Risk assessment of microbiological hazards in foods: an international approach

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Food safety has always been an important issue, and currently it is high on the political agenda of many countries. The reasons for this are manifold. More than ever before, there is strong consumer awareness of food quality and safety, and this continues to increase. New risks and challenges are emerging as a result of changes in the methods of food production at the farm and processing levels. Further challenges arise from the emergence and re-emergence of food-borne pathogens. Consumption patterns are changing and consumer demands regarding such issues as the variety and shelf-life of foods, as well as the preservation techniques used, are changing. Furthermore, the expansion of international trade in food has also increased the risk of infectious agents being disseminated from the original point of production to locations thousands of kilometres away. The consequence of this is that there is an increased risk to human health as well as implications for international trade in food.

Risk analysis

Risk analysis has evolved over the last decade within the Codex Alimentarius Commission (CAC). Since the Uruguay Round Trade Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) entered into force in 1995, the importance of risk analysis has increased. Risk analysis is now considered to be an integral part of the decision-making process of Codex. CAC has adopted definitions of risk analysis terms related to food safety and statements of principle relating to the role of food safety risk assessment. Furthermore, in 1999, it adopted the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC, 1999a). These were developed by the Codex Committee on Food Hygiene (CCFH), which is currently developing Principles and Guidelines for the Conduct of Microbiological Risk Management.

In addition to these developments in risk assessment, the 22nd Session of CAC requested FAO and the World Health

Organization (WHO) to convene an international advisory body on the microbiological aspects of food safety in order to address, in particular, microbiological risk assessments (CAC, 1997). In response to this and as follow-up on their previous activities in the area of risk analysis, FAO and WHO convened an expert consultation in March 1999 to examine the issue of microbiological risk assessment (MRA) in an international forum. The main outcome of this expert consultation was an outline strategy and mechanism for addressing MRA at the international level (Box 1).

Subsequently, at its 32nd Session in November 1999, CCFH recognized that there are significant public health problems related to microbiological hazards in foods (CAC, 1999b). It identified 21 pathogen-commodity combinations of concern and prioritized these according to such criteria as the significance of the public health problem, the extent of the problem in relation to geographic distribution and international trade and the availability of data and other information with which to conduct a risk assessment. CCFH suggested that FAO and WHO convene ad hoc expert consultations to provide advice on MRA, and also recommended that these consultations be conducted according to the format outlined at the 1999 expert consultation (Box 1).

BOX 1

Recommendations of the Joint FAO/WHO Expert Consultation on Microbiological Risk Assessment, 1999

"A vehicle for the provision of expert advice on microbiological food safety risk assessment should be established by FAO and WHO. Initially this vehicle should take the form of a series of meetings of experts ...". The scope of the meetings should be to:

- **review and interpret existing MRAs to provide the scientific advice requested by FAO, WHO and CAC;**
- **advise on how risk assessments conducted at the national level can be applied to international issues;**
- **provide guidance on MRA practices.**

The primary outputs of expert consultations should be:

- **advice in response to specific requests from FAO, WHO and CAC;**
- **evaluation of existing risk assessments in relation to the principles for the conduct of MRAs;**
- **evaluation of the international applicability of existing risk assessments, including the need for additional data or related information;**
- **evaluation of the likely impacts of different risk management options.**

Source: WHO, 1999.

Microbiological risk assessment: an international approach

Risk assessment is one of the components of risk analysis – which can be defined as being an overall strategy for addressing risk that includes risk management and risk communication. The importance of an overlap between these three elements (risk assessment, risk management and risk communication) is well recognized, but some functional separation is also necessary. In relation to risk assessment, such separation ensures that issues are addressed in a transparent manner using a scientific basis. CAC defines risk assessment as a scientifically based process consisting of the following four steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization. The risk assessment process is a means of providing an estimate of the probability and severity of illness attributable to a particular pathogen-commodity combination. The four-step process enables this to be carried out in a systematic manner, but the extent to which the steps are carried out will be dependent on the scope of the risk assessment. This can be defined clearly by the risk manager through ongoing dialogue with the risk assessor.

The carrying out of an MRA is recognized as a resource-intensive task requiring a multidisciplinary approach. While MRA is becoming an important tool for assessing the risks to human health from food-borne pathogens and can be used in the elaboration of standards for food in international trade, it is not within the capacity of many, perhaps most, countries to carry out a complete MRA. Yet, food-borne illness is among the most widespread

The risk assessment process provides an estimate of the probability and severity of illness attributable to a pathogen-commodity combination

public health problems and creates social and economic burdens as well as human suffering, making it a concern that all countries need to address. Risk assessment is a tool that can be used in the management of the risks posed by food-borne pathogens.

