



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS (CCFICS)

Twenty-seventh Session

Cairns, Australia

16 - 20 September 2024

DISCUSSION PAPER ON THE STANDARDIZATION OF SANITARY REQUIREMENTS

(Prepared by Brazil with the assistance of Australia, New Zealand, Spain and the United States of America)

Background

1. At the 26th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS26) in 2023, Brazil introduced a discussion paper and project document for a proposal for new work on the standardization of the sanitary requirements noting the various challenges associated with electronic certification, including non-unique requirements, repetitive information, and lack of consistency and transparency in communication. It was pointed out that the main point of the proposal was to promote the use of electronic certification which could improve food safety and simplifying and expediting clearance processes while maintaining the flexibility of countries to define specific requirements.
2. CCFICS26 welcomed the proposal, noted that the project was complex and supported undertaking a pilot project. It was suggested that the pilot project focus on a single commodity to assess the feasibility of the proposal, against other models.
3. CCFICS26 requested Brazil with the assistance of Australia, New Zealand, Spain and the United States of America to prepare an updated discussion paper and project document for further consideration at CCFICS27. Other Members were also encouraged to come forward.

Introduction

4. The United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) publishes and constantly updates a Business Requirement Specification (BRS) and a Data Requirement Specification (RSM) that standardizes the syntax of electronic information exchanged between importing and exporting governments. The standard is known by the name e-CERT.
5. Adopters of electronic certification usually transpose information from paper to electronic format and keep the existing wording of the sanitary requirements.
6. The existing wording for sanitary certificates was conceived to be humanly readable and is agreed upon between two sanitary authorities. In many sanitary certificates analyzed, the following issues were identified:
 - a lot of work is required by the authorities to semantically agree on a certificate and create the related wording.
 - Requirements are not unique and does not carry a unique identification (the same requirement repeats two or more times throughout the certificate).
 - Several requirements are presented in one sentence.
 - If one or more certificate requirements is not applicable to export consignments, the text is often unused (strikethrough).
 - Some countries must manage hundreds of different certificate models due to the wording of the sanitary requirements.

7. Digitally meaning, the issues presented above do not allow to create of a fully electronic SPS certificate, that can be verified and automatically processed during the issuance, exchange, and validation procedures by electronic platforms like a single window or risk analysis systems.
8. The issues can be minimized, or even solved, with a global standard of sanitary requirements, from a semantic point of view. A unique ID and possible attributes must be defined for each requirement, creating a menu of requirements that countries will rely on during the agreement negotiation.
9. Also, the unique ID will allow countries to manage only one certificate model, which can carry several sets of requirements depending on what was agreed.
10. The Harmonized System Codes (HS Codes), administrated by World Customs Organization (WCO), and ICD-11, administrated by World Health Organization (WHO), are examples of a successful implementation of a harmonization and semantic definition that leverage their related operations.

Discussion

11. This discussion paper recognizes that an importing country should be able to define not only the requirements that must be presented in the certificate, but also related metadata and the languages to be used.
12. On the other side, the free definition of requirements can lead countries into a long negotiation process and guide the agreed certificate far from the best practices presented by Codex Guidelines for Design, Production, Issuance and use of Generic Official Certificates (CXG 38-2001).
13. Also, the free definition of requirements turns the implementation and use of e-CERT harder, making countries to build complex systems to manage all agreed possibilities.
14. The following example represents two paragraphs of the requirements agreed between Brazil and a third country. The same issues can be observed throughout the 600 certificate models that Brazil manage:

Paragraph #1: *"The products were obtained, processed, packaged and packed in hygienic conditions. They do not contain neither they have been added any substance harmful to human health and do not cause the spread of animal diseases."*

Paragraph #2: *"A foot-and-mouth disease (FMD) virus inactivation treatment of milk products has been carried out in any stage of production by any of the following methods (strikeout what does not match):*

- I. a minimum temperature of 132°C for at least one second in liquid form (UHT);*
- II. (pH less than 7.0) a minimum temperature of 72°C for at least 15 seconds in liquid form (HTST);*
- III. (pH 7.0 or greater) HTST applied twice;*
- IV. maintaining a pH less than 6 for at least one hour".*

