Codex Alimentarius: food quality and safety standards for international trade

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Summary
Since 1962, the Codex Alimentarius Commission (CAC) of the Food and Agriculture Organisation/World Health Organisation has been responsible for developing standards, guidelines and other recommendations on the quality and safety of food to protect the health of consumers and to ensure fair practices in food trade. The mission of the CAC remains relevant, but a number of factors have shown the need for new techniques to form the basis of food standards, the most important of which is risk analysis. The authors give a brief description of the role and work of the CAC and the efforts deployed by the Commission to respond to the challenges posed by new approaches to government regulation, harmonisation of national requirements based on international standards and the role of civil society.

Keywords

Introduction

In March 1991, a Joint Conference on Food Standards, Chemicals in Foods and Food Trade was convened in Rome, Italy, by the Food and Agriculture Organisation (FAO)/World Health Organisation (WHO). Nearly 400 participants from 78 countries with observers from 28 international organisations attended this Conference. Among the many important recommendations which emanated from this meeting was the recommendation that the Codex Alimentarius, the relevant subsidiary committees and the expert committees which provide scientific advice 'continue to base their evaluations on suitable scientific principles and ensure consistency in their risk assessment determinations'. Consequently, scientific committees such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) were encouraged to reinforce risk assessment procedures (3).

In December 1992, the International Conference on Nutrition, another jointly sponsored conference of the FAO and WHO, also convened in Rome, affirmed that ensuring quality and safety of food was essential to improve the overall nutritional status of people. Furthermore, the Conference decided that governments should take the necessary measures to protect the health and safety of the consumer by assuring an adequate supply of wholesome, high-quality and safe food (4). Committed to the Rome Declaration on World Food Security and the World Food Summit Plan of Action, governments have stressed the need to improve access to safe and nutritionally adequate food supplies (2).

Over the past decade, important changes have taken place which have had a significant impact on food control, including the development of food standards. The first of these changes is the resources constraints on all governments and the impact on the ability of food control authorities to operate in an environment where costs for the services required to provide the level of protection demanded by the consumers continue to escalate. Demands are being made for governments to provide more with less resources, without sacrificing consumer protection or increasing the risks to human health from food hazards. As a result, food control officials have been re-examining food control programmes, in a search for ways in which efficiency can be enhanced. These officials are re-assessing priorities and are developing new approaches to assure food quality and safety and protect
public health. Some of the approaches are rather dramatic and range from eliminating all services which are not specifically related to food safety issues to contracting out the task of performing food control activities to private third parties.

Another change has been the shift in the views of both government and industry alike; this implies that the food industry should accept a greater share of the responsibility for the quality and safety of food products. Along with that notion, the industry is keen to provide greater input in the formulation of national regulatory policy. Industry is willing to accept the responsibility for the quality and safety of products. The continued success of industry in the market place is dependent upon consumer confidence in quality and safety. As a consequence, many food control officials at the government level are re-defining their role to provide the scientific and technical basis and support necessary for the development of mandatory regulations, when necessary, and voluntary guidelines, recommendations and standards to serve as national criteria for food safety compliance. Through official food control monitoring, auditing and verifying measures, the public is assured that an acceptable level of public health protection is being provided by government.

Another important factor which has had an impact on the direction which food control is taking today is the changes which have taken place at the international level, particularly in the international trade of food. For many countries, these changes have resulted in a re-evaluation of national import food trade requirements and of the ability to meet food exporting requirements, taking into account the new requirements.

Codex Alimentarius

'Codex' is a word frequently used in the food industry, by consumers and by food regulators to denote a product, a process, and people. Codex is all of these, but to understand the role of the Codex in food legislation and trade, a clear understanding of the meaning of the words used is required.

