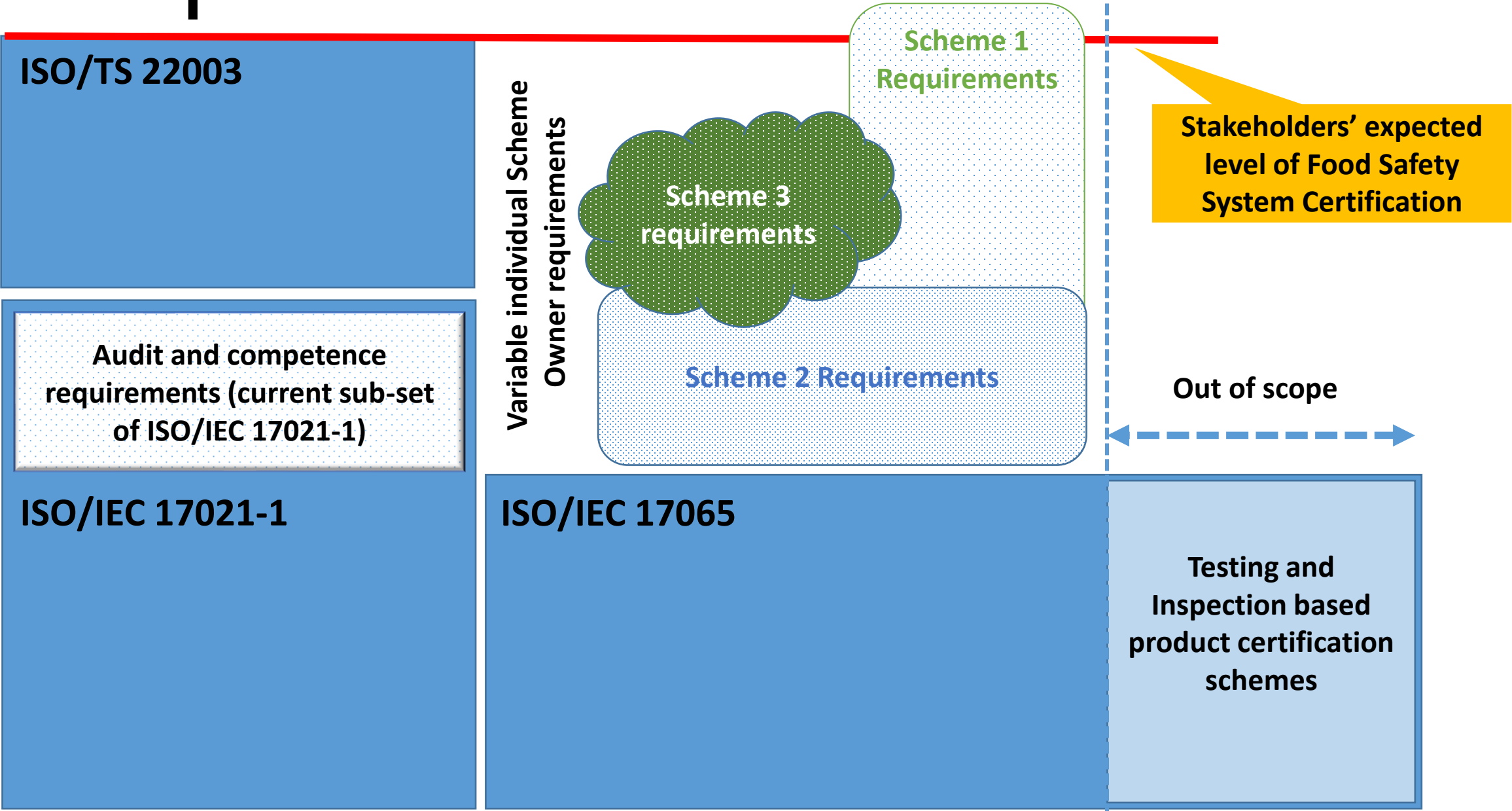
Scheme 2 Requirements

Stakeholders' expected level of Food Safety System Certification

