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## **MICROBIAL RISK ASSESSMENT: STAGES AND APPLICATION IN THE EVALUATION OF WATER QUALITY**

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### **ABSTRACT**

This work presents the stages of microbial risk assessment and its application in the evaluation of drinking and recreational water quality. The stages are hazard identification, exposure assessment, dose-response relationship and risk characterization. Hazard identification is related to the presence of microorganism and toxins and their association with specific diseases. Exposure assessment includes the intensity, frequency and duration of human exposure to a specific agent. The aim of dose-response relationship is to obtain a mathematical relationship between the amount of microorganism (concentration) and adverse effects on human health. Risk characterization represents the integration of the previous stages. Risk assessment is a tool used for decision making and for providing information to take control and intervention measures, as well as to evaluate the impact of these actions. It provides support to a decision-making process based on scientific results in several areas of knowledge. In Brazil, risk assessment is a recent but promising area of research, for the management of water quality, such as catchment points and recreational waters, especially in periurban areas of metropolitan regions, which show precarious sanitary conditions.

**Key words:** Microbial risk assessment. Water quality. Risk management.

## INTRODUCTION

Scientific and technological advance have brought great benefits to contemporary society, such as an increase in people's life expectancy and a cure for some illnesses. However, the accentuated consumption of natural resources resulting from the intense rhythm of production has resulted in an environmental crisis, caused by the significant destruction of eco-systems, as well as by the increase in poverty, hunger and the inequalities in income distribution both internally, as well as between countries (United Nations Conference, Agenda 21, 1995).

According to NARDOCCI (1999), the potential impact of technological development, changes in life-style, as well as an increase in the awareness of the dangers to health and safety, have placed risks to the environment and its quality among the greatest current concerns of society. Therefore, the assessment and management of risks are among the most important current activities of scientists, politicians, regulatory bodies and also the public in general.

Risk assessment may be defined as the process of estimating the probability of an event happening and its magnitude, also taking into account, among other aspects, the adverse effects to the economy, to health and to safety, over a particular period of time (GERBA, 2000). It is possible, for example, to calculate (or estimate) the health risk associated with the presence of pesticides in food that is also susceptible to contamination by the pathogenic micro-organisms, which may also be found in water used for human consumption.

Risk assessment emerged between the 1940s and 1950s with the growth in nuclear activity. The assessments were used in industrial oil refineries, nuclear power stations and aerospace research locations.

In the environmental area this tool began to be recognized and used with publication of the *Guidelines for Carcinogenic Risk Assessment* by the U.S. Environmental Protection Agency (USEPA) in 1976 (GERBA, 2000). Estimates of the incidence of cancer associated with the industrial emissions of a particular chemical substance may be carried out with the intention of protecting the health of workers and neighboring communities.

Public health issues related to the presence of micro-organisms in public drinking water and recreational water are not recent, but assessment of the microbial risk is, because this is a new approach to the management of the risks associated with water-borne illnesses.

Therefore, this work proposes to present the stages in microbial risk assessment and its application in the assessment of the quality of water coming from catchment areas and that used for recreational purposes.

### **Microbial risk assessment**

Risk assessment is a relatively recent area of knowledge and still not duly consolidated, either as far as the basis of its concepts, or the terminology used are concerned. In Brazil, where the difficulties are amplified by the lack of accurateness in the translation of terms taken from international literature, discussions and reflections in the academic field are still in their initial phase. An example of this problem refers to the confusion that exists between the terms *risk* and *hazard* [*risco* and *perigo* in Portuguese]. These terms can be used as synonyms in common speech, but they are quite different concepts in the scientific field. *Hazard* or *perigo* is a property, a qualitative characteristic, while *risk* or *risco* is a quantitative, adimensional and probabilistic magnitude.

Also, the terms *risk analysis* and *risk assessment* have been sometimes used as a synonym and sometimes as different stages. However, distinguishing between these stages is not essential for understanding the problems and we can state without prejudice that the current study on risks includes the risk assessment, management and communication stages, although there is also no consensus about the content of each stage, their interfaces and correlations.