15. In the sentences above, the following requirements are stated:

- In Paragraph #1:
 1. *The products were obtained in hygienic conditions;*
 2. *The products were processed in hygienic conditions;*
 3. *The products were packaged in hygienic conditions;*
 4. *The products were packed in hygienic conditions;*
 5. *The products do not contain neither they have been added substance harmful to human health;*
 6. *The products do not cause the spread of animal diseases*
- In Paragraph #2:
 1. *A foot-and-mouth disease (FMD) virus inactivation treatment of milk products has been carried out in any stage of production by a minimum temperature of 132°C for at least one second in liquid form (UHT); or*
 2. *A foot-and-mouth disease (FMD) virus inactivation treatment of milk products has been carried out in any stage of production by a minimum temperature of 72°C for at least 15 seconds in liquid form if pH less than 7.0 (HTST); or*
 3. *A foot-and-mouth disease (FMD) virus inactivation treatment of milk products has been carried out in any stage of production, twice, by a minimum temperature of 72°C for at least 15 seconds in liquid form if pH more than 7.0 (HTST); or*

4. *A foot-and-mouth disease (FMD) virus inactivation treatment of milk products has been carried out in any stage of production by maintaining a pH less than 6 for at least one hour.*
16. If it is not easy for a human to split this information into objective items, a computer is not able to verify if all the requirements are presented, even with advanced artificial intelligence models.
17. The existing systematic is not designed to scale and to be digitally processed by computers in the e-CERT era. Also, an objective and harmonized requirement list can lead countries into a safer negotiation for both sides.
18. Other benefits that the standardization of requirements can enable are:
 - collection, comparison and analysis of statistics
 - reduction of the expenses incurred by redescribing in the course of international trade
 - facilitation of the standardization of trade documentation
 - facilitation of the data transmission and processing.
19. The central hypothesis poses the following question: *Is it possible to convey the same message of the existing attestations using fewer, more standardized terms?*
20. CCFICS26 welcomed the proposal, noted that the project was complex and supported undertaking a pilot project. On the basis this recommendation, a pilot project was developed by Brazil together with an international collaborative team. The pilot project has demonstrated the feasibility of adopting a standardization approach, which includes enhanced clarity, reduced complexity, and the facilitation of automated processing systems. Collectively, these improvements contribute to more efficient and reliable international trade practices.
21. Behind most standardization initiatives, there is a technique called ontology. Ontology is a special way of organizing and labeling things to help with understanding and finding them.
22. Ontology can be used in any knowledge domain. For example, in a library, ontology relies on the organization of the catalog system where books are grouped by genre (mystery, science fiction, history), and each book has details like author, title, and publication year. Additionally, it includes information about the aisle, shelf, and section where the book is located. This comprehensive organization helps quickly find a book, understand what it is about, and know exactly where to locate it within the library.
23. The pilot project was conducted based on theoretical and methodological foundations such as ontology, context-free grammar, natural language processing, and corpus linguistics.
24. A total of 42 sanitary certificates for dairy products were provided by Australia, Brazil, Canada, Mexico, the Netherlands, Spain, and the United States of America for use in the project. The existing attestations were analyzed using both qualitative and quantitative techniques, as detailed in the project report – [PILOT PROJECT REPORT - DETAILED VERSION.](#)
25. Artificial Intelligence tools were developed to significantly reduce the human effort required, especially when dealing with repetitive and tedious tasks. It is important to highlight that this kind of work can also be executed without AI techniques.
26. The results demonstrated that by applying techniques as indicated in the report, it is possible to structure the data into [Subject, Predicate, Object], also known as triples. This approach makes it easier to capture and understand the relationships between different entities.
27. From the initial 1,281 triplets extracted from the dairy certificates, 1,163 were used to perform the standardization exercise. This process resulted in 53 subjects, 71 predicates, 53 objects, and related metadata, referred to in the pilot as 'standardized terms'
28. The term 'standardized terms' does not reflect approval or definition from CCFICS, Codex Alimentarius, or any other related organization, department, or committee. It merely reflects the results of the pilot study to understand the feasibility of standardizing terms for use in Health Requirements. When this and other related documents mention "standardized terms," they refer only to the scope of this study and nothing more.
29. The 'standardized terms' will form what is known in context-free grammar as a subset of English grammar. This subset comprises specific terms and relationships that are essential when defining attestations.
30. Using the same two paragraphs presented above as an example, the attestations can be rewritten using the 'standardized terms':

- In Paragraph #1:

SUBJECT	PREDICATE	OBJECT
PRODUCT	obtainedIn	CONDITION #type(Hygienic)
PRODUCT	processedIn	CONDITION #type(Hygienic)
PROCESS #type(Packaging)	compliesWith	CONDITION #type(Hygienic)
PRODUCT	freeFrom	SUBSTANCE #type(HarmfulSubstances)
PRODUCT	freeFrom	DISEASE #type(Animal)