On the other hand, risk assessment can also be used to justify the introduction of more stringent standards for imported foods. A knowledge of MRA is therefore also important for trade purposes, and there is a need to provide countries with the tools for understanding and, if possible, carrying out MRA. This need, combined with CAC's and CCFH's requests for scientific advice on MRA, has led FAO and WHO to undertake a programme of activities to address the issue of MRA at the international level (Figure).

The aim of the joint programme is to provide a transparent review of scientific opinion on the state of the art of MRA, and to develop the means of achieving sound quantitative risk assessments of specific pathogen-commodity combinations. The work includes an evaluation of existing risk assessments; a review of the available data and current risk assessment methodologies, highlighting their strengths and weaknesses and how they may be applied; provision of examples; and identification of ongoing data and information needs. As it is developed, such information is being made accessible through the FAO Web site.

The work is currently focusing on the following pathogen-commodity combinations:

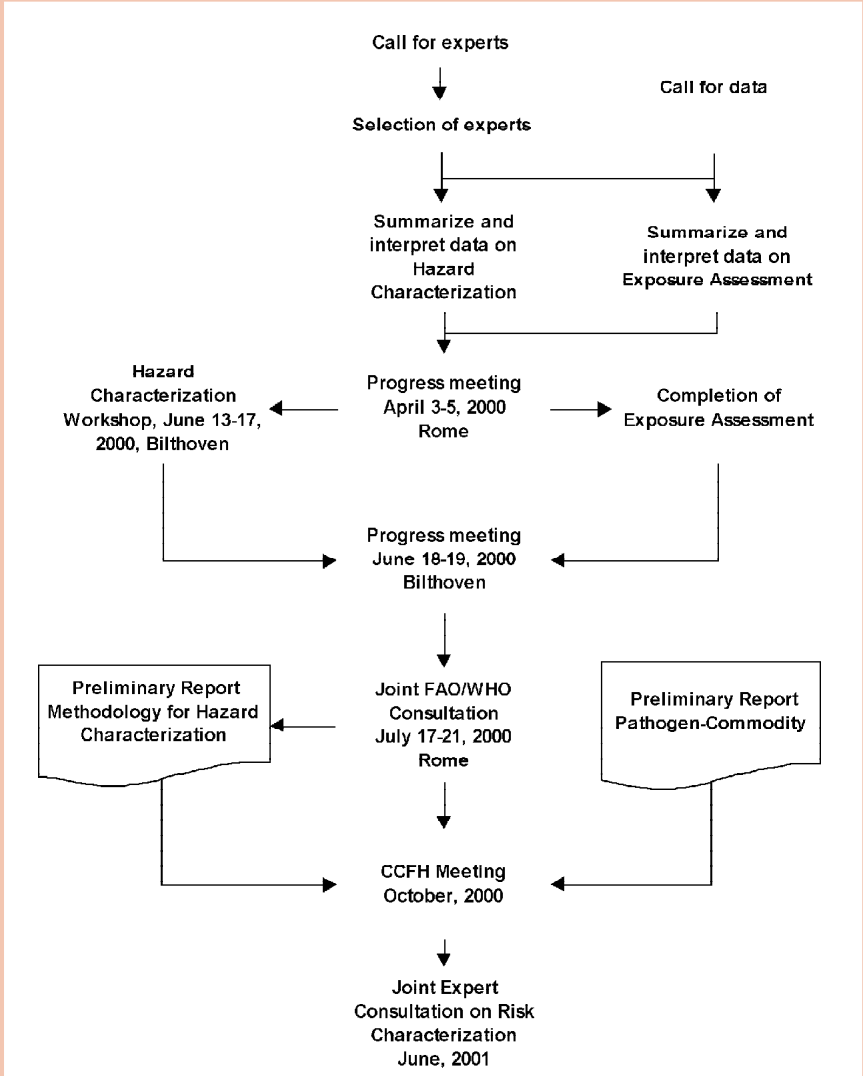
- *Salmonella* spp. in broilers;
- *Salmonella* enteriditis in eggs;
- *Listeria monocytogenes* in ready-to-eat foods.