The first consolidation of scientific knowledge on risk assessment was developed by the *National Academy of Sciences* (NAS 1983), which structured it into four main stages: identification of the hazard, assessment of exposure, assessment of the dose-response relationship and the characterization of risk, as presented in Figure 1.

In the case of microbial risk assessment hazard identification refers to the presence of micro-organisms and/or their toxins associated with a specific illness or deterioration of the same. Therefore, the question is: Does the hazard exist? To reply to it we need to look

for information about pathogens, either in fact or potential, through clinical and epidemiological studies of microbial characterization and studies of the ecology of the illnesses. This information is of relevance at this stage of the study in order to assess if a particular etiological agent, here called a hazard, produces some health threat (GERBA, 2000, PEÑA, *et al*, 2001,WHO, 2004). According to HAAS *et al* (1999) identification of a microbial (hazard) agent may follow the following stages: a) identification of the etiological agent of a particular illness, in accordance with the postulates of Koch; b) diagnosis, which identifies the symptomology, the infection and the presence of micro-organisms in clinical samples of the host (blood, pus, feces); c) understanding the process triggered off by the illness from exposure to infection (colonization in the human organism) to the development of symptoms, the illness and death; d) identification of possible transmission pathways; e) analysis of the virulence factors of the micro-organism and its life cycle; f) assessment of the incidence and prevalence of the illness in the population (endemic risk) and investigation of outbreaks (epidemic risk); g) development of models (usually models using animals); h) assessment of the role of the host's immunological system in fighting the infection and the possible development of vaccines for prevention, and; i) the correlation of epidemiological studies with possible exposure pathways.

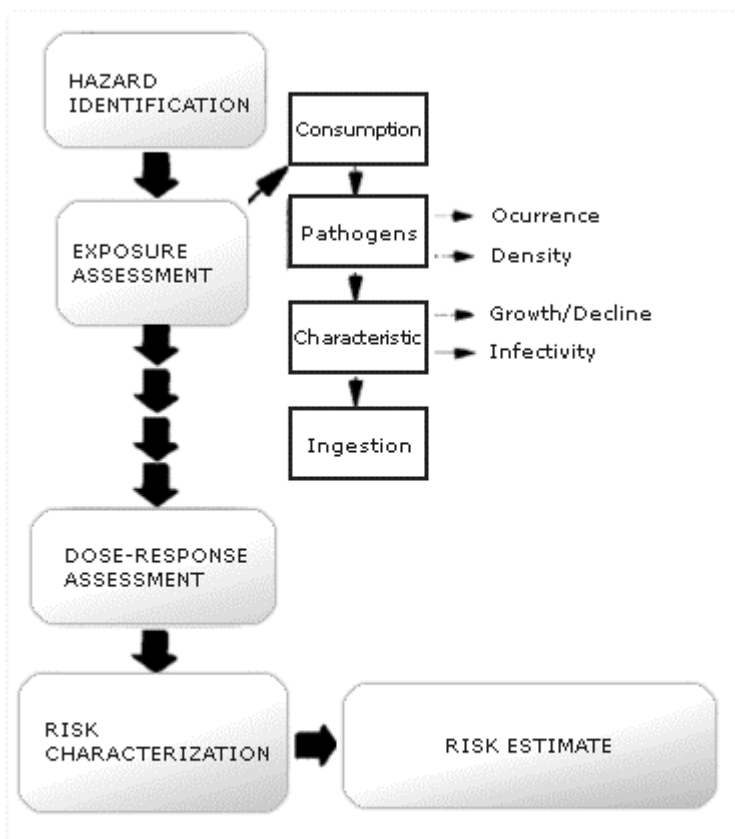


Figure 1: Example of the structure for microbial risk assessment (adapted from MARKS et al., 1998)

The exposure assessment stage refers to the measuring process or the estimate of the intensity, frequency and duration of human exposure to a particular agent, with the purpose of determining the quantity of organisms that correspond to a single exposure or the total quantity of organisms that comprise a set of exposures (HAAS *et al.* 1999, GERBA, 2000). Exposure to contaminants may occur via pathways such as inhalation, ingestion and dermal or cutaneous contact. The sources of contamination, the transport and transformation mechanism and also the exposure routes of a micro-organism from the source to contact with the exposed population, including the pathway by which it entered the host, are important factors to be considered in the assessment stage. The concentrations of exposure are obtained from laboratory measurements and/or estimated by mathematical modeling. Therefore, quantification of the dose that entered the organism may involve equations with three sets of variables: concentration of the micro-organism,

rates of exposure (intensity, frequency, duration) and host characteristics (weight, immunity).