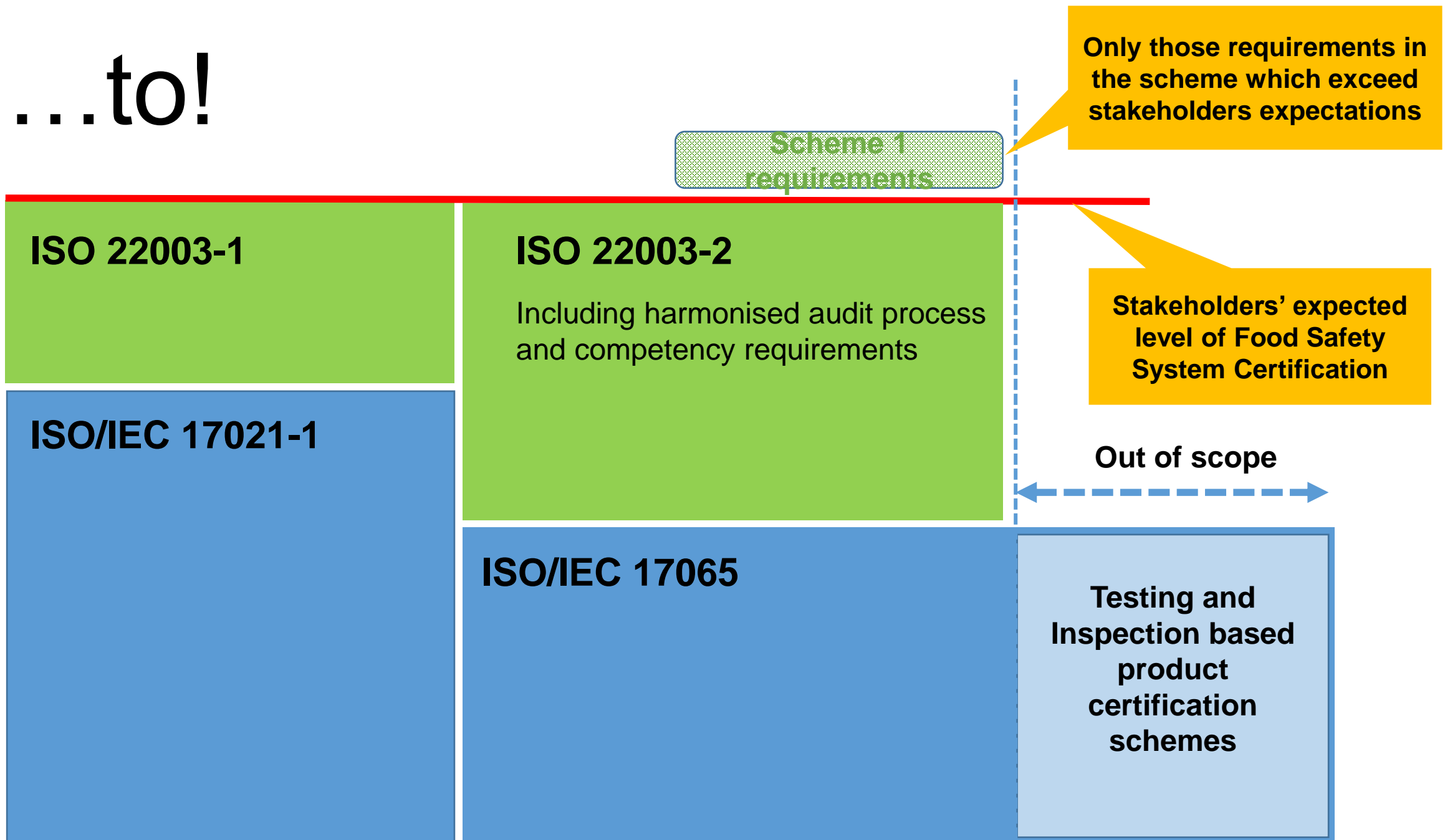
Out of scope

ISO/IEC 17065

Testing and Inspection based product certification schemes



...to!