Salmonellosis is one of the most frequently reported food-borne diseases worldwide, with poultry and poultry products being common vehicles of the disease. The annual incidence of Salmonellosis in the United States, for example, is estimated at 1.4 million cases but more than 99 percent of patients recover fully (CDC, 2000). Listeriosis, on the other hand, is a relatively rare disease, but when it does occur it can be severe with fatality rates of 20 to 30 percent among hospitalized patients (McLaughlin, 1996).

Expert drafting groups were established to address the first three steps of risk assessment – i.e. hazard identification, exposure assessment and hazard characterization – for these pathogen-commodity combinations. Hazard identification is the identification of the biological agent capable of causing the adverse health effects that may be present in a particular food or group of foods. Exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the biological agent via food, as well as via exposure from other sources, if relevant. Hazard characterization is the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the biological agents that may be present in food, and in such cases a dose-response assessment should be performed if the data are obtainable.

In October 2000, five technical documents were prepared, the contents of which are summarized in the Table. In addition to providing in-depth analysis of hazard characterization and an exposure assessment of the specific pathogen combinations, each document identifies

FAO/WHO activities on risk assessment of microbiological hazards in foods



Summary of contents of the technical documents

Title and authors	Summary of contents
1. Hazard identification and hazard characterization of Salmonella in broilers and eggs. A. Fazil, R. Morales, A. Lammerding, A. Vicari and F. Kasuga.	Aim: To evaluate the nature of the adverse health effects associated with food-borne non-typhoid and non-paratyphoid Salmonella spp. and to assess the dose-response relationship.[1] Includes: * a review of the reported hazard; characterization models that have been used to estimate the dose-response relationship; * a summary of data appropriate for dose-response estimations; * a comparison between the dose-response curves and the outbreak data to equate the model with observed information.
2. Exposure assessment of Salmonella Enteritidis in eggs. E. Ebel, F. Kasagu, W. Schlosser and S. Yamamoto	Aim: To compare existing techniques and practices used to construct an exposure assessment for S. enteritidis in eggs and provide a framework for future exposure assessments. Includes: * a review of five previously prepared exposure assessments; * a summary of published and non-published research on S. enteritidis occurrence and concentration.
3. Exposure assessment of Salmonella spp. in broilers. L. Kelly, W. Anderson and E. Snary.	Aim: To develop a model framework, highlighting ideal data requirements and possible methodologies for Salmonella spp. in broilers because, to date, no full quantitative exposure assessments have been undertaken. Includes: * available data for developing such models; * an assessment of the usefulness of the data; * examples of models as a means of illustrating possible methodologies related to individual steps that could be included within a full model.
4. Hazard identification and hazard characterization of Listeria monocytogenes in ready-to-eat foods. R. Buchanan and R. Lindqvist.	Aim: Quantitative evaluation of the nature of the adverse health effects associated with L. monocytogenes in ready-to-eat foods, and assessment of the relationship between the dose and the response. Includes: * a review and summary of the relevant literature and the available dose-response models; * comparison and evaluation of a number of dose-response models based on epidemiological data, animal studies, expert elicitation or combinations of these.
5. Exposure assessment of L. monocytogenes in ready-to-eat foods. T. Ross, E. Todd and M. Smith.	Aim: To provide an overview of issues to be considered in exposure assessment, a description and evaluation of the methods that can be used and the available information, and to demonstrate the application of exposure assessment. Includes: * a glossary of technical terms; * a review and assessment of 11 examples of existing exposure assessments; * seven new exposure assessments; * a specific example comparing the effect of zero tolerance and a tolerance of 100 CFU/g at the point of consumption.

[1] The dose-response relationship is the relationship between the magnitude of the exposure (the dose) to the biological agent and the severity and/or frequency of associated adverse health effects (the response).

gaps in the data that need to be filled, makes recommendations for future work and includes an extensive bibliography of relevant data and information sources.

A further aim of this joint FAO/WHO undertaking on MRA is the development of guidelines relating to the different steps of risk assessment, such as hazard characterization and exposure assessment. The purpose of such guidelines is to help the risk assessor, the risk manager and other interested parties to understand the principles and science behind the risk assessment steps. The guidelines document was initiated during a workshop on hazard characterization in June 2000, and a preliminary text has been elaborated. This text includes guidance on the types of data needed and the means of assessing the adequacy of available data as well as information on the process, principles and methods of hazard characterization.

The technical documents and the guidelines on hazard characterization were reviewed by an expert consultation at FAO headquarters in Rome on 17 to 21 July 2000. The purpose of this meeting was to obtain an expert review of, and input into, the documentation developed so as to continue its elaboration, as well as to provide scientific advice to FAO and WHO member countries and Codex on the risk assessment of *Salmonella* spp. in broilers and eggs and of *Listeria monocytogenes* in ready-to-eat foods.

