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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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GUIDELINES FOR THE OBTAINING OF DATA OF INTEREST FOR MICROBIOLOGICAL RISK ASSESSMENT

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Zoonosis (INPPAZ)**

BACKGROUND

At the 11th Session of the Codex Coordinating Committee for Latin America and the Caribbean - CCLAC, held in Montevideo, Uruguay from 8 to 11 December 1998, the Committee discussed the subject - Salmonella in poultry and eggs as an item of the agenda. During the discussion of this item the delegations emphasized the importance of this subject, related with outbreaks of foodborne diseases by this agent and in these food products, as well as the importance of microbial pathogens in foods of its own countries. The Delegations also expressed the importance of discussing about pathogens in general. PAHO, represented by INPPAZ and the Delegation of Brazil were requested to prepare a document to make a follow up of this issue for the next meeting (Item 8, paragraphs 49 and 50, ALINORM 99/36).

Considering the activities developed by CCFH and the activities of the FAO/WHO Microbiological Risk Assessment Group on the subject of Salmonella in poultry and eggs, INPPAZ and the Brazilian Delegation considered that it would be necessary to change the approach of the document in order to contribute with the MRA Group since this Group needed data from Latin America and the Caribbean. As a consequence Brazil and INPPAZ proposed to elaborate Guidelines to help the countries of the Region to obtain data and later on to present it to the MRA Group.

Considering that FAO/WHO during Codex meetings proposed to capacitate the countries in the Risk Analysis subject, and that INPPAZ had organized laboratory training in microbiological analysis, especially with emerging diseases (paragraph 49, ALINORM 99/36), the development of activities of risk assessment of microbiological hazards in foods in the Region would count on INPPAZ support.

2. INTRODUCTION

Risk assessment is a component of Risk Analysis. Risk Analysis is a process consisting of three components: risk assessment, risk management and risk communication. The primary purpose of Risk Analysis is to provide an objective basis for the obtaining of scientific data for the characterization of problems related with foods, as well as to identify those considered as priorities as risk of microbiological hazards expression by the different foods and to recommend the most effective way for its control.

The countries of LAC Region that participate in regional and international food trade, mainly as exporters, have being already developing risk management system for food hazards, particularly the implementation of the Recommended Code of Hygienic Practices and HACCP.

The WTO Agreement on Sanitary and Phytosanitary Measures establishes that food safety should be developed by importer and exporter countries with scientific basis. In order to fulfill with this Agreement and in order to consider the most significant hazards that must be controlled by RCP and HACCP (risk management), it is important for the countries to establish guidelines for collecting data and conducting a risk microbiological assessment in foods: hazard identification and characterization, exposition assessment and risk characterization. The development of these activities is fundamental and urgent in order to guarantee that the risk management activities are consistent and recognized as effective at international trade and to assure the protection of consumers health.

3. SCOPE

This document has the objective of establishing guidelines for obtaining scientific data for the microbiological risk assessment of food hazards to guide the activities of risk management, i.e. Hygiene Practices and HACCP systems.

4. REFERENCES

- Recommended International Code of Practice – General Principles of Food Hygiene
- Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application
- Principles and Guidelines for Microbiological Risk Assessment
- Principles for the Establishment and Application of Microbiological Criteria for Foods

5. DEFINITIONS*

- Hazard
- Risk
- Risk analysis
- Risk assessment
- Hazard identification
- Hazard characterization
- Dose-response assessment
- Exposure assessment
- Risk characterization

- Risk management
- Risk communication

*According the definitions in the Procedural Manual – Eleventh edition.

6. INTRODUCTION TO RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOODS

The risk assessment of microbiological hazards in foods is one of the most important components of Risk Analysis. When the consumer's health problems are known, it is possible to identify priorities related with food-agent-consumer complex. The necessary data for risk assessment are those that permit to assess the agent behavior in each step of the food chain, the impact and the way it affects consumer's health. Among these data, the follow are the most important:

Foodborne Diseases: traditionally, the data of foodborne diseases are basically those related to public health problems and those used for the correction of the situation that contributes with its occurrence. Data of more serious diseases than that related to digestive tract are not compiled and as a consequence the complete and total vision of health implication, social and economical impact of foodborne disease is not available in its real magnitude.

Occurrence and concentration of food pathogens in the food chain: the accumulate knowledge of food pathogens occurrence in the origin and of the contamination in all food chain has basically a qualitative assessment of pathogens presence. These data are most related to the ecology of these microorganisms and not with its concentration or dimension of contamination in primary products and the different ways of contamination and control in all the food chain.