JWG36 – Expanded to deal with Part 2

- Following approval of the ISO 22003-2 NWIP, the membership of JWG36 was expanded to more than 100 experts, either directly by new experts coming from new liaison organizations or through appointment by national standards bodies.
- Expertise of JWG36 covered wide range of experts in food safety, conformity assessment, food safety management systems and food safety certification schemes.
- Schemes and organizations at the table now included: GFSI, SQFI, IFS, BRCGS, GLOBALG.A.P., CanadaGAP, FSSC 22000, JFSM, AsiaGAP, FAMi-QS, GMP+, IQNet, IFPS, IPC, IIOC

Benefits of the harmonized approach

- **Industry** will have a clear set of criteria to compare food safety certification schemes and meet customer expectations. Easier for SMEs to participate in the supply chain.
- At the **intergovernmental** level (CODEX) there will be consistency across accredited certification approaches. National Competent Authorities will have an improved basis for recognition of 3rd party assurance schemes for food safety.
- Food safety **auditors** will have clear harmonized requirements for audit process and competence. This could help to stop the flight of auditors out of auditing food safety at a time when we need to increase auditor capacity.



What does ISO
22003-1 add to
ISO/IEC
17021-1:2015

What does ISO 22003-1:2022 add to ISO/IEC 17021-1:2015

ISO/IEC 17021-1:2015 – Table of Contents

1. Scope
 2. Normative References
 3. Terms and definitions
 4. Principles
 5. General requirements
 6. Structural requirements
 7. Resource requirements
 8. Information requirements
 9. Process requirements
 10. Management system requirements
- Annex A (Normative) Required knowledge and skills
- Annex B (informative) Possible evaluation methods
- Annex C (informative) Example of process flow for maintaining competence
- Annex D (informative) Desired personal behaviour
- Annex E (informative) Audit and certification process

- First - Part 1 incorporates all the requirements of ISO/IEC 17021-1:2015
- Then – Part 1 revises the Scope statement of ISO/TS 22003:2013 and the Normative references and adds several new Terms and definitions
- Next - Part 1 adds requirements to clauses 7, 8, and 9 of ISO/IEC 17021-1
- Finally – Part 1 revises the normative annexes A, B and C of ISO/TS 22003:2013 based on the now common annexes for Parts 1 & 2 and by adding the content of Annex A of ISO/IEC 17021-1 to the revised Annex C.

ISO 22003-1 additions – Clause 3

3.1 Carried over the FSMS definition from 2013

set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve food safety management system objectives

3.2 Includes a new HACCP Study definition

Hazard analysis for a family of products/ service/process with similar hazards and similar processes and technology (e.g. production, packaging, storage or implementation of services).



ISO 22003-1 Additions - Clause 7



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- 7.1.1 defines certification functions within the CB
- 7.1.2 establishes technical requirements based on Annex a and competence requirements based on Annex C
- 7.1.3 requires CBs to evaluate food safety knowledge & sets knowledge requirements for evaluators of personnel competence

ISO 22003-1 Additions – Clause 8



- 8.2 requires use of Table A.1 for scopes on certification documents
- 8.3 and 8.4 provides additional guidance on the use of marks