Summary of the expert consultation

The expert consultation noted that MRAs could have a wide range of applications in food safety. Ideally, a risk assessment should encompass all components of the food system, from production to consumption, so that risk factors and strategies to reduce them can be thoroughly described. An MRA can be used for a number of purposes, including to create broad food safety policies, develop sanitary measures that achieve specific food safety goals and elaborate standards for food.

The consultation recognized the comprehensiveness and scientific value of the technical reports presented and concluded that they considerably advance current knowledge on the general development of hazard characterization and exposure assessments. The reports also enhance specific knowledge in relation to the pathogen-commodity combinations identified as significant food safety problems by CCFH. In the absence of specific risk management guidance, the consultation endorsed the approach taken by FAO, WHO and the expert drafting groups in developing hazard characterizations and exposure assessments

for *L. monocytogenes* in ready-to-eat foods and *Salmonella* spp. in broilers and eggs. Although not tailored to achieve specified risk management goals, this practical approach advances international understanding in a broad sense and provides a strong platform for future provision of risk assessment advice as requested by FAO and WHO member countries CCFH and other stakeholders.

The expert consultation recognized that international scientific cooperation and peer review are essential to the development of credible hazard characterization and exposure assessments for the purpose of risk characterization. It agreed on the general applicability of modelling approaches taken and reflected on the critical importance of adequate data input to satisfy risk management goals. It also recognized technical areas where scientific consensus has not been achieved, and ongoing scientific dialogue is necessary to resolve such issues. The consultation stressed that the purpose and scope of individual risk assessments will influence data acquisition needs.

It was emphasized that FAO and WHO need to continue their support of expert consultations in relation to completing risk assessment of the pathogen-commodity combinations identified as significant food safety problems by CCFH. It was also stressed that such risk assessments need to be applicable to developing countries and that specific data requirements are needed to

A microbiological risk assessment can be used to create broad food safety policies, develop sanitary measures that achieve specific food safety goals and elaborate standards for food

BOX 2

Recommendations of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods

17 to 21 July 2000, FAO headquarters, Rome[1]

The consultation recommended that FAO and WHO should:

- **continue their ongoing work on developing guidelines for hazard characterization;**
- **initiate a similar process for developing guidelines for exposure assessment;**
- **continue to support the technical development of hazard characterization and exposure assessment for the three pathogen-commodity combinations described in this article and identified by CCFH as candidates for risk assessment;**
- **facilitate the acquisition of data for hazard characterization and exposure assessment for identified food safety priorities, to the greatest extent possible;**
- **promote the collection of national-level consumption data, including population variability, portion size and frequency of consumption;**
- **promote acquisition of model input data from different regions in order to maximize the applicability of existing exposure models;**
- **promote the establishment of regional centres for the collection of information on disease incidence on a global scale, so as to enhance the validation of risk assessment models;**
- **develop a framework document for guiding the establishment of repositories for food safety data that are critical for effective risk assessment;**
- **facilitate direct technical cooperation between developed and developing countries so that the latter can achieve the technical capability required to carry out MRA. This support should take into consideration the local situation so that the results can be sustainable;**
- **explore ways of evaluating further the importance of food-saving systems that have recently been recognized as useful means of obtaining quantitative data in the case of outbreaks.**

In addition, the consultation recommended that:

- **any requests by risk managers for the development of hazard characterization or exposure assessment should include a clear description of purpose and scope;**
- **reporting of prevalence and concentration of specific hazards at different steps of the full exposure pathway should be encouraged in all regions of the world;**
- **FAO and WHO should be encouraged to assist developing countries in the preparation of project proposals on MRA activities for presentation to potential donors.**

