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A regulatory perspective on the potential uses of microbial risk assessment in international trade

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Abstract

The recent ratification of the World Trade Organisation Agreement will arguably be the most important factor in developing new sanitary measures for the international trade in food over the next decade. There is a markedly increased desire for quantitative data on the microbial risks associated with different classes of foods, and traditional good manufacturing practice (GMP)-based food hygiene requirements are coming under increasing challenge.

As the risk assessment paradigm is increasing applied and as decision-making criteria for risk management become established, more emphasis will be placed on predictive microbiology as a means of generating exposure data and establishing critical limits for Hazard Analysis Critical Control Point (HACCP) plans. In this respect, developing international guidelines for risk management arguably presents the greatest challenge in establishing and maintaining quantitative Sanitary and Phytosanitary (SP) measures for food in international trade, and for judging their equivalence.

Where specific industry sectors and regulators do not have jurisdiction over the entire food chain, from production of raw materials through to consumption, it will be difficult to apply the risk assessment paradigm in the design of HACCP plans. Thus, it appears that default to food safety objectives for many segments of food production chains subject to application of HACCP plans is inevitable in the medium term.

Keywords: Microbial risk assessment; Risk assessment; Risk analysis; Food safety; HACCP

1. Introduction

International debate over the role of science in designing and applying food control programmes has increasingly focused the attention of the Codex Alimentarius Commission (CAC) on risk analysis in the elaboration of standards and guidelines for the international trade in food. These standards and guidelines are especially important in terms of the future multilateral trade work of the World Trade Organisation (WTO), resulting from the GATT Uruguay Round Agreements on Sanitary and Phyto-

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sanitary (SP) measures and Technical Barriers to Trade (TBT).

The application of a risk analysis approach (risk assessment, risk management and risk communication) has the potential to allow an overall assessment of risks and benefits in food hygiene programmes and improve the scientific elaboration of standards and guidelines for food safety. Additionally, inspection and monitoring resources can be allocated in a manner that is proportional to their greatest ability to ensure food safety.

"Risk analysis" in one form or another has ostensibly been applied to the assessment of chemical hazards in foods in international trade for many years, but a critical evaluation suggested that the principles of risk assessment and risk management had not been systematically applied within the Codex system for this class of hazards (Hathaway, 1993). The Codex Executive Committee subsequently agreed that there was a need "for scientific analysis and advice, together with risk analysis, to form the basis of the development of standards, guidelines and recommendations" (Anon., 1994). The Medium Term Plan of the CAC now specifies development of a horizontal approach to risk assessment for *all* classes of foodborne hazards as a priority area for work (Anon., 1995a), however, a systematic strategy to progress this Plan has yet to be developed. Even at an elementary level, there is still confusion within Codex over general elements of risk analysis and vocabulary and in this respect, the recent Joint Food and Agriculture Organisation (FAO)/World Health Organisation (WHO) Expert Consultation on Application of Risk Analysis to Food Standards Issues (Anon., 1995b) has initiated the task of elaborating a consistent Codex-wide approach.

2. World trade organisation

The recent ratification of the WTO Agreement will arguably be the most important factor in developing new approaches and requirements for the international trade in food over the next decade. In bringing an internationally agreed discipline to the application of SP measures, the WTO Agreement also upholds the right of countries to protect themselves according to their "chosen level of protection".

In encouraging different countries to base their SP measures for food as much as possible on Codex standards and guidelines, it is hoped that the WTO Agreement will foster global harmonisation of such measures. This inevitably requires the establishment of harmonised risk assessment and risk management frameworks. The SP rules can be briefly summarised as follows:

- SP measures must be based on scientific evidence or, where appropriate, scientific risk assessment.
- Application of SP measures must be non-discriminatory, i.e., consistency is required in risk management decisions.
- Transparency must be maintained with respect to rule-making.
- SP measures must be used that create the least distortion to trade, i.e., there must be consideration of alternative measures that achieve the same health objective.
- The concept of regionalisation must be applied, i.e., adaptation of import requirements to the sanitary conditions of a specific zone or area.
- The equivalence of SP measures must be accepted if an exporting country can objectively demonstrate that it's controls provide the importing country's desired level of protection.