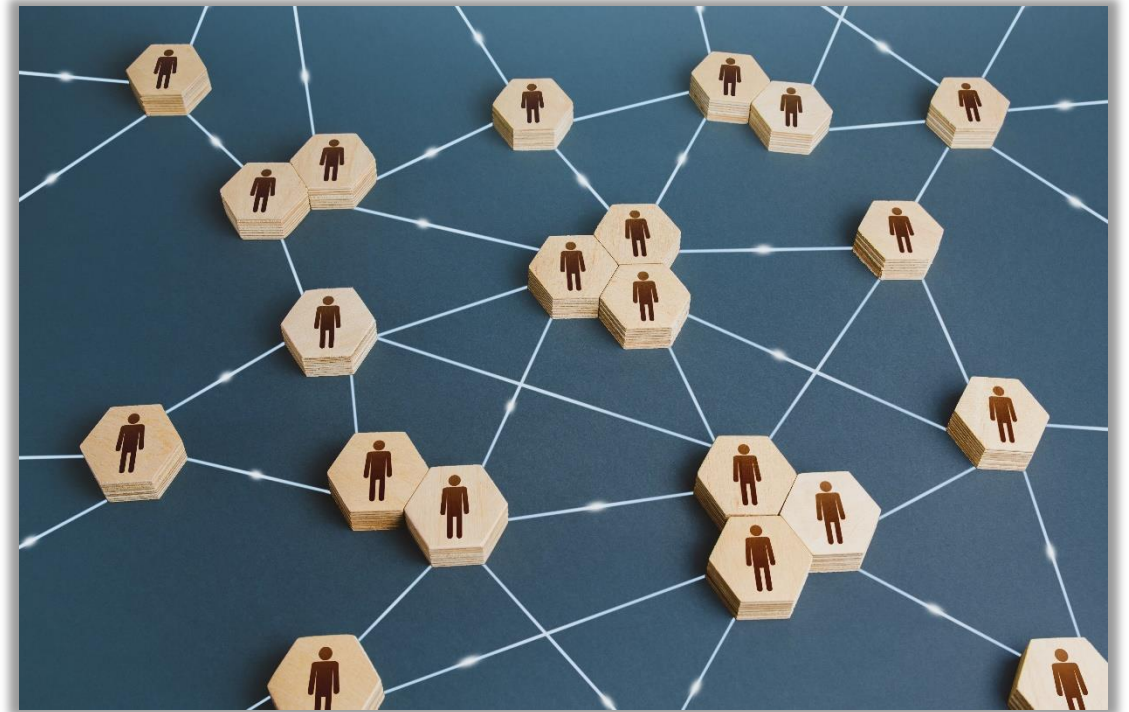
ISO 22003-1 Additions – Clause 9

- 9 is re-arranged to conform to new structure in ISO/IEC 17021-1
- 9.1.1 audit duration based on a food business operator's (FBO) submission of information re Annexes A & B
- 9.1.2 requires Annex A to be used to define certification scope
- 9.1.3 sets conditions for choosing audit time & season
- 9.1.4 covers defining, determining & documenting audit time



ISO 22003-1 Additions – Clause 9

- 9.1.5 Multi-site sampling for FSMS expanded
 - Conditions definition not changed from 2013 (i.e. central function & network of sites) and provides examples
 - Requires effective auditing & a documented rationale based on specified conditions
 - Changes in formulae with different formulae for Categories A and B and E, F and G
 - A and B – $y = \sqrt{x}$
 - E, F and G – $y = 20 + \sqrt{x}$
 - Requires FBO to do internal audits
 - Ties corrective action on major findings at any site to certification of all the sites



ISO 22003-1 Additions – Clause 9



- 9.3.2 sets food safety expectations for initial audits (e.g. PRPs, hazard analysis, hazard control plan, validation, verification, etc.)
- 9.3.3 covers externally developed elements of a FSMS
- 9.3.4 covers regulatory compliance
- 9.3.5 requires stage 1 to be on the FBO's premises
- 9.3.6 set maximum interval between stages 1 & 2
- 9.6.2 covers unannounced audits

A pair of hands is shown holding four eggs. The eggs are of different colors: two are brown, one is light blue, and one is light beige. The hands are positioned as if presenting the eggs. The background is a blurred, light-colored surface.

Annex E removed

- No longer necessary with the development of ISO 22003-2, and this annex was utilised as the basis for that work item

What does ISO 22003-2 add to ISO/IEC 17065:2012



What does ISO 22003-2:2022 add to ISO/IEC 17065:2012

ISO/IEC 17065:2012 – Table of Contents

1. Scope
 2. Normative References
 3. Terms and definitions
 4. General requirements
 5. Structural requirements
 6. Resource requirements
 7. Process requirements
 8. Management system requirements
- Annex A (Informative) Principles for product certification bodies and their certification activities
- Annex B (informative) Application of this International Standard for processes and services

- First - Part 2 incorporates all the requirements of ISO/IEC 17065:2012
- Then – Part 2 sets out the Scope statement and the Normative references and adds 17 new Terms and definitions
- Next - Part 2 adds requirements to clauses 4, 6 and 7 of ISO/IEC 17065
- Finally – Part 2 includes the common normative annexes A, B and C from Part 1

Common elements with flexibility

- General Requirements
- Structural Requirements
- Resource Requirements
- Process Requirements
- Management System Requirements
- Normative Annex's
 - A – Classification of Food Chain Categories
 - B – Minimum Audit Duration
 - C - Competence

Key to success was a **flexible** “shall”:

“Where a scheme owner has established its own rules for determination of categories, the outcome of the scheme rules shall apply provided the scheme rules are not less than those required in clause 7 and related annexes as a common basis.”