Hazards additional data: the pathogens isolated from foods need a better characterization in order to have a more complete identification: serotyping, phagotyping, exo and endo toxins production, antibiotics sensibility/resistance, pH tolerance depending on kind of acid used, thermo resistance and others that help in the characterization of hazards with increased potential of pathogenicity and resistance to medical treatment.

Factors that affect microorganisms in foods: the study of factors that affect microorganisms in foods is an indispensable basis for technological development in order to achieve an effective control. Although in general, this is restricted to transformation and final preparation step. It is necessary a more comprehensive knowledge on other steps, as primary production, transportation and others.

Predictive microbiology: predictive microbiology by mathematical data is an important tool to estimate growth and reduction curves of microorganisms in different step of the food chain. It is important to evaluate the behavior of microorganisms in foods and to predict number and condition on these foods just before consumption. These data are not available in the necessary measure in order to identify and select the most effective control technology. The identification is important for risk managers. This activity needs to involve mathematics and statistics professionals.

Host data: identification of sensitive consumer is restricted, by now, to extreme age people and personal affected by metabolic deficiencies to same food components or ingredients. More broad studies, comprising social and ethnical factors, personal immunity, food habits, generally are not associated to foodborne outbreak elucidation.

Doses-response: studies of cause-effect of pathogen ingestion are obtained mainly in human volunteers that are adult and healthy. Animal experiments are not always applicable in order to

have a direct relation of doses-response in humans, except for some toxins, as the botulinical and marine ones.

Validation of control measures and critical limits: considering the available technological processes for hazard control in foods it is imperative to validate control measures and critical limits to assure quali and quantitatively the real dimension of control obtained by the risk managers.

Risk assessment is an ordered scientific process, which has humans' diseases as central point. It considers occurrence and gravity of diseases to establish control priorities. A complete identification and characterization of hazard is necessary for its qualification. The doses-response for all consumers' group is not frequent in the scientific documents, although they are necessary for risk assessment. Concentration and/or reduction of pathogen studies in each step of the food chain is necessary to a complete vision of the risk.

Risk management, as applied in the General Code of Hygiene Practices and HACCP System needs scientific data, not only for the identification of the most significant hazards but also for the selection and the evaluation of the impact of the applied control measure and critical limits. The validation of the control measures and the critical limits is a necessary activity to assure food safety.

7. ACTIVITIES TO BE DEVELOPED TO PERFORM A MICROBIOLOGICAL RISK ASSESSMENT IN FOODS

The activities necessary to perform a microbiological risk assessment are, in principle, the search of scientific support to clearly establish the priorities of research and of control in each step of the food chain, in each country. The involvement of science and technology capacitating sector is a tool that helps to obtain relevant data and information.

Professional interaction and liaison among people involved in this field is extremely important. The central point to gather data and information may be defined and could be the government agencies. The most important is to identify a point or a service that can manage information and data and that can provide national discussion and helps in the definition of strategies to perform a transparent risk assessment. Considering this background the activities of microbiological risk assessment should be conducted in order to:

1. Form a group of multidisciplinary professionals, at national level to foment and order microbiological risk assessment activities. This group may have, but is not limited to, food microbiologists, epidemiologists, clinical medicine, food technologists, food regulators, mathematical and statistics professionals.
2. Capacitate the participants of the multidisciplinary group and others related with food control, such as universities, primary producers, industries, distributors and traders, consumers' protection agencies and others, on Risk Analysis.
3. Establish national programs for obtaining complete data about food borne diseases occurrences, including epidemiological and severity of long term and disease health complications related with concurrent diseases and others, necessary to a complete comprehension of hazard impact in the population and consumers.
4. Search data from hospital epidemiologist and clinical medicine about the frequency of occurrence of diseases potentially transmitted by foods, not included in food analysis. Also it is necessary to know about the occurrence of chronic and acute diseases by hazards that may be related with food, as not viral hepatitis, arthritis, and meningitis. The immunity condition and characteristic of the population is of great interest, to evaluate endemic and epidemic

possibilities, considering the presence of the hazard in foods and also to determine decreased biological resistance to those hazards.

5. Establish national programs to determine presence and number of microbiological hazards in foods, from the primary production till final consumption. The microbiological agents isolated from foods, should be object of further identification and characterization, as serotype, toxin production, antibiotic sensibility/resistance, not usual pH, Aw and thermal resistance.
6. Select and establish mathematical models for growth and reduction studies, considering diverse matrix of foods and including that similar and possible as food vehicle. Also, to determine models for risk characterization.
7. Increment studies of technological process from primary production till consumption, in order to evaluate quali and quantitatively the control impact on hazard and corresponding risk, in order to facilitate selection of the more effective ones. Validation of control measures and critical limits may be included, in the effort to assure food safety.