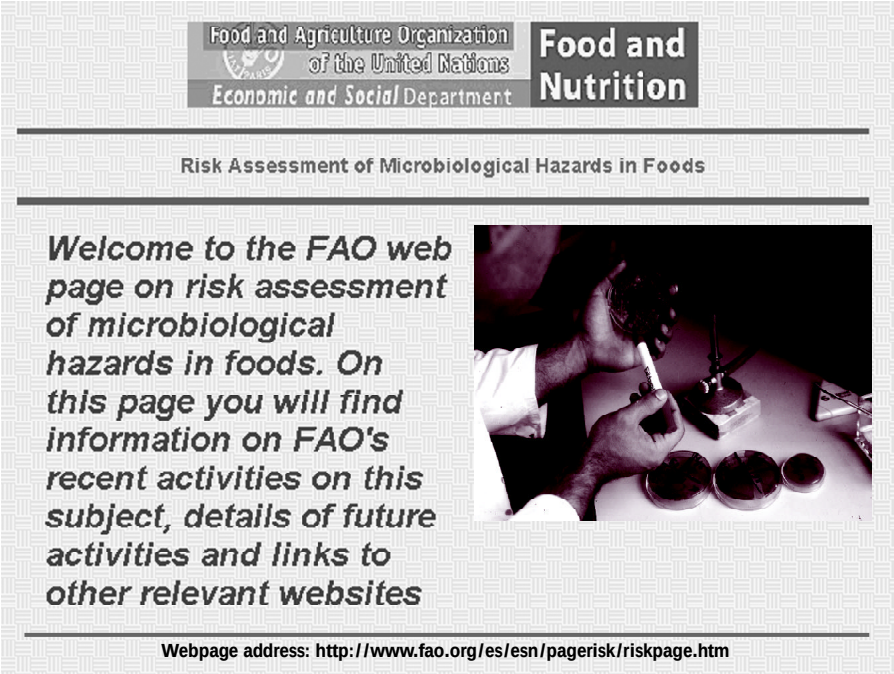
[1] FAO, 2000.

achieve this. Likewise, it was recognized that a prerequisite for further development of MRA in developing countries is the provision of appropriate technical advice, assistance and training. The recommendations of the expert consultation are outlined in Box 2.

The report of the consultation, the technical documents on hazard characterization and exposure assessment, and the draft guidelines for hazard characterization are available on the FAO Web site at: www.fao.org/waicent/faoinfo/economic/esn/pagerisk/riskpage.htm

Future work

The expert consultation and the technical documents identify a number of issues that should be addressed before risk assessment of these pathogen-commodity combinations can be completed. In particular, there is a need for additional data, better access to relevant data collected by government and industry, and guidance from risk managers on the risk reduction measures to be considered in the further elaboration of the risk assessments and the target population of the risk estimate. The technical documents prepared by the expert drafting groups have been posted on the FAO Web site for public comment. All comments on the scientific content of the reports, and of additional relevant scientific data and information, will be considered by FAO and WHO and, where pertinent, will be taken into account in the revision of the technical documents by the expert drafting groups. During the next year the final step of the risk assessment process (risk characterization) will integrate the three previous steps, in order to obtain a risk estimate that provides a qualitative or quantitative forecast of the likelihood and severity of adverse effects in a given population. The reports on risk characterization will be reviewed by a Joint FAO/WHO Expert Consultation on Microbiological Risk Assessment, to be held in 2001 with the aim of finalizing the risk assessments of *Salmonella* spp. in broilers and eggs and *L. monocytogenes* in ready-to-eat foods by October 2001.



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Risk assessment of microbiological hazards in foods: an international approach

Currently, there is increasing consumer awareness of food quality and safety and new risks and challenges related to changes in food production and the emergence and re-emergence of food-borne pathogens. The expansion of international trade in food has increased the risk of infectious agents being disseminated from the original point of production to locations far away.

Food safety risk analysis has evolved over the last decade within the Codex Alimentarius Commission (CAC). Since the Uruguay Round Trade Agreement on the Application of Sanitary and Phytosanitary Measures in 1995, the significance of risk analysis has increased. Risk assessment is one of the components of risk analysis – which can be defined as being an overall strategy for addressing risk that includes risk management and risk communication. CAC defines risk assessment as a scientifically based process consisting of the following four steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.

FAO and the World Health Organization (WHO) have embarked on a programme of activities on the microbiological aspects of food safety in order to address, in particular, microbiological risk assessment (MRA). This article reviews the decisions of recent expert consultations and explains the strategy and mechanism for addressing microbiological risk assessment at the international level. The aim of the joint programme is to provide a transparent review of scientific opinion on the state of the art of MRA, and to develop the means of achieving sound quantitative risk assessments of specific pathogen-commodity combinations. As it is being developed, such information is made accessible through the FAO Web site. This work is currently focusing on the following pathogen-commodity combinations: *Salmonella* spp. in broilers, *Salmonella* enteriditis in eggs, and *Listeria monocytogenes* in ready-to-eat foods.