Variations appear 4 times in Part 2:

- ✓ Process Requirements
- ✓ Annex A - Categories
- ✓ Annex B - Minimum Audit Duration
- ✓ Annex C - Competence

Main additions for ISO/IEC17065 based FSS

ISO 22003-2 Scope - Clause 1

- Clarification that it does not apply to:
 - ISO/IEC 17065 based food safety schemes that do not include both internationally accepted principles of food safety and management system elements or
 - ISO/IEC 17065 food safety schemes that are **solely** based on product testing or inspection

ISO 22003-2 – Terms and definitions - Clause 3

Part 2 adds 17 new definitions to align the two parts including:

- Food safety related terms such as prerequisite programmes, control measures, HACCP study
 - *food safety system (FFS): Prerequisite programmes, supplemented with control measures, as appropriate, based on internationally accepted principles of food safety, combined with management system elements, that, when implemented by the organization, provide products and services that are safe, according to their intended use*
- Management system terms such as audit, auditor, audit time, audit duration, permanent and temporary sites
 - *management system elements: Elements of a management system (e.g. management commitment, responsibility and review, documented information, internal audit) that support the production of safe food.*

ISO 22003-2 adds to Clauses 4 & 6

- 4.1 Legal & contractual matters
 - New 4.1.2 identification of the FSS's category or subcategory (Annex A)
- 6 Resources
 - Clause 6.2.1 of ISO/IEC 17065: 2012 indicates that for management system auditing, the CB shall meet the applicable requirements of ISO/IEC 17021.
 - Part 2 now includes requirements referred to in 6.2.1 of ISO/IEC 17065 (e.g. ISO 22003-2, clause 7 & Annexes A, B & C)



ISO 22003-2 - Process requirements - Clause 7

- ISO 22003-2 – Clause 7 – brings ISO/IEC 17021-1 audit approach to FSS scheme certifications under ISO/IEC 17065
- ISO/IEC 17065 uses the term ‘evaluation’ as the document forms the basis of a myriad of schemes which utilize different types of conformity assessment in the ‘evaluation’ of a product, process or service
- ISO/IEC 17021-1 and ISO 22003-1 use the term “audit” as they cover conformity assessment of management systems
- ISO 22003-2 was written for those FSS schemes that require an ‘audit’ of ‘management system elements’ consistent with the requirements of ISO/IEC 17065 6.2.1.
- This approach was agreed by the stakeholder members of the JWG36 and endorsed by votes within both ISO CASCO and ISO/TC34/SC17.

ISO 22003-2 - Process requirements - Clause 7

- Major changes to ISO/IEC 17065 evaluation approach include requirements related to:
 - Application Review
 - Evaluation / Evaluation Plan (e.g. audit objectives, scope & criteria; audit time, audit plan)
 - Evaluation personnel (i.e. audit team, technical experts, observers, guides);
 - Evaluation tasks (e.g. multi-site sampling);
 - Conducting the audit (e.g. meetings, communications, collecting & verifying evidence, reporting findings)
 - Nonconformities & their resolution (e.g. cause analysis, corrections & corrective actions);
 - Documentation (audit report);
 - Special evaluation activities (e.g. scope extension)
- These audit approach requirements are similar to those in ISO/IEC 17021-1 (clause 9) but do not mirror them. There are differences that take into account practical differences between FSMS and FSS certifications (e.g. annual vs triennial certification cycles).