- In Paragraph #2:

SUBJECT	PREDICATE	OBJECT
RAWMATERIAL #type(Milk)	subjectedTo	TREATMENT #type(UHT) #tempMin(132) #tempUnit(Celsius) #timeMin(1) #timeUnit(second) #target (<i>FMD virus inactivation</i>)
RAWMATERIAL #type(Milk) #ph(7orLower)	subjectedTo	TREATMENT #type(HTST) #tempMin(72) #tempUnit(Celsius) #timeMin(15) #timeUnit(second) #target (<i>FMD virus inactivation</i>)
RAWMATERIAL #type(Milk) #ph(7orHigher)	subjectedTo	TREATMENT #type(HTST) #tempMin(72) #tempUnit(Celsius) #timeMin(15) #timeUnit(second) #occurrence(twice) #target (<i>FMD virus inactivation</i>)
RAWMATERIAL #type(Milk)	subjectedTo	TREATMENT #timeMin(1) #timeUnit(hour) #ph(6orLower) #target (<i>FMD virus inactivation</i>)

31. It's important to highlight that the knowledge underlying the existing attestations and the triplets is the same. The difference lies in the format of how the knowledge is exchanged, which will lead to better mutual understanding and automated validation.

32. With a standardized format, If a requirement is not met, the related ID and description will not be presented into the document, in paper or electronic formats. Computers and humans can easily check the information and countries will be able to implement real digital systems, able to track and trace requirements.
33. This new structure can be linked with species classification, the Harmonized System, ISO codes, EDIFACT¹ definitions, and several other standards to leverage the capability of cross-check data, contributing to safety at borders.
34. The pilot demonstrated the profound benefits of moving towards a standardized approach. This includes enhanced clarity, reduced complexity, and the facilitation of automated processing systems, which collectively contribute to more efficient and reliable international trade practices.
35. Also, the pilot highlighted the challenges involved in harmonizing knowledge and defining standards. However, it also provided valuable insights into how these challenges could be systematically addressed through collaborative efforts and the adoption of innovative technologies.

Recommendations

36. The Committee is invited to
 - a) Support the proposal for the new work on the standardization of sanitary requirements as set out in the attached project document (**Appendix I**).
 - b) establish an Electronic Working Group (EWG) to define the criteria and method to evaluate the existing requirements in order to propose the taxonomy and ontology on the standardization to represent sanitary requirements that can be applied to any type of product.

¹ United Nations/Electronic Data Interchange for Administration, Commerce and Transport (UN/EDIFACT)

PROJECT DOCUMENT

STANDARDIZATION OF SANITARY REQUIREMENTS

1. Purpose of proposed Standard

The purpose of the work is to develop a global standard to represent sanitary requirements in health certificates. Harmonized syntax and semantics would turn the negotiation for a new certificate, and the update of an existing one, into a very objective activity. Also, it will turn the e-CERT implementation easier, because digital verifications can be implemented and automatized into processes and an accurate language is very important to avoid confusion on what is intended to achieve. The standard would not be mandatory and are not specific for electronic documents.

The following activities are proposed:

- Establish a full-project structure: create of a group of project managers, engineers specialized in ontologies and domain experts;
- Assess and refine the pilot results: validate the theoretical and methodological foundations and results, remove ambiguities and establish univocal relationships between the natural language text of the requirement and its translation into triples;
- Gather information: Collect all relevant documents, guidelines, and regulations related to sanitary requirements, including any existing standards or best practices.
- Identify key concepts: Analyze the gathered information to extract the most important concepts, entities, and relationships.
- Reuse of Existing Ontologies: identify the possibility to integrate and adapt existing ontologies, promoting consistency and saving time.
- Create a taxonomy: Organize the sanitary requirements into a hierarchical classification system based on their characteristics, such as the type of requirement, the hazard it addresses, or the level of risk it represents.
- Develop an ontology: define the attributes and relationships between the concepts within the sanitary requirements domain. This might include specifying the conditions under which a requirement applies, how different requirements are related, or any constraints or rules that govern their implementation.
- Validate and refine: Evaluate the taxonomy and ontology for accuracy, consistency, and completeness. Refine when necessary.
- Implement and maintain: Help to integrate the taxonomy and ontology into the relevant systems, processes, or tools.
- Define the next scope: determine the specific domain and scope of the sanitary requirements.

2. Relevance and Timeliness

Countries are facing challenges to implement electronic certification systems. The OECD paper entitled *Electronic Sanitary Certificates for Trade in Animal Products (2023)* identified that “*At present, there is no “one” international standardised sanitary certificate schema for all countries that can facilitate the standardised exchange and processing of e-sanitary certificates*”.