Évaluation des risques microbiologiques présentés par les denrées alimentaires: approche internationale

À l'heure actuelle, les consommateurs sont de plus en plus attentifs à la qualité et à la sécurité sanitaire de leur alimentation et aux nouveaux risques et défis liés à l'évolution de la production alimentaire, ainsi qu'à l'émergence ou à la réémergence de pathogènes transmis par les aliments. L'expansion du commerce international des denrées alimentaires augmente le risque de diffusion des agents infectieux du lieu de production à des endroits éloignés.

Depuis 10 ans, l'analyse des risques aux fins de contrôle de la sécurité sanitaire des aliments a beaucoup évolué au sein de la Commission du Codex Alimentarius. Depuis l'adoption en 1995 de l'Accord sur le commerce du cycle d'Uruguay sur l'application des mesures sanitaires et phytosanitaires, l'importance de l'analyse des risques n'a fait que croître. L'évaluation des risques est l'une des composantes de l'analyse des risques – stratégie globale de prise en compte des risques qui inclut la gestion des risques et la communication sur les risques. La Commission du Codex Alimentarius définit l'évaluation des risques comme un processus fondé sur des données scientifiques qui comprend les étapes ci-après: i) identification des dangers; ii) caractérisation des dangers; iii) évaluation de l'exposition; et iv) caractérisation des risques.

La FAO et l'Organisation mondiale de la santé (OMS) ont lancé un programme d'activités sur les aspects microbiologiques de la sécurité sanitaire des aliments et plus particulièrement sur l'évaluation des risques microbiologiques. L'auteur passe en revue les décisions de consultations d'experts tenues récemment et explique la stratégie et le mécanisme adoptés au niveau international pour évaluer les risques microbiologiques. Ce programme conjoint a pour objet de faire le point sur les connaissances scientifiques en matière d'évaluation des risques microbiologiques, et d'élaborer des méthodes permettant d'évaluer quantitativement les risques liés à des combinaisons spécifiques produits/pathogènes. À mesure que ce travail progresse, les résultats en sont affichés sur le site Web de la FAO. Le programme est actuellement axé sur les combinaisons produits/pathogènes ci-après: *Salmonella* spp. dans les poulets, *Salmonella* enteriditis dans les œufs et *Listeria monocytogenes* dans les aliments prêts à consommer.

Evaluación de riesgos microbiológicos en los alimentos: enfoque internacional

En la actualidad, los consumidores son cada vez más conscientes de la calidad e inocuidad de los alimentos, los nuevos riesgos y problemas debidos a cambios en la producción alimentaria y la aparición y reaparición de patógenos transmitidos por los alimentos. La expansión del comercio internacional de alimentos ha aumentado el riesgo de que los agentes infecciosos se propaguen desde el punto original de producción hasta lugares muy distantes.

Dentro de la Comisión del Codex Alimentarius, el análisis de los riesgos para la inocuidad de los alimentos ha evolucionado en el último decenio. Desde que en 1995 se aprobó el Acuerdo de la Ronda de Uruguay sobre la Aplicación de medidas sanitarias y fitosanitarias, ha aumentado la importancia del análisis de riesgos. La evaluación de riesgos es uno de los componentes de este análisis, que constituye una estrategia global para hacer frente a los riesgos de la que también forman parte la gestión de riesgos y la comunicación de riesgos. La Comisión del Codex Alimentarius define la evaluación de riesgos como un proceso basado en conocimientos científicos que consta de las siguientes fases: *i*) determinación del peligro, *ii*) caracterización del peligro, *iii*) evaluación de la exposición y *iv*) caracterización del riesgo.

La FAO y la Organización Mundial de la Salud (OMS) han iniciado un programa de actividades relacionado con los aspectos microbiológicos de la inocuidad de los alimentos para acometer, en particular, evaluaciones de riesgos microbiológicos. El autor examina las decisiones de recientes consultas de expertos y explica la estrategia y el mecanismo para abordar la evaluación de riesgos microbiológicos a nivel internacional. La finalidad de ese programa conjunto es proporcionar un examen transparente de las opiniones científicas sobre los últimos avances en la evaluación de riesgos microbiológicos y crear los medios para realizar evaluaciones cuantitativas adecuadas de los riesgos de determinadas combinaciones de patógenos y productos. Se facilita el acceso a esta información, a medida que se desarrolla, a través del sitio de la FAO en Internet. La labor se centra actualmente en las siguientes combinaciones de patógenos y productos:

Salmonella spp. en pollos para asar, *Salmonella* enteriditis en huevos y *Listeria monocytogenes* en alimentos listos para el consumo.