Harmonization through Common Normative Annexes A, B, C

ISO 22003-1 & ISO 22003-2 - Annexes A, B, C, D

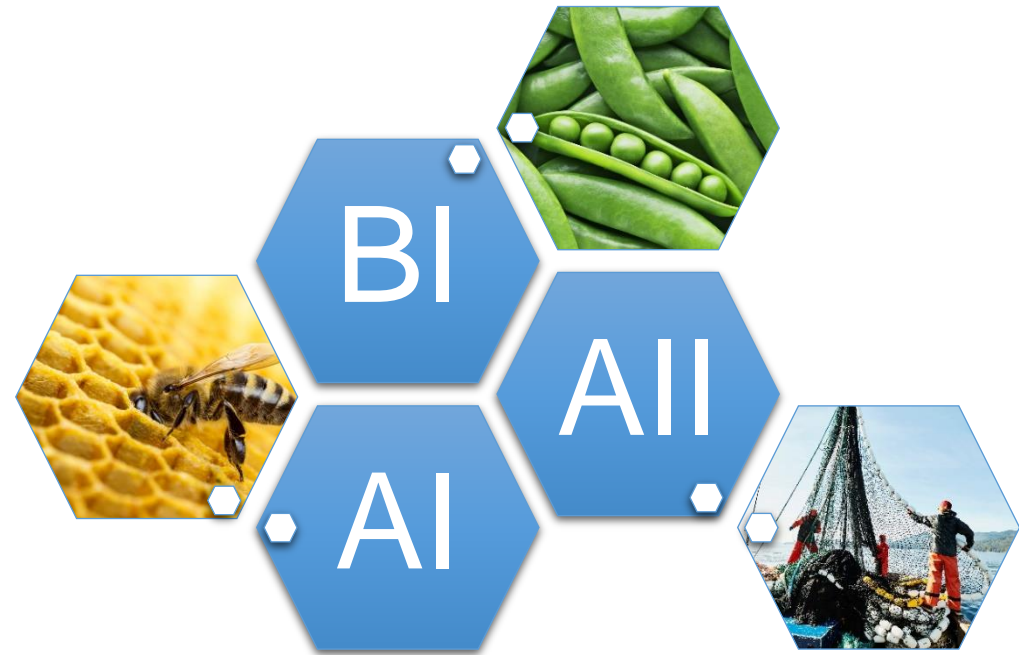
- Annex A – Classification of food chain categories
 - Normative
 - Common to both Part 1 & Part 2
- Annex B – Minimum Audit Duration
 - Normative
 - Common to both Part 1 & Part 2
 - Some differences related to certification cycle (e.g. 3 years vs 1 year)
- Annex C - Required food safety management system knowledge and skills to determine competence
 - Normative
 - Common to Parts 1 & 2
- Annex D - Guidance on generic certification functions
 - Informative
 - Applies only to Part 1

Annex A - Classification of food chain categories

- Divides the food supply chain into:
 - 9 Clusters (e.g. primary production, processing food for humans & animals)
 - 11 Categories (e.g. food processing, feed processing)
 - 12 Subcategories (e.g. farming animals, farming fish,)
- Used either at the subcategory or category level for
 - CB scopes of accreditation or recognition
 - FBO scopes of FSMS or FSS
 - Auditor competence
 - Audit duration in combination with Annex B
 - FBO PRPs where appropriate
- FSMS & FSS certification schemes can vary/exceed but Annex A is a minimum

ISO 22003-1 - Annex A changes from 2013 version

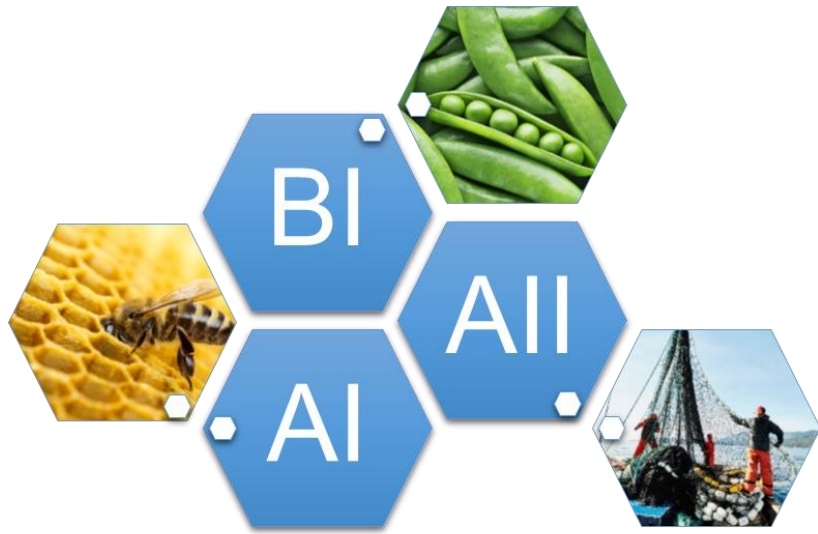
- Requirements for the use of the categories in table A.1 have changed from the 2013 version. Now used to define:
 - CB scope to the subcategory or category
 - Auditor **and** audit team competence to subcategory or category
- Reference to ISO/TS 22002 series for PRPs removed
- Provides a scheme owner has established their own requirements added



