Food Safety—Internationally Agreed Framework

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Summary Food safety is very important to protect the health of consumers. In this manuscript, internationally agreed concepts and requirements of food safety and risk analysis are briefly explained along with the topics of symposium.

Key Words food safety, risk analysis, risk management, risk communication, Codex Alimentarius Commission, World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures

Introduction For human life and health, foods are essential and extremely important, not only for the growth and promoting health but also for pleasure and joy of eating. It is one of the important policies of national governments to provide sufficient amount of nutritious and safe foods at affordable prices to their nationals. At the time of writing this manuscript, food security has become even more important than before due to the Ukrainian crisis, high price of energy, shortage of fertilizer supply, and prospect of poor harvests of certain staple foods. However, since the focus of the symposium is on the safety of foods, this manuscript explains the internationally agreed principles on food safety and related issues.

It is generally regarded that food safety falls under the responsibilities of the producers, manufacturers, distributors, retailers and others involved in the food chain. However, governments and consumers should bear certain responsibilities, either by establishing effective regulations and enforcement or keeping good practices in selecting and handling foods correctly, e.g., refrigeration of perishable foods at home or observing the handling instructions stated on the food labels.

WTO Agreements and Codex Alimentarius Commission

Food safety has continued to be an important issue in the world for protecting the health of consumers. Food safety has been said to be used as a barrier to trade and therefore, in relation to food trade, there have been two relevant Agreements of the World Trade Organization (WTO) for its members. The first one is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement; WTO) (1) and it covers measures for human, animal and plant life and health in relation to international trade. The SPS Agreement applies to food safety and covers pathogenic microorganisms/parasites, food additives, contaminants/natural toxins, residues of pesticides and veterinary drugs in foods. It also covers analytical methods and labelling related to food safety. The other agreement is the Agreement on Technical Barriers to Trade (TBT Agreement; WTO) (2), which covers any issues not covered by the SPS Agreement, e.g., nutrition and analytical methods and labelling not associated with food safety.

The SPS Agreement specifies three international standard-setting bodies in Article 3 and Annex A; in the area of food safety, it is the Codex Alimentarius Commission (CAC). It is important to note that for ensuring the safety of foods of animal origin, the safety of feeds fed to food-producing animals is essential. In the rest of this manuscript, only food safety-related areas of the SPS Agreement are described. The requirements of WTO also apply to the CAC. The CAC is a joint FAO/WHO intergovernmental organization consisting of its Executive Committee, 10 general subject committees, 12 commodity committees (4 active and 8 adjourned sine die), and 6 regional committees. The CAC develops standards, codes of practice, guidelines and other recommendations through discussions among its members. The SPS Agreement states that to harmonize food safety measures on as wide a basis as possible, WTO members shall base their measures on Codex standards, guidelines or recommendations, where they exist (Article 3.1), and that WTO members shall play a full part, within the limits of their resources, in the CAC to promote the development and periodic review of standards, guidelines and recommendations (Article 3.4).

However, the SPS Agreement allows introducing or maintaining measures resulting in a higher level of protection than would be achieved by Codex standards, guidelines or recommendations, if there is a scientific justification or as a consequence of the level of health protection a WTO member determines to be appropriate (Article 3.3).

Science-based approach

The SPS Agreement stipulates in Article 2.2 that any food safety measure is applied only to the extent necessary to protect human life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.

In 1995, the CAC agreed on the “Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other
Factors Are Taken into Account”. The first of the four statements specifies that the recommendations of CAC shall be based on the principle of sound scientific analysis and evidence (contained in the Codex Alimentarius Commission Procedural Manual).

Risk analysis
The SPS Agreement stipulates in Article 5.1 that any food safety measures are based on an assessment, as appropriate to the circumstances, of the risks to human life or health, taking into account risk assessment techniques developed by the CAC.

The CAC first implemented risk analysis in 1993. Since then, risk analysis has been the solid basis of the food safety-related work of the CAC and many Codex members. The CAC established the “Statements of Principle Relating to the Role of Food Safety Risk Assessment” and adopted the “Definitions of Risk Analysis Terms Related to Food Safety” in 1997, and the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” (2003). A number of recommendations were developed and adopted on risk analysis for use by governments in specific food safety areas (available on the Codex website as the recommendations to Codex members) and for use by specific Codex committees dealing with food safety (contained in the Procedural Manual).

The risk analysis framework for food safety consists of risk assessment, risk management and risk communication. The CAC serves as “risk manager”. The CAC depends on independent scientific advisory bodies to serve as “risk assessors”: Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) working on pathogenic microorganisms and parasites; Joint FAO/WHO Expert Committee on Food Additives (JECFA) working on food additives, contaminants, natural toxins and residues of veterinary drugs; Joint FAO/WHO Meeting on Pesticide Residues (JMPR) working on pesticide residues; and ad hoc expert consultations as necessary. The priority lists of microorganisms/parasites and chemicals to be evaluated are developed by the Codex committees responsible for the issues and then approved by the CAC. There are certain requirements, such as data availability, need for international standards/recommendations. In these scientific advisory bodies, competent experts participate as individual scientists rather than representing their organizations, governments or the countries to which they belong.

The borderline between risk assessment and risk management may seem to differ slightly between related governmental organizations. The categorization of chemicals may also differ from country to country, e.g., insecticides sprayed in the housing of livestock or poultry, or on beehives are categorized as veterinary drugs in some countries and as pesticides in other countries.

