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International risk assessment leading to development of food safety standards

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Abstract

The Sanitary and Phytosanitary (SPS) Agreement under the World Trade Organisation (WTO) provides the right to member countries trading in food commodities to take measures to protect plant, animal and human health. However, these measures cannot be arbitrary, but should be based on scientific risk assessments performed according to international standards. The agreement also requires countries to adopt international standards such as those developed by the Codex Alimentarius Commission for food safety and by the World Animal Health Organization (OIE) for animal health. Scientific risk assessments required for development of food safety standards are performed by FAO/WHO. Some examples of food safety standards set by the Codex Alimentarius Commission based on risk assessments are microbiological criteria for *Listeria monocytogenes* in ready to eat foods and Guidelines for control of pathogenic *Vibrio* spp in sea foods.

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*Keywords:*Codex alimentarius;vibrio spp;sea food;food safety

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1. Introduction

International trade in different food commodities is increasing and seafood is one of the most traded products. According to FAO, close to 40% of global fish production goes to international trade and global trade of fish and fishery products reached $136 billion in 2013[1]. The World Trade Organisation (WTO) member countries signed the Sanitary and Phytosanitary (SPS) Agreement in 1995, which gives the right to member countries the right to adopt measures to protect plant, animal and human health. However, the measures should not be arbitrary, but be based on scientific risk assessments performed according to internationally accepted methods. The SPS agreement encourages member countries to adopt international standards and the agreement recognizes Codex Alimentarius Commission as the international body for setting up standards related to food safety and the World Organisation of Animal Health (OIE) for setting up standards for animal health.

Risk analysis involves three major components (a) risk assessment (b) risk management and (c) risk communication. Risk assessment is a scientific process and requires multi-disciplinary expertise eg in microbiology, chemical pollutants and contaminants, epidemiology and public health, food production and processing technology, statistics and modeling. Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards**,** consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. At international level, food safety risk assessments are performed by joint FAO/WHO bodies such as JEMRA (Joint FAO/WHO Expert meeting on Microbiological Risk assessment), JECFA (Joint FAO/WHO Expert Committee on Food Additives) and JMPR (Joint FAO/WHO Expert meeting on Pesticide Residues). Risk management is a process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options such as setting up microbiological criteria, maximum levels of additives or chemicals or maximum residue limits for pesticides or antibiotics. Risk communication means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

The importance of risk assessment for developing food safety standard can be illustrated with the example of *Listeria monocytogenes*as indicated below.

2. Case study of Listeria monocytogenes

Listeria monocytogenes was identified as a foodborne pathogen in the 1980's. Though this organism rarely causes disease in healthy individuals, it affects immunocompromised individuals and pregnant women. Though listeriosis is a rather rare disease, high mortality rate (20-30%) and association with commercially processed foods makes this important. When food safety issue related to this pathogen was identified, the first response of most regulatory agencies was to impose a "zero tolerance" for this organism in foods. But some countries were of the opinion that up to 100 *L. monocytogenes*/g could be permitted. This is because of the wide presence of this organism in the food processing environments. Among fish products, smoked fish is particularly susceptible for contamination with this organism. There have been several outbreaks of listeriosis associated with smoked fish and lack of harmonized international standards was leading to trade disruptions. Recognizing this, the 33rd Session of Codex alimentarius Commission requested FAO/WHO to perform risk assessment for *L. monocytogenes*. They asked the following risk assessment questions (a) Estimate the risk of illness when the level of the organism in food ranges from absence in 25g or 1000 colony forming units per gram or per milliliter of the food at the point of consumption (b) Estimate the risk of illness for different susceptible population groups relative to the general population (c) Estimate the risk of illness from foods that support or do not support the growth of L. monocytogenes at specified storage temperature and shelf life conditions.

JEMRA expert group decided to focus on four ready to eat foods ie. pasteurized milk, ice cream, fermented meat and cold smoked fish[2]. Pasterurised milk has very low levels and frequency of contamination, but allows growth of the organism during storage. Ice cream does not support growth during storage. Fermented meat could be often contaminated, but the final composition prevents the growth of *L. monocytogenes* during storage. Cold smoked fish is often contaminated, does not involve a lethal processing step and will permit growth of L. monocytogenes. Risk estimates indicated that for milk, the risk per serving is low ($5x10^{-9}$/serving) but due to high frequency of

consumption, milk accounts for significant number of illness. In the case of smoked fish, the risk per serving is higher ($2.1x10^{-8}$/serving), but since consumption frequency is lower, its contribution to total illness is moderate.

To address the question on the impact of regulatory levels on the illness, the Expert Group worked out "what if" scenario". The risk estimates included that there can be tenfold increase in illness rate, when the prescribed level of the organism at the point of consumption changes from absence in 25g to 100/g. But the Experts noted that even in countries implementing "zero tolerance" (absence in 25g), epidemiological records show that there are illnesses occurring and in most such cases, the level of *L. monocytogenes* exceeds 100/g in the consumed product. This suggests that though a "absence in 25g" is prescribed, a certain proportion of products produced will not be able to met this criterion. This is because it is extremely difficult to eliminate this organism from processing environments. Tenfold difference in risk of illness would be the estimate if 100% of the products meet this criterion. But when there are "defects" happening, what is the impact on the risk? The FAO/WHO risk assessment model addressed this question. The results show that as the proportion of "defects" increase from 0% to 0.001% (1 in 100,000), there is negligible difference in the illness rate between the two criteria. Further, the FAO/WHO risk assessment showed that the potential for growth in the food considerably influences the risk. Therefore, control measures that have an impact on both the frequency and level of contamination will reduce the risk.

Considering these outputs of the FAO/WHO risk assessment, the Codex Alimentarius Commission agreed for a criterion of n=5, c=0, m=100 for ready to eat foods that do not permit the growth of L. monocytogenes and n=5, C=0, m=<0.04/g in foods that permit growth[3]. This case study shows how use of risk assessment allowed development of science based microbiological standards in foods.

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