The words Codex Alimentarius are Latin, meaning food law or food code. This accurately describes the Codex Alimentarius—a collection of food standards developed and presented in a unified, codified manner. Associated with these standards are documents such as codes of hygienic and good manufacturing practices (GMPs), recognised methods of analysis and sampling, general principles and guidelines. The Codex Alimentarius contains standards for all the principal foods, whether processed, semi-processed or raw, in the form in which they reach the consumer. However, for practical reasons, no standards exist for fresh, perishable commodities which do not move widely in international trade, such as milk.

The Codex Alimentarius currently comprises over 300 standards, guidelines and other recommendations relating to food quality, composition and safety. To support the scientific basis for Codex work, FAO and WHO Expert Panels and Committees have evaluated the safety-in-use of pesticides, food additives and veterinary drugs and the presence of environmental and other contaminants in foods. Other FAO and WHO Expert Panels and Consultations have provided scientific advice on matters such as nutrient reference values for labelling purposes and how to incorporate risk assessment principles into the Codex Alimentarius. The Codex Alimentarius is published in thirteen volumes, arranged by subject matter.

Codex standards

Codex standards define the identity of the product and describe the basic composition and quality factors required for international trade. To protect the health of consumers, provisions on food additives, contaminants and hygiene requirements form a central core of each standard. Codex standards and codes are supplemented by interpretative documents which prescribe basic principles or provide supplementary information. Until recently, standards have been the principal instruments of international harmonisation.

The introduction of risk analysis as a discipline in standardisation opens new possibilities for harmonisation. For example, in codes of hygienic practice, guidelines and similar texts, the Codex is now specifying the risk-based objectives which need to be met. The detailed provisions in these texts may only be but one set of rules that could meet the same objectives. The basis for determining ‘equivalence’ is provided by specifying these risk-based objectives.

An example is the Codex work on the 'Recommended International Code of Practice – General principles of food hygiene'. The revised version of this basic text sets out provisions for GMPs based on risk assessment principles. This text incorporates the hazard analysis and critical control point (HACCP) food safety assurance system (8).

Similarly, the 'Principles of food import and export inspection and certification' set out the rules for government-to-government assurances that basic quality requirements—including food safety—are met (7). The Principles recognise the equivalence of different systems in achieving identical food safety goals. With increasing international trade in foodstuffs and the specific requirements of the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), there is a need for uniform guidelines for inspection and certification procedures in all countries. The work of the Codex Committee on food import/export inspection and certification systems will have a strong influence on matters related to the trade of food. The Committee is examining
those measures which are necessary to improve the certification process for foods, including the aspects of inspection and laboratory techniques. Efforts of the Committee are made to ensure that inspection and certification procedures meet the requirements of the SPS Agreement, namely: transparency, equivalency and based on risk assessment.

Labelling requirements are often quite detailed and are linked to the basic requirement under the 'General standard for the labelling of prepackaged foods' that food 'shall not be described or presented... in a manner which is false, misleading, or deceptive, or is likely to give an erroneous impression regarding its character in any respect' (6). Labelling guidelines, for example on nutrition or on claims, are intended to supplement the 'General standard for the labelling of prepackaged foods' by providing detailed interpretation of critical issues.

Methods of analysis and sampling are listed by reference to internationally available standards, as required. Whether the concept of equivalence can be extended to cover traditionally fixed standards, such as methods of analysis, remains to be seen.

Codex guidelines for chemical contaminants and radionuclides are intended to facilitate international trade. If a guideline level is exceeded, governments must decide whether to restrict national distribution of the commodity or establish specific conditions for sale.

The Codex Alimentarius Commission

The Codex Alimentarius is the product of the inter-governmental body known as the Codex Alimentarius Commission (CAC), established by the FAO in 1961 (1). Since 1962, the CAC has been responsible for implementing the Joint FAO/WHO Food Standards Programme. The objectives of the Programme are to protect the health of consumers, to ensure fair practices in the food trade and to coordinate all food standards work.

The CAC is an inter-governmental body with a membership of 159 Governments at 1 November 1997. Membership is open to all Member Nations and Associate Members of the FAO and/or WHO. In addition, observers from international scientific associations, the food industry and trade, as well as consumers, may attend sessions of the CAC and subsidiary bodies. The CAC meets every two years in Rome and Geneva.