ISO 22003-1 Annex A Table A.1 - Changes from 2013 version

- Addition of subcategories
 - BIII – Pre-processing handling of plant products
 - C0 – Animal Primary conversion
- Separate clusters for Categories H, I and J
- Removal of subcategories:
 - D - Feed and animal food processing
 - G - Transport and Storage Services
- Editorial changes in some headings and examples.

ISO 22003-2 Annex A



- Same as Annex A – ISO 22003-1
- Intentional to ensure that the food chain categories in Annex A aligned with Part 1, including their application
- FSS scheme owners can establish their own rules for determination of subcategories/categories provided that the scheme rules are not less than those in Annex A

Annex B – Minimum Audit Duration – Common requirements

- Annex B in Parts 1 & 2 share common requirements
- B.1 covers expected *audit outcomes*, for example, assessing:
 - Implementation of PRPs, control measures
 - Meeting regulatory requirements
 - Management of change, etc.
- B.2 *aspects to be considered in determining audit duration*, for example
 - Requirements of the standard or scheme
 - FBO category or subcategory
 - Known hazards
 - Site size, number of sites, locations, seasonality, etc.

Annex B – Minimum Audit Duration – Differences

- Annex B in Parts 1 & 2 have differences
- B.3 Calculation of minimum audit duration
 - Both Parts use a formula approach with common elements (category or subcategory, basic site audit duration/days, number of additional HACCP studies (in audit days), effective number of full-time equivalent employees)
 - However,
 - Part 1 recognizes that FSMS certifications are for 3 years and calculates audit duration for the initial certification/recertification audit & for surveillance audits
 - Part 2 recognizes that FSS certifications are annual (for 1 year) & introduces a reduction factor to the annual audit calculation
 - Tables B.1 are slightly different, but each table sets variables for each category or subcategory
 - In Part 2 – categories A & B have different formula from that used for categories C through K

Annex B – Other changes from ISO 22003:2013

- Inclusion of reference to scheme requirements & provides for variation by schemes above the minimums established in Annex B
- Inclusion of specific reference to multi-site and integrated management systems
- Removed consideration of the absence of certified management system from table and calculation
- Table expanded to the subcategory level
- Small adjustments in the minimum on-site audit days & FTE considerations



Annex B - Audit duration

- Added that in determining the audit duration the certification body shall consider that the audit duration may include inspection, sampling and testing, management system auditing.
- For audit time calculation, some minor changes in the effective number of FTE personnel for the different categories and new calculation basis in case of combined audit and of multisite audits.