Risk assessment consists of hazard identification, hazard characterization, exposure assessment and risk characterization. The outcome of the risk assessment is risk estimate, the qualitative and/or quantitative estimation of risk resulting from risk characterization. The order of steps may be different between microorganisms and chemicals. The safety of food in relation to specific microorganism or chemicals is determined by comparing the estimated dietary exposure and the results of hazard characterization. For estimating dietary exposure, it is essential to make food consumption data available to hand. As many agricultural produce and animal-origin foods are consumed by humans after processing and cooking, depending on the food of concern, it is of extreme importance how the consumption data are obtained and compiled. In many countries, the food consumption data used for exposure assessment are the data obtained from the nutritional survey with some different data compilation and analysis. Exposure assessment depends on the concentrations/amounts of the hazards (microorganisms, parasites or chemicals), the amount of consumption of a food(s) that contain(s) the specific hazard, and toxicity of the hazards of concern. For a chemical, the typical products of hazard characterization after reviewing metabolism data and toxicological data on laboratory animals are health-based guidance values (HBGVs) such as: acceptable daily intake (ADI, amount of a chemical that can be ingested daily over a lifetime without appreciable risk), for intentionally used chemicals) or tolerable daily (weekly, monthly) intake (TD(W, M)I), and acute reference dose (ARD, amount of a chemical that can be ingested in a period of 24 h or less without injury). When there is no acute toxicity concern, ARD is not necessary. TDI (or TWI, TMI) is established for chemicals unintentionally present in foods, such as contaminants, natural toxins and those chemicals previously registered as pesticides but their registration was revoked. The ADI is expressed by JECFA and JMPR as a range, such as 0–0.01 mg/kg bw or 0.05–0.5 mg/kg bw. The latter type of description applies to a chemical that is regarded as both nutrient and contaminant.

Risk management consists of preliminary risk management activities, evaluation of risk management options, and monitoring and review of the decision taken. As risk managers, Codex committees are responsible for developing maximum use levels for food additives, maximum levels (MLs) for contaminants and natural toxins, maximum residue limits (MRLs) for pesticides and veterinary drugs, and microbiological criteria for pathogenic microorganisms, codes of practice or codes of hygienic practice, guidelines and any other recommendations to protect the health of consumers. For residues of pesticides and veterinary drugs, JMPR and JECFA evaluate various data including toxicological data, analytical methods, use pattern and trial data and estimate and recommend MRLs to the Codex Committee on Pesticide Residues and Codex Committee on Residues of Veterinary Drugs in Foods, respectively. For contaminants and natural toxins, JECFA evaluates toxicological data and occurrence data/exposure and provides such advice as “need to reduce intake” or “collect more occurrence data” to the Codex Committee on Contaminants in Foods (CCCF).
CCCF, then, start collecting scientific data on a contaminant/toxin in a certain food or group of foods. With the valid data obtained through good planning, good sampling practice and validated analytical methods following GLP will be used for estimating appropriate MLs for the contaminant/toxin by applying the ALARA Principle (as low as reasonably achievable). For each candidate ML, possible rejection rate and reduction of dietary exposure are calculated using the GEMS/Food Cluster Diets (available from the WHO website). Based on these data and impact on the food availability or food security and other impacts, the CCCF discusses the appropriateness of MLs and agrees on specific draft MLs for adoption by the CAC.

Risk communication is more under the responsibility of governments of Codex members. However, the CAC is required to clearly explain the basis of its decisions.

**Topics for symposium**

The objective of the symposium is to provide some information about how to deal with food safety and what has been studied on microbiological and chemical hazards. The presentations include the following topics:

1. Internationally agreed framework in food safety—Codex Alimentarius Commission and risk analysis
   The duties and activities of the CAC in the area of food safety will be explained by the Secretary of the Codex Alimentarius Commission, Mr. Tom Hellandt. Activities in other areas than food safety will also be explained.

2. Risk management for microbial hazards in foods
   The presentation by Dr. Yoshimasa Sasaki (National Institute of Health Sciences, Japan) will focus on microbiological risk management, taking into account the whole food chain using as an example Salmonella infection/contamination in chickens and chicken eggs in the whole chain of egg production and distribution in Japan.

3. Precision food safety—using whole genome data to inform risk assessment in food safety
   Professor Seamus Fanning (University College Dublin) will introduce the application of DNA sequencing in the context of microbiological food safety, including strategies to accurately identify bacteria and genotypes of importance to food safety while considering challenges to food microbiological risk assessment of the future.

4. US Food and Drug Administration activities to address chemical contaminants in food
   Dr. Paul South will introduce how the FDA ensures that the food supply in the USA is safe for consumption with regard to food-borne natural and anthropogenic chemical contaminants. His presentation covers analytical methods, monitoring, and risk analysis.

5. Excess intake of micronutrients: evaluating the risks for human health
   In the not-so-long past, nutritional science dealt with “deficiency”. With new era of fortification and functional foods, which are effective for better nutritional status, there may be a possibility of adverse health risk from excess consumption. Dr. Agnes de Sesmaisons Lecarre (European Food Safety Authority) will introduce new questions and challenges to the traditional conceptual framework of tolerable upper intake level.

**Disclosure of state of COI**

No conflicts of interest to be declared.

**REFERENCES**