The Codex Alimentarius procedures

'Codex' is also a process, the careful deliberative process of elaborating standards, codes of practice, guidelines and other Codex recommendations, and of keeping these current and up-to-date. For more than thirty years, the CAC has viewed the harmonisation of national food standards as a basic goal. In practice, this task has been complicated by the many different uses made of food standards. Since 1991, the CAC has revised and simplified Codex standards so that the features most commonly applied by Member Governments can be used as a basis for harmonisation.

TheCodex Alimentarius procedures for the elaboration of standards are designed to ensure the highest level of consultation between all interested parties. Although at times the process can be lengthy and cumbersome, changes made to the formal elaboration procedures following the 1991 Conference on Food Standards, Chemicals in Foods and Food Trade now allow for rapid adoption of standards where there is a high measure of consensus. The exchange of comments from governments by correspondence between sessions of Committees greatly facilitates the elaboration process.

To clarify the process by which the CAC develops standards, guidelines and other recommendations, 'Four statements of principle' have been adopted by the Commission (10). These four statements are as follows:

'1) The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, so that the standards assure the quality and safety of the food supply.

2) When elaborating and deciding upon food standards, Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.

3) In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

4) When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.'

Codex standards as a basis of national legislation

Since the 1991 FAO/WHO Conference on Food Standards, Chemicals in Foods and Food Trade, the basic structure of standards has been modified by the CAC. As stated above, each standard still contains core elements which deal with essential provisions relating to the use of additives, the presence of contaminants, food hygiene matters and food labelling. However, these general subject matters are being
extended beyond the scope of the individual Codex commodity standards. A general standard for the use of food additives is being prepared. By using an 'additive-by-additive' approach, it is hoped that the standard will provide a framework for regulating the safe and acceptable use of food additives in general. Similarly, with chemical and environmental contaminants, a more global approach is being used to provide guidance on controls of contamination whenever detected in foods. This will successfully mirror the approach which has been used by the Codex Committee on Pesticide Residues over many years.

The principal consideration which inspires the development of any Codex standard, guideline or other recommendation is the protection of the health of the consumer. In this regard, Codex recommendations are similar to regulations promulgated under national food law. Differing interpretations of the scientific data available on consumer health protection can lead to differences in national regulations, even if these differences are not being exploited to establish non-tariff trade barriers. The Codex process narrows these differences of interpretation and provides the basis for removing unjustified or arbitrary trade barriers based on consumer health protection claims. These approaches are more consistent with trends in modern food regulatory systems and, as a result, should facilitate the harmonisation process. This has been recognised in the SPS Agreement.

### Codex standards as a basis for trade

Measures directed towards ensuring fair practice in food trade are also legitimately within the scope of Codex. Foremost among these are the prevention of deceptive or fraudulent practices and the control of unjustified claims. These are matters covered by the WTO Agreement on Technical Barriers to Trade (TBT Agreement) and include issues such as labelling and nutrition guidelines, optional quality factors contained either in standards or in other advisory texts, and processing and production methods contained in Codes of Practice (other than those with a food hygiene purpose). Some of these texts are complete in themselves, while others may be seen as providing support or additional interpretative material for adopted standards and codes. Under the TBT Agreement, WTO Members are encouraged to use international standards including Codex standards, codes, guidelines and related texts. Where the establishment of technical regulations is required at the national level, governments shall use relevant international standards or parts thereof, except where these would be ineffective or inappropriate. Similarly, where voluntary standards are being established by a national standardising body, the standardising body shall also use relevant international standards or parts thereof.

The Codex 'General guidelines on claims' and the 'Guidelines on nutrition labelling' are advisory texts supporting the Codex 'General standard for the labelling of prepackaged foods'. Since the regulation of claims and nutrition labelling by governments is most usually effected by technical regulations as defined, these texts should be used by governments when formulating national technical regulations in these areas. Similar considerations would apply to national regulations in the areas covered by Codex guidelines, as described below.