Create an XML file for electronic certification embedded with information that is presented on paper is not difficult. The challenge, and the real watershed, is to create digital and automated processes that will improve safety at the same time that reduces bureaucracy at borders.

Digital transformation seems a buzzword nowadays, but the truth is that it can only be achieved with new processes and new tools, designed with a digital mindset, reusing data throughout the supply chain, integrating public and private institutions.

The standardization proposed will enable the digital mindset for the sanitary requirements, making the journey to the electronic certification easier and faster. The lack of schema highlighted by OECD can be at least minimize, or even solved.

3. The main aspects to be covered

As already implemented in other areas, like the Harmonized System and International Code of Diseases, a structured taxonomy must be defined to represent the categories and subcategories of requirements. The requirements must be analyzed based on three principles:

- What will be the requirement;
- In which category it belongs;
- Which are the related attributes (Ontology).

Attributes must be defined when requirements vary based on a place, procedure or any kind of variation. In addition, attributes can be used to carry specific data, like a fixed value or a range of temperature. The syntax and semantics of the attributes must follow other data standards already published.

4. Assessment against the Criteria for the Establishment of Work Priorities

The proposal is consistent with the criteria as follows:

General Criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work will enable a more organized and systematized approach to sanitary requirements, that can be applied from production to certification of plant and animal products. This holistic structure will leverage controls allowing automated checks to be performed by autonomous systems. Better processes lead to better results, and in this case, deliver a safer product for consumption.

Criteria applicable to General Subjects

a) Diversification of national legislations and apparent resultant or potential impediments to international trade

The development of the proposed standard would assist in achieving harmonization at global level, facilitate the agreement of requirements and also the control of their compliance by the national authority.

b) Scope of work and establishment of priorities between the various sections of the work

Refer to scope of work above.

c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

Similar work was performed for other areas, like WCO and WHO as explained in the Introduction above.

d) Amenability of the subject of the proposal to standardisation

The deliverables of the working group will be proposed as a new standard.

e) Consideration of the global magnitude of the problem or issue

Manage hundreds of certificate models may lead to errors and inefficient processes and controls. Countries are having difficulties to implement electronic certification systems mainly related to the incorporation of the e-CERT document into the existing processes. The standardization will enable that new processes may be designed and implemented based on data collection and reuse, private-public interoperability and track and trace strategies.

5. Relevance to Codex strategic objectives

The project proposal outlined above relates to the Codex Alimentarius Commission's Strategic Plan for 2020-2025 in several ways:

1. Establish international food standards that address current and emerging food safety and quality issues: The proposal aims to standardize sanitary requirements and develop a global standard for requirements that can be digitally processed, which would contribute to international food safety standards and facilitate trade.
2. Ensure the application of risk analysis principles in the development of Codex standards: By creating a standardized, digitally processable set of sanitary requirements, the proposal would allow for improved risk analysis and data-driven decision-making.
3. Facilitate the effective participation of all Codex members, particularly developing countries, in the standard-setting process: The proposed standardization of sanitary requirements would simplify the process for all countries, making it easier for developing countries to participate in trade negotiations and comply with international food safety standards.
4. Implement effective and efficient work management systems and practices: The proposal focuses on creating a harmonized and semantic standard for sanitary requirements, which would lead to more efficient work management systems and practices in the context of sanitary certificates and e-CERT implementation.

5. Strengthen communication and promote the use and understanding of Codex standards and related texts: By standardizing the sanitary requirements, the proposal would make it easier for countries to communicate, understand, and implement Codex standards in their trade agreements and certification processes.

6. Information on the relation between the proposal and other Codex documents

The proposed standard creation will help to address the objectives presented by the documents below.

1. Codex Guidelines for Design, Production, Issuance and use of Generic Official certificates (CXG 38-2001)
2. Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CXG 60-2006)

7. Identification of any requirement for and availability of expert scientific advice

Taxonomy and ontology experts are required to establish the base on what the project will be implemented. The project aims at standardising the representation of existing knowledge without adding any new knowledge and it demands a multidisciplinary team. Depending on the achievements, additional expert advice from the FAO or WHO, may be sought should need arise.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

Technical input will be necessary from external consultants and domain experts in order achieve the best possible results.

9. Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the timeframe for developing a standard should normally not exceed five years

Subject to the Codex Alimentarius Commission approval, it is expected that the new work can be completed within two or three sessions of CCFICS.