It is clear that these rules rely on two primary elements: Quantitative, scientifically justified SP standards and guidelines; and their fair and open application. It is essential to examine the first element if risk analysis is to be genuinely applied to contamination of food with microbial pathogens, which is now accepted on a world-wide basis as the most important cause of human foodborne illness. How is the scientific data to be generated, and how will acceptable levels of food safety be determined?

3. Foodborne microbial hazards

It is inevitable that many foods, either in the raw or ready-to-eat form, will have some level of microbial contamination (or microbial toxin) at the point of consumption. A plethora of Codex and national hygiene requirements have been established, mostly based on good manufacturing practice (GMP) and end-product testing, to control foodborne illness attributable to this contamination. These GMP-based

requirements have evolved from general principles of hygiene, are usually qualitative, and rarely formulated according to an objective assessment of risks to human health.

With the advent of the WTO Agreement, traditional GMP-based food hygiene requirements are under increasing challenge. In addition, the regulatory authorities of many countries are suffering severe budgetary constraints at the same time as they are being increasingly criticised for inadequate control of foodborne microbial risks to human health. The outcome is a markedly increased desire for quantitative data on foodborne microbial risks associated with different classes of foods, so that regulatory decision-making mandates (including cost/benefit analyses of hygiene requirements) can be achieved.

In an open and transparent decision-making environment, national controlling authorities are well aware that they are increasingly vulnerable if they make deficient decisions for control of a class of foodborne hazards, where elimination is generally not an option. Microbial hazards are almost always present and "acceptable" levels should be defined. Recognition of this increased regulatory responsibility has been a major factor in the endorsement of the HACCP system of food control, and it's consequent acceptance by the CAC.

4. HACCP

A HACCP approach should be evaluated for use in all key segments of a food production, processing, storage, distribution and consumption chain where microbial pathogens can enter the food, or growth can be potentiated. The principles of application of HACCP are concerned with focusing control efforts on critical control points (CCPs). Control of microbial hazards involves decisions on what are "acceptable" levels of contamination at each process step and there is a presumption that the critical limits utilised in the HACCP plan will bear a quantitative epidemiological relationship with outcomes in terms of food safety. Notermans et al. (1995) take this principle one step further and consider that a CCP should be defined as "an operation (practice, procedure, process, etc.) at which control should be exercised to achieve a quantifiable reduction in a hazard, or it's stabilisation, that leads to an acceptable, safe food product". There is a specific need for on-line monitoring parameters at CCPs that have a quantitative association with "acceptable levels" of microbial contamination.

Thus, there is an inescapable requirement for some form of risk assessment if a HACCP plan is to be genuinely applied, and consistent decisions on CCPs and critical limits will largely rest on a practical and systematic risk analysis process (van Schothorst, 1992). Inherent in this approach is the contention that the application of genuine HACCP-based systems should be aimed at providing improved food safety assurances compared to those provided by adherence to GMP, and/or should provide greater benefit/cost ratios for particular food safety characteristics than those achieved by GMP (Hathaway, 1995).

Unfortunately, the current literature describing application of HACCP systems rarely considers the difference between a reduction in the level of *hazards* in food during a particular segment of production or processing, and a reduction in *risk* for consumers. Although HACCP-based food control systems are often justified solely on the basis of being able to reduce or "minimise" *hazards* during one segment of the food production/processing system, it is contended that assigning critical limits on this basis alone will often be insufficient; the goal of a HACCP system should be to significantly reduce the *risk* of foodborne illness.

5. Microbial risk assessment

As a consequence of the emerging regulatory environment detailed above, "microbial risk assessment" is now a commonly heard phrase during discussion of food safety and international trade. Given that SP measures must be based on "scientific evidence, or where appropriate, scientific risk assessment", a formal approach to the use of microbial risk assessment is required for the quantitative evaluation of the microbial safety of foods. The primary use for this risk assessment information is likely to be in the design of HACCP plans and in the judgment of equivalence of national food safety systems.

Any health risk assessment contains four analytical steps (Anon., 1986):

- Hazard identification — the qualitative indication that a substance/agent may adversely affect human health;
- Hazard characterisation — the qualitative and quantitative evaluation of the nature of the adverse effects, and may include dose/response;
- Exposure characterisation — the qualitative and quantitative evaluation of the degree of human exposure that is likely to occur;
- Risk characterisation — integration of the above steps into a quantitative estimation of the adverse effects that are likely to occur in a given population, to be used in decision-making.

