CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 8 **CRD02**

September 2023

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON GENERAL PRINCIPLES

Thirty-third Session

Bordeaux, France

2-6 October 2023

DISCUSSION PAPER ON PRACTICAL TOOLKITS TO PROMOTE THE USE OF CODEX STANDARDS AND GUIDELINES

Prepared by the United Kingdom

INTRODUCTION

1.1 This paper is presented for the purpose of starting a broad discussion amongst Codex members and observers on the merits of Codex developing supporting toolkits that might help increase the use of Codex standards by national governments. The paper uses as an illustration of the idea, the potential value of a Codex self-assessment toolkit anchored in the working principles for risk analysis. As such it develops the thinking around the use by national authorities of a toolkit to benchmark their capacity and capability to carry out risk analysis.

1.2 Members' views are sought on the broader concept of toolkits and the appetite amongst Codex members to further consider whether there might be a role for Codex to develop toolkits to support its current and future strategic ambitions and goals. This discussion paper also invites views on the illustrative example used to further explore the idea of a Codex self-assessment toolkit for risk analysis. The purpose of this illustration is to provide context that helps orientate members towards an open and broad-based discussion, not to urge new work on this or any other specific topic.

CONTEXT

2.1 Codex's parent bodies recently reaffirmed the importance of risk analysis to national food control systems. The **WHO Global Strategy for Food Safety 2022-2030**[1] commented that "*the principles for the application of risk analysis are well described by Codex Alimentarius, however many members need to invest in capacity-building for risk assessment and should source risk analysis experiences from beyond national borders to strengthen risk management decisions and technical capacity"*.

2.2 Whilst the principles are well understood there is a paucity of practical guidance that could help a member integrate risk analysis across their food control system. A similar theme emerged in the **FAO Strategic Priorities for Food Safety**[2] publication which stated that "*greater investment in capacity and resources are necessary for FAO Members to use the risk analysis paradigm to guide food control programmes. This is crucial especially in contexts where resources are limited to begin with"*.

2.3 The development by Codex of a broader range of toolkits that help authorities implement Codex standards would help deliver Strategic Goal 3 in the current Strategic Plan: *to increase the impact through the recognition and use of Codex standards.*

[1] WHO Global Strategy For Food Safety 2022-2030: towards stronger food safety systems and global cooperation

[2] FAO Strategic Priorities for Food Safety within the FAO Strategic Framework 2022-2031

BACKGROUND

3.1 The well-described principles for risk analysis reside in two foundational Codex texts. The first, adopted in 2003 are for application within the framework of the Codex Alimentarius Commission (Codex Procedural Manual, Section 4, 28th Edition). This text describes the internal governance arrangements and process used to elaborate science-based standards. The principles are directed at the CAC, its Subsidiary Bodies, and the WHO/FAO Joint Expert Bodies. Supporting procedural[3] texts were developed subsequently and describe in more detail the risk analysis methodology to foster consistency in approach across the subsidiary bodies. Whilst there are some differences in the way the subsidiary bodies apply the working principles the Secretariat concluded in their 2016 review that *there did not seem to be impediments for the effective use of the present risk analysis principles of Codex committees (CX/GP 16/30/4).* In summary, Codex members are very familiar with the application of the working principles for risk analysis that are used to develop science-based standards.

3.2 The second text was adopted in 2007 and contains the ***Working Principles for Risk Analysis for Food Safety Application by Governments*** (CAC/GL 62-2007). It provides guidance to national governments for the conduct of risk assessment, risk management and risk communication with regards to food related risks to human health. To date, barring a handful of targeted examples (see paragraph 6.2), Codex has chosen not to elaborate additional text to promote and support the integration of the risk analysis principles at a food system control level. Embedding the risk analysis principles at a system level would be entirely consistent with Principle 6 of the National Food Control System (NFCS)[4] guidelines which states that *competent authorities should make decisions within their national food control system based on scientific information, evidence and/or risk analysis principles as appropriate*.