### The role of Codex in food legislation and trade

The CAC has no authority over Members to oblige them to implement Codex standards which are recommendations to governments for use as national food regulations. Governments which wish to use these standards are invited to 'accept' Codex standards under the terms of the General Principles of the Codex Alimentarius (9). 'Acceptance' requires that Member Governments allow free distribution of the product nationally, using the name and description specified by the standard, provided that the product meets all relevant requirements of the standard. Governments must also prevent the distribution, under the same name and description, of products which do not conform to the standard. In practice, this means establishing identical national standards. Governments have been unwilling to do this for a variety of reasons.

As codes of hygienic practice and similar instruments are applied by exporting countries, they are currently excluded from the Codex acceptance procedures, even though these are important for harmonising food hygiene requirements. (The Codex acceptance procedures can be applied only by importing countries.)

The SPS and TBT Agreements do not require governments to 'accept' standards under these conditions. The Agreements do require that Codex or international standards, or relevant parts thereof, be 'used' when national standards are established. The idea of 'using' international and Codex standards, guidelines and other recommendations is much more flexible and wider in scope than the idea of acceptance. There is a question of whether 'acceptance', as described above, has any relevance in the light of the SPS and TBT Agreements. The Agreements provide a mechanism for Codex standards, guidelines and related texts to be adopted and used by governments.

The SPS Agreement states that national measures which conform to Codex standards and other recommendations are deemed necessary to protect health and obliges governments which choose to apply stricter standards to justify this. More flexible than the Codex acceptance procedures, the TBT
Agreement allows governments to choose relevant parts of Codex standards when formulating technical regulations. Even voluntary standards used by commercial partners should be based on the relevant sections of Codex standards.

The Codex therefore has a major influence on food regulation and trade. By participating in the Codex process, governments, industry and consumers give tacit recognition to the importance and relevance of Codex standards, guidelines and other recommendations.

Impact of change on the Codex Alimentarius

The principal role of the CAC is to develop standards for food, whether processed, semi-processed or raw, which can be recommended for adoption by governments. The aim of the Commission is to harmonise and co-ordinate all efforts related to work on food standards, whether undertaken by governments or non-governmental organisations. The mandate of the CAC is to protect the health of consumers and to ensure fair practice in the food trade. Coverage extends to all the principal foods entering international trade, ranging from meat, fruit and vegetables and fish, to commodities such as edible ices, juices and bottled water.

The Codex Alimentarius facilitates trade and does not impose unnecessary or artificial barriers. The Codex follows a detailed set of rules which govern procedures which, in turn, lead to the development of international food standards which can be accepted by governments. Products which comply with these standards can move freely in international trade without jeopardising the health or interests of consumers. In addition, industry can trade in foods which comply with Codex standards, thereby guaranteeing products which are accepted as being safe internationally.

Codex and quality control

The entire work of Codex is related to quality control, albeit quality control restricted to consumer protection, health and trade. The mandate of Codex does not include the establishment of quality standards in areas unrelated to the Codex charter of protection of the health of consumers and economic interests, and ensuring fair practice in the trade in food. Consequently, Codex standards have no direct role in areas such as environmental protection, animal welfare or the protection of endangered species, unless such issues directly affect food safety.

General approach to quality control by Codex

In consistency with the objective of consumer protection, Codex standards provide as much flexibility as possible. The reasons for this flexibility include the need to accommodate the different circumstances which prevail in different geographic areas, different countries and different industries, together with the need to avoid restricting technical innovation and efficiency in the food production industries. Codex standards have no role in creating either advantages or disadvantages for developing country producers and processors in comparison to their counterparts in developed countries.

In the past and in some instances, Codex standards have concentrated upon end-point inspection and tended to be restrictive on ways of meeting desired objectives. This has changed. The current approach is one of setting desired objectives, but of allowing scope for different approaches in achieving the desired end-point. This is the concept of 'equivalence', provided for in the SPS Agreement.