The dose-response relationship results from experimental studies, which should provide evidence as to what concentration of the etiological agent is having an adverse effect on the health of the exposed population. In other words the dose-response relationship aims at establishing a mathematical relationship between the quantity (concentration) of a micro-organism to which the person or population is exposed and the risk of this concentration producing adverse effects. MARKS *et al.* (1998) point out that the number of organisms ingested can affect the probability and severity of the illness. Illnesses result from a complex process of interactions between the host, the pathogen and the environment, which in some cases is not fully understood.

A lot of research with volunteers has been done with the aim of identifying the reference dose for infectivity. In the case of a virus the studies are done with viruses that have been attenuated by vaccines or grown in laboratories. Among the various consequences of an infection are:

- **the possibility of sub-clinical illnesses** (asymptomatic), which are those that result in symptoms that are not the obvious ones, such as fever, headaches or diarrhea. In other words, individuals may be host to the pathogenic agent and transmit it to others without themselves being ill. The reason for clinical and sub-clinical infections varies from agent to agent, especially with viruses. In some cases the probability of developing a clinical illness bears no relationship to the dose received by an individual via ingestion.
- **the development of clinical illnesses;** various factors may interfere, such as age, for example. In the case of hepatitis A, the clinical symptoms may vary from 5% in children under 5 years of age up to 75% in adults. On the other hand, children are more susceptible to developing retroviral gastroenteritis.

Therefore, the dose-response models do not only cover the probability of infection, the probability that the infection will result in an illness and the probability that the illness will result in death. It is important to point out that information is not always available about the dose-response relationship of pathogenic organisms and the effects produced in hosts.

In this sense, the use of mathematical functions for estimating this relationship and the choice of the model must be always very carefully chosen.

Risk characterization represents the integration of the previous stages – risk identification, assessment of exposure and assessment of dose-response for determining the risk estimate. Therefore, this phase establishes the quantitative and qualitative estimate of the probability and severity of adverse effects that may afflict a certain population (WHO, 2004). It has to be pointed out, however, that these estimates must be accompanied by the magnitude of the uncertainty of the estimated risk. The sources of uncertainty must be included such as, extrapolating high doses for low doses, extrapolating the response in animals for that in human beings, extrapolating one transmission pathway for another, the limitation of analytical methods and the estimated exposure.

Assessment of the uncertainties is a very important aspect in the process of risk assessment. There are cases in which some sources of uncertainty may be quantified and in other cases where a qualitative treatment may be applied to them, but they must always be considered and assessed. According to GERBA (2000) two strategies may be used to characterize uncertainty: sensitivity analyses and the Monte Carlo simulation. The sensitivity analysis comprises analyzing the uncertainty of each parameter used in carrying out the study and assessing the impact of each of them on the final result. In the Monte Carlo simulation, however, it is assumed that all the parameters are random and therefore, instead of varying each one of these parameters separately, software is used that selects the randomly distributed data and uses mathematical functions each time, over and over again. The result obtained corresponds, therefore, to the exposure values or risk corresponding to a specific probability that is reliable at the 95% level.

Risk management provides an approach aimed at controlling risks, by considering the cost-benefit of introducing improvements, for example, in the treatment system of water collected for consumption, in addition to providing information about exposure limit policies. According to GERBA (2000), USEPA in the United States uses the concept of acceptable risk and suggests that a risk of annual infections of 1/10,000 is a suitable level for guaranteeing the safety of water used for human consumption. To achieve this level treatment stations of water used for human consumption must be 99.99% efficient at

removing *Giardia* and enteric viruses. In this way the cost of treating water is possible, leading to a reduction in the costs associated with health services and productivity.

Risk communication is also an important management tool, which aims at guaranteeing an exchange of information between interested parties, such as government managers, technicians, social stakeholders and others.