3.3 Several supporting tools and guides have been developed since the working principles for risk analysis were adopted in 2007, for example the **FAO's and WHO's *Food Safety Risk Analysis Tools***[5] and their ***Food Control System Assessment Tool***[6]***.*** The former provides targeted support on specific issues (e.g., risk assessment of Cronobacter spp. in powdered infant formula). The latter which was finalised in 2019 enables authorities to analyse the performance of their control system with a view to identifying areas for improvement. It touches on aspects of risk analysis, including the knowledge and use by Competent Authorities of a risk analysis framework, although there are gaps that could be filled through additional supportive and complementary tools, for example those outlined in the bullet points in paragraph 4.1 below. There is also a FAO/WHO "Diagnostic Tool for Assessing the Status of National Codex Programmes" which is used by applicants to the Codex Trust Fund. It allows countries to take stock from time to time of their national Codex programme with a view to identifying areas for improvement.

3.4 Toolkits are rare in Codex though CCFICS developed a framework for authorities to performance manage their NFCS which was adopted in 2017 and is intended to encourage continuous improvement in much the same way as the FAO/WHO tool. UNIDO has also developed a draft toolkit to support members' use of and implementation of the recently adopted CCFICS voluntary third-party assurance guidelines (CXG 93-2021). There is also little data or research on the extent to which the current (FAO/WHO & Codex) tools are used.

DISCUSSION

4.1 Toolkits are used to turn theory into practice with a view to ensuring consistency and coherence in approach. Toolkits that help members understand what good looks like can also enable members to translate Codex standards to their national settings/control system and help foster more consistency in the application of international standards. A Codex self-assessment toolkit anchored around the ***Working Principles for Risk Analysis for Food Safety Application by Governments*** would support the goals, objectives and outcomes contained in the Codex Strategic Plan[7], by helping to *increase impact through the recognition and use of Codex standards*, and *increased use of Codex standards in the development of national food standards and regulations.* A Codex toolkit could help promote the use of an internationally agreed approach to risk analysis by providing a high-level understanding of the practical measures that need to be put in place to implement them. Such a toolkit would be for use by policy practitioners and seek to complement, not replace existing tools, for example by helping to reinforce the key components of risk analysis set out in the ***FAO/WHO Food Control System Assessment Tool***. A complementary Codex toolkit whilst helping to reinforce the

[3] Codex Procedural Manual, Section 4: Risk Analysis
[4] CXG/GL 82-2013
[5] http://www.fstools.org/
[6] https://www.fao.org/food-safety/food-control-systems/assessment-tool/en/
[7] Codex Strategic Plan 2020-2025

fundamental elements needed for risk analysis would also provide additional supplementary information to guide authorities in a capacity and capability assessment, this could include:

- the ability to analyse the whole or parts of a national food control system.
- helping national authorities understand what 'good' looks like through use of a scoring system/scale of advancement rather than by providing yes/no answers to whether the country has certain elements in place.
- providing users with more in-depth analysis of certain aspects e.g.:
    - problem formulation,
    - risk assessment steps such as exposure assessment,
    - assessment of different types of hazards e.g., microbiological and chemical risk assessment,
    - quality assurance.
- inclusivity by providing an opportunity for Codex members to share their experiences and contribute to the development of the toolkit; and;
- enhanced status and potential increased use of a branded Codex toolkit that could help foster consistency.

4.2 As the *Working Principles for Risk Analysis for Food Safety Application by Governments* are a foundational text developed by CCGP this committee appears to be the natural home to explore in more depth the value of such a toolkit to guide members in their application of risk analysis. Other Codex subsidiary bodies could consider whether the development of supporting toolkits might lead to increased use of existing, or planned standards/texts and in doing so help foster greater consistency and confidence in food control systems across the globe. Codex branded toolkits would be an innovation and signal members' determination to promote the use of Codex standards and texts. As a member-driven organisation, it is legitimate for members to consider new approaches that support the use and implementation of Codex standards and texts.

4.3 A risk analysis toolkit could help improve an authority's self-awareness and enable them to identify gaps or weaknesses in their system, or parts of it, which they could then address through more targeted interventions, potentially with assistance from a range of capacity building organisations such as, but not limited to: Codex's parent bodies, the WTO's Standards and Trade Development Facility (STDF), the United Nations Industrial Development Organisation (UNIDO). The toolkit may also have utility for Codex Trust Fund applicants as it could help signpost where improvements are needed and lead to funding that supports integration of the risk analysis principles across their food safety control system. Increased take up of the working principles through use of the toolkit would also, over time, lead to the submission of more and better quality (geographically representative) data for the risk assessments carried out by the WHO/FAO Joint Expert Bodies.

4.4 When choosing to implement a Codex standard, authorities often have to interpret and adapt the standard so that it takes account of national circumstances, settings, and legislative frameworks. This may lead to inconsistencies in application which a practical toolkit could help address.