It is usual for food standards matters to be subject to official government controls, particularly for foods which move in international trade. The reason for this is that official government certification is normally required as a condition of importation into market countries. With the tendency towards limiting the size and cost of government services, the trend towards full cost recovery from producers and industry for government services and the emphasis on efficient production, an increasing number of government food control services are adopting the approach of industry quality control with official monitoring.

A key element in the development of Codex standards, recommended codes of practice and guidelines is the use of the risk analysis approach. This approach, which is of particular relevance to matters pertaining to the protection of human health, comprises two elements, namely: risk assessment and risk management. The Codex Executive Committee has recently directed all Codex committees to describe the basis of the risk analysis methods used; each description will then become a fundamental part of all future standards.

Quality assurance systems have become a focal point for inclusion in the work of Codex. As an example, the CAC has recently adopted guidelines for the application of the HACCP system. In adopting this approach, the CAC has recognised the HACCP system as a tool to assess hazards and establish control systems which focus on preventive measures, instead of relying primarily on end-product testing. The value of HACCPs is that the system can be applied throughout the food chain, from the primary producer to the consumer. In addition to enhancing food safety, the HACCP system ensures that better use is made of resources and a more timely response is given to problems. Assistance in the inspection and certification service provided by regulatory authorities is another benefit derived from this system, which can also be integrated into more general quality assurance systems which are now being adopted more widely by the food industry. The HACCP approach, in conjunction with the use of GMPs, is strongly endorsed and recommended by Codex.
Primary influences on the Codex approach

Although not the sole motivation, recent agreements on international trade have provided a major impetus to the increasing use by Codex of formal risk assessment and quality control systems such as HACCP. These agreements, specifically the WTO Agreements, the Mercosur Agreement and the North American Free Trade Agreement (NAFTA), are designed to minimise restrictions to trade. These agreements address technical barriers to trade, including measures required to protect human health, and consequently are closely linked to the trade of food.

Measures necessary to protect human health, which is one of the fundamental reasons for the existence of Codex standards, are addressed in the SPS Agreement. This agreement places an obligation on nations to ensure that SPS measures have a scientific justification, do not arbitrarily or unjustifiably discriminate between nations, are not applied in a manner which would constitute a disguised restriction on trade, are not more restrictive to trade than is necessary to provide the chosen appropriate level of protection, and are established and maintained in an open and transparent manner. A further provision includes the presumption that any nation is complying with the SPS Agreement obligations when national measures conform to the standards established by an appropriate international standard setting organisation. Codex standards, codes of practice and guidelines dealing with food additives and contaminants, pesticide residues, veterinary drug residues and hygiene measures are relevant to the evaluation of national measures under the SPS Agreement. These are the developments within international trading arrangements which are currently influencing the Codex approach to quality control issues.

The future for Codex

The future direction of Codex with respect to quality control will continue to be influenced by the need to satisfy the criteria established within the SPS and TBT Agreements. In addition to the requirement that measures based on the protection of human health be scientifically justified, be no more restrictive than necessary and be developed in a transparent manner, a clear identification must be made of those measures which are necessary to protect human health from measures based on other criteria, such as non-protective quality measures. Furthermore, where measures are included that are non-protective quality standards, they will be clearly identified as being of an advisory, non-mandatory, nature. Frequent reviews will be made to ensure that Codex standards remain based on valid current scientific knowledge, to ensure they do not become dated.

These two Agreements are compelling governments, to a large degree, to avoid the creation of non-tariff barriers due to individual ideas of food safety. This will lead to the obligatory use of Codex recommendations internationally. Thus, while Codex recommendations may or may not be accepted as such, as a result of this Agreement they have assumed a completely new dimension as a 'benchmark' or 'yardstick' of national requirements. Members of the WTO are required to submit scientific justifications for food import restrictions based on national regulations which are stricter than Codex standards.