Stage	Objective
<b>Hazard identification</b>	Description of the acute and chronic effects on health associated with a specific micro-organism, including everything from transmission pathways to the host.
<b>Assessment of dose-response</b>	Characterization of the relationship between the various doses administered and the incidence of their effects on health.
<b>Assessment of exposure</b>	Determination of the size and nature of the exposed population and routes, concentration and duration of exposure.
<b>Characterization of risk</b>	Integration of information obtained in the previous stages to estimate the magnitude of the public health problems and to assess the variability and uncertainties.

**Table 1:** Risk assessment paradigms for the purpose of considering human health  
 Source: Adapted from HAAS et al., 1999

### The application of microbial risk assessment

To protect the health of the population it is not enough merely to check the sanitary quality of water used for human consumption, using laboratory analyses in order to obtain information such as the concentration of a certain pathogenic micro-organism or, to establish its presence or absence in the samples. In Brazil, the sanitary quality of water for consumption or for recreational purposes is established by Ministerial Directive 518 issued by the Health Ministry on March 25, 2004, and by CONAMA (National Environment Council) Resolution 274, dated November 29, 2000, respectively. The classic bacteriological indicators of drinking water quality, thermotolerant coliforms and *Escherichia coli* are not effective when it comes to assessing the occurrence and efficiency of the removal of pathogenic protozoa and viruses in water treatment stations (ROSE; GERBA, 1991, GALE, 2001).



Pathogenic micro-organisms may reach locations that supply water for human consumption and for recreational purposes due to contamination by excreta as a result of crossed connections and maintenance problems. The emergence and re-emergence of pathogens brings to the fore issues relative to the sanitary quality of water: "Is checking that the bacteriological standards established by law are met enough to guarantee the quality of drinking water and that used for recreational purposes?", "Does meeting these standards really promote and protect the health of users?".

There are various stories of the occurrence of pathogens (re) emerging in water (HAAS *et al.*, p.18, 1999, RUSIN *et al.*, p. 447, 2000, WHO, 2003; WHO, 2004). It is worth mentioning as an example the classic case of Milwaukee, in Wisconsin (USA, where the public water system was contaminated by the protozoa, *Cryptosporidium*, which affected the health of 403,000 people of whom 4,400 were hospitalized and 69 died. The probable cause was the contamination of treated water by human and animal (bovine or equine) excreta. (SOLO-GABRIELE; NEUMEISTER, 1996).

Monitoring the occurrence of pathogens in order to assess the sanitary quality of drinking water and that used for recreational purposes has proved to be unfeasible, both from the technical as well as from the economic point of view, due to the large diversity of pathogens, the high cost and complexity of laboratory analyses and the health risk to technicians because of the constant manipulation of these organisms. Therefore, assessment of the microbial risk consists in having a tool that can be used for estimating the possible adverse effects to health when pathogenic organisms are present in water samples in order to guide control and intervention measures, as well as to assess the impact of the actions carried out.

The World Health Organization (WHO, 2004), in its *Guidelines for drinking-water quality*, considers microbial risk assessment as a way of estimating the risks to human health associated with the quality of drinking water. There are many stories about the application of microbial risk assessment models to different types and uses of water (GERBA;ROSE,1991, GERBA *et al.*,1996, CRABTREE *et al.*,1997, STINE *et al.*,2005, SCHIJVEN *et al.*,2005, BROOKS *et al.*,2005)

## General considerations

Bearing in mind the above, the assessment of microbial risk is a decision-making tool and may be used for:

- estimating the adverse effects to health associated with pathogenic organisms present in samples of treated water and that used for recreational purposes;
- decision making at various levels of action;
- providing support for decisions based on scientific results.

It is worth pointing out that when conducting the studies the whole risk assessment process must be transparent at every stage and well documented, making clear that there is the opportunity for future reassessment.

In Brazil, this is a recent, but promising area of research, both from the scientific point of view, as well as from the management of the quality of the water resources used for providing public drinking water and for recreational purposes is concerned, especially in peri-urban areas of metropolitan regions, where socio-environmental conditions are obviously precarious and where there is a demand for the prioritization of actions for intervening, in order to preserve water sources to protect human health and to optimize the use of public funds needed for investment.

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