4.5 There are a number of practical issues associated with toolkits, for example ease of use and maintenance of the content so that they remain relevant and up-to-date, also availability in different languages and the quality/format of the output from use of the toolkit. In an increasingly digitized world, it would be prudent to explore how toolkits are published, for example a self-assessment toolkit that will allow authorities to assess their capacity and capability against the working principles for risk analysis may benefit from being made available online, perhaps as an interactive toolkit capable of producing reports that authorities can use to prioritise the parts of their system most in need of improvement.

4.6 It is however important to also differentiate between practical guidance and a toolkit. The former helps authorities to interpret and implement requirements whilst the latter has an output and helps authorities to understand what needs to be in place and may objectively score what is in place (level of advancement). Interactive toolkits can also be used at regular intervals to measure progress over time by comparing outputs.

UK EXPERIENCE

5.1 Over the last five years the UK's Food Standards Agency (FSA) has grown considerably and strengthened its food safety risk analysis capacity and capability as a central competent authority for food and feed. FSA sought to align its approach to international standards, including those elaborated by Codex, when changes to the UK's regulatory system compelled it to critically assess what was needed to take on new national food safety responsibilities. This process led to a major overhaul of the UK's food control system and supporting regulatory framework. The Codex Working Principles for Risk Analysis for Application by Governments were

used as the starting point for that journey to ensure the UK's system aligned with international norms. The UK found that, as noted by WHO, whilst the risk analysis principles were well-established it was challenging to know how to integrate them to our control system. It is fair to say that there was no single off-the-shelf guidance.

5.2 This experience did however provide the UK with some unique insights which could be shared with members, perhaps through the development of a self-assessment toolkit that complements and supplements existing tools and texts. Other members may wish to share their experience, challenges and insights in applying and integrating the Codex risk analysis principles to their regulatory system.

APPROACH

6.1 A risk analysis toolkit designed with practical application in mind would need to cover the three disciplines, risk assessment, risk management and risk communication. It might use a similar approach to that set down in the World Organisation for Animal Health (WOAH) 'Tool for the Evaluation of Performance of Veterinary Services'[8].

6.2 This approach would involve identifying the fundamental components that an authority needs to have in place in order to implement the risk analysis principles described in CAC/GL 62-2007 (and potentially in more issue-specific Codex guidelines such as CAC/GL 30-1999[9], CAC/GL 63-2007[10]). These could then be further divided into sub-categories of critical components, which would be defined and described using various levels of advancement and scoring. For example, a fundamental component needed to deliver the risk assessment principles is human resources, which could then be further broken down into critical components such as internal expertise and training etc. Each critical component could then be defined and described using levels of advancement scores (e.g., 1-5).

6.3 The toolkit would be for use by national authorities on a self-assessment basis with the outputs used internally to prioritise and target improvements to the whole or parts of a NFCS and as appropriate support bids for external funding. It is not suggested that the outputs would be collated and centrally reported, for example in a manner similar to the WHO Electronic IHR States Parties Self-Assessment Annual Reporting Tool (e-SPAR).[11]

6.4 The toolkit would sit alongside and be used in conjunction with existing resources such as the FAO/WHO Food Control System Assessment Tool.[12] It would not seek to replicate within national authorities the internal governance arrangements and structure within Codex but would help authorities engage more effectively in that process.

SUMMARY

- The development by Codex of additional supportive toolkits to help members interpret and use Codex standards is entirely consistent with the current Strategic Plan covering the period 2020 – 2025 and the early thinking on the next Strategic Plan for 2026-2031. Specifically Strategic Goal 3 which is likely to be retained in the new plan and describes as a key outcome the *increased use of Codex standards in the development of national food standards and regulations.*
- Members' views are sought on the broader concept of toolkits and the potential value of a risk analysis self-assessment toolkit and other toolkits that could help members align with Codex standards, as well as the appetite within Codex to develop such toolkits.

[8] OIE Tool for the Evaluation of Performance of Veterinary Services
[9] CAC/GL 30-1999 Codex Principles and Guidelines for the Conduct of Microbiological Risk Assessment
[10] CAC/GL 63-2007 Codex Principles and Guidelines for the Conduct of Microbiological Risk Management
[11] Electronic State Parties Self-Assessment Annual Reporting Tool (e-SPAR)
[12] FAO/WHO Food Control System Assessment Tool