Hazard analysis and risk assessment have assumed greater importance as a result of new trading rules. The SPS and TBT Agreements have placed new emphasis on risk assessment related to the international trade of safe food. Food standards are being re-evaluated and considered more from a horizontal view, with food safety considerations as the primary focus.

In 1993, the results of a review of the risk analysis procedures used by the CAC and subsidiary and advisory bodies were published. The conclusions reported that the approach taken by expert scientific advisory committees such as the JMPR and JECFA in determining acceptable daily intake (ADI) followed acceptable procedures and contained many elements of risk analysis. Consequently, the assessments of both bodies could be characterised as being based on risk analysis. However, the imposition of specific margins of safety in determinations meant that the ADIs were not strictly a quantitative measure of an acceptable level of risk. The Codex Committees which translated the technical advice from the JMPR and JECFA into draft Codex standards did so on the basis of consensus and that any quantitative 'risk balancing' was not governed by specific decision-making criteria, and international agreement did not exist on the methods to be used in risk analysis (5).

As a result of these findings, the CAC concluded that risk assessment decisions by the JMPR and JECFA need to be re-assessed, with the development of an interactive model for all risk assessment decisions. In addition, the risk assessment framework of the JMPR and JECFA needs to characterise uncertainty as explicitly as possible. Furthermore, Codex Committees need to adopt common risk analysis principles and procedures, and need to be encouraged to use formal quantitative exposure assessments as part of risk assessment.

The application of formal risk assessment to standards, guidelines and other recommendations in relation to the prevention of foodborne illnesses from specific microbiological pathogens is a science which is still in its infancy (11), but the CAC has taken the first steps to develop a consistent science-based approach to future recommendations in this area.

Conclusion

Resolving food safety issues is fundamentally dependent upon recognising and addressing adequately the basic needs of public health protection. Food control measures, including the development of food standards, should be firmly based on...
an assessment of the hazards associated with food and the risks such hazards pose to human health and life. In the past, the assessment of food hazards and the associated human risk were performed on an informal basis, frequently in the absence of necessary scientific data, using methods which were still evolving and were often questionable. Resource constraints and the need to bring about greater effectiveness in controlling emerging food safety problems are causing concern in almost all countries. Changes in international trading rules related to food safety assurance have placed new pressure on many developed and developing countries alike to review and revise existing regulations related to sanitary and phytosanitary food standards to avoid conflict with international trade agreements.

If food control authorities and those involved in international trade are to maintain their credibility with consumers and the food industries, decisions taken in the name of consumer protection must be consistent, transparent, based on sound scientific evidence and derived from the use of recognised and acceptable risk analysis procedures. The process should include consumers, industry, the scientific and academic community and other interested parties where possible.

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**Codex Alimentarius : qualité des produits alimentaires et normes de sécurité régissant les échanges internationaux**

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**Résumé**


**Mots-clés**

Codex Alimentarius: calidad de los alimentos y normas de seguridad para los intercambios internacionales

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Resumen
La Comisión del Codex Alimentarius de la Organización de las Naciones Unidas para la Agricultura y la Alimentación/Organización Mundial de la Salud asume, desde 1962, la responsabilidad de redactar normas, directivas y recomendaciones en materia de calidad y protección alimentaria, destinadas a proteger la salud del consumidor y a garantizar que los intercambios se basen en prácticas justas. Esta misión de la Comisión sigue siendo relevante, pero un número de factores han mostrado la necesidad de utilizar nuevas técnicas para fundamentar la normalización de los productos alimentarios, entre las que se destaca en primer lugar el análisis de riesgos. Los autores describen brevemente el papel y labor de la Comisión, así como la forma en que ha sabido responder a los nuevos enfoques en materia de reglamentación gubernamental, a la necesaria armonización de las exigencias nacionales con las normas internacionales y al papel desempeñado por la sociedad civil.

Palabras clave

References