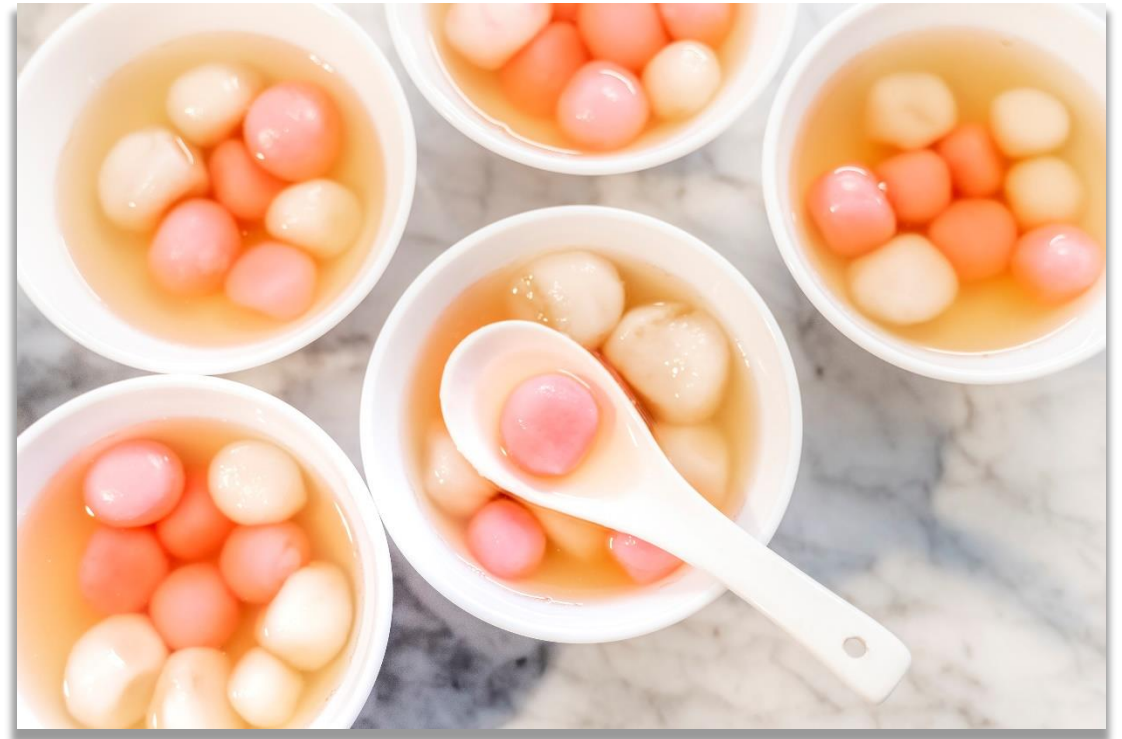
Annex C – Knowledge and skills to determine competence



- Annex C in both Part 1 and Part 2 is basically the same (some minor differences in terms related to FSMS or FSS)
- Intentional to ensure that the food chain categories in Annex A aligned with Part 1, including their application
- Intentional that the competencies for the audit of a food safety management system (FSMS) and food safety system (FSS) were considered equivalent.

Annex C – Knowledge and skills to determine competence

- Covers three certification functions:
 - Application review to determine auditor competence, audit team composition & audit time
 - Auditing & leading the audit team
 - Reviewing audit reports & making certification decisions



Annex C – Knowledge and skills to determine competence

- Covers 19 bodies of knowledge/skill:
 - Application review
 - Food chain categories
 - Auditor competences re categories/subcategories
 - Generic audit principles
 - Managing an audit
 - Business sector practices, processes, etc
 - FBO types, practices, etc
 - FBO leadership roles, etc
 - Applicable normative documents
 - Relevant products/processes of FBO
 - Identification of hazards, regulations, etc
 - Application of principles of food safety
 - Category/subcategory practices & vocabulary
 - FBO external communication responsibilities
 - Evaluation of audit reports, corrective actions, etc
 - Communication skills
 - Ability to read & write
 - Audit presentation
 - Ability to interview

Annex C changes from ISO 22003:2013 version

- Reduction in the certification functions to align with ISO/IEC 17021-1
- Now incorporates ISO/IEC 17021-1 Annex A competencies
- Changes in the actual competencies
- Will require mapping by the certification bodies, as the correlation with 2013 version is not obvious

ISO 22003-1 – Annex D - Guidance on generic certification functions

- Annex D is Informative and applies only to ISO 22003-1
- Annex D covers guidance on:
 - Application review
 - Selection of audit teams
 - Planning audit activities
 - Auditing (e.g. document review, opening & closing meetings, collecting information, audit reporting, post-audit activities)
 - Certification decision making
 - Developing professional competence



Final thoughts



CB benefits

- Common auditor qualifications baseline - Annex A subcategories
- Common auditor competence baseline – Annex C
- Common audit duration baseline – Annex B
- Common “audit” process training – Cause 7

Final thoughts

- Food Businesses have choices – FSMS or Product + FSS
- Food Safety Schemes have choices – ISO 22003-1 or -2
- CBs and ABs have obligations & opportunities
- Public and private sectors expect transparency and comparability
- Consumers deserve food safety
- Creating ISO 22003-1 and -2 advances all these objectives



Thank you

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