Microbiologists are well aware of the challenges that microbial risk assessment presents if the above paradigm is to be satisfied. Particular problems relate to the fluctuating levels of microbes at different process steps, and the wide range of factors (host, agent and food) affecting human susceptibility to infection.

It is likely that initial microbial risk assessments for food will mostly be concerned with evaluating different *levels* of microbial contamination that are continuously incurred from a particular segment of the food chain. This could focus on:

- Measuring microbial levels that constitute current and reasonably achievable GMP for particular segments of food production/processing systems;
- Measuring differences in these levels that may be brought about by altering food production/process specifications, hygiene requirements or technological interventions;
- Using microbial risk assessment (as methodology becomes available) to determine the effect on food safety of established microbial levels, and any changes in established levels;
- Applying HACCP food control systems which ensure that the hygiene parameters chosen as representative of an acceptable level of microbial safety are met on a continuous basis;
- Investigating the ability to exclude sporadic contamination with known pathogens (e.g., *Escherichia coli* O157:H7) by preventing their introduction to the food chain, especially via the raw material.

Construction of a scenario tree describing all process steps from production through to the intended end-uses of a food product (and preparation for consumption) collectively describe the risk model, and targeted research is required to accumulate appropriate microbial data. Because of the variability and limited precision inherent in this type of data, stochastic modelling that allows estimation of outputs that are biologically realistic appears to offer the most promise. New PC software programmes such as @RISK (Palisade Corporation, New York, USA) make such modelling a more accessible proposition than in the past.

A HACCP system designed according to this approach may not necessarily be concerned with setting specific pass or fail standards for a food during an intermediate segment of a food production chain; the industry or regulatory response to a deviation from critical limits may be the immediate imposition of better controls.

Several countries have initiated detailed research programmes to determine the microbial profiles of fresh meat carcasses as a first step in formal microbial risk assessment for this class of food. In an ideal world, a genuine HACCP system to control microbial contamination of fresh meat carcasses would only include a pathogen reduction activity as a CCP if existing levels of contamination were compared with those brought about by the pathogen reduction activity, and a risk assessment could demonstrate a quantitative and worthwhile improvement in food safety.

6. Problems

The desire of the WTO and national controlling authorities for quantitative, scientifically justified food safety measures must be tempered according to: the ability of the global scientific community to generate the necessary data and the current lack of internationally agreed-upon microbial risk assessment and risk management frameworks.

6.1. Data requirements

The microbial risk assessment paradigm requires quantitative data to:

- Determine the exposure of the consumer to microbial hazards at the point of consumption;
- Characterise this exposure (ideally by reference to a dose/response curve) to determine the probability and severity of foodborne illness in a given population, i.e., risk.

Exposure data can be generated from a detailed understanding of the level of contamination in raw materials, and the effect of different process steps and food composition on microbial levels, including the extent of cross-contamination and redistribution. Currently, there is only limited data available for such purposes, and an inability to measure changes in virulence of microbial hazards during estimation of exposure can be a shortcoming. Predictive microbiological models are likely to have increasing application as a means of defining HACCP on-line monitoring parameters that will achieve selected microbial outcomes.

Dose/response data that allows estimation of the probability of different health outcomes from varying levels of exposure is also limited for specific foods and specific microbial hazards. Despite the difficulties in generating this data, disease outbreak information has been accumulated to define dose/responses for some common microbial hazards (Rose and Gerba, 1991) and further work is in progress (Anon., 1995d).

Addressing the shortage of data is the first step, if Codex, national regulatory authorities and industry are to take a quantitative approach to implement genuine risk-based HACCP programmes for food safety.

6.2. Microbial risk assessment framework

There is a priority need for development of internationally agreed principles of risk assessment, tailored to foodborne microbial hazards. The Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues has begun this task (Anon., 1995b) and there would logically be a progression to the development of a comprehensive strategy for incorporating a risk assessment approach, wherever appropriate, throughout the Codex system.

Specific industry sectors and regulators rarely have control and/or jurisdiction over the entire food chain, from production of raw materials through to consumption. This is particularly the case for foods in international trade, where raw materials are often produced in one country and processed and consumed in another. In this situation, it is difficult to apply the microbial risk assessment paradigm and establish critical limits for identified CCPs on this basis.

In these cases, it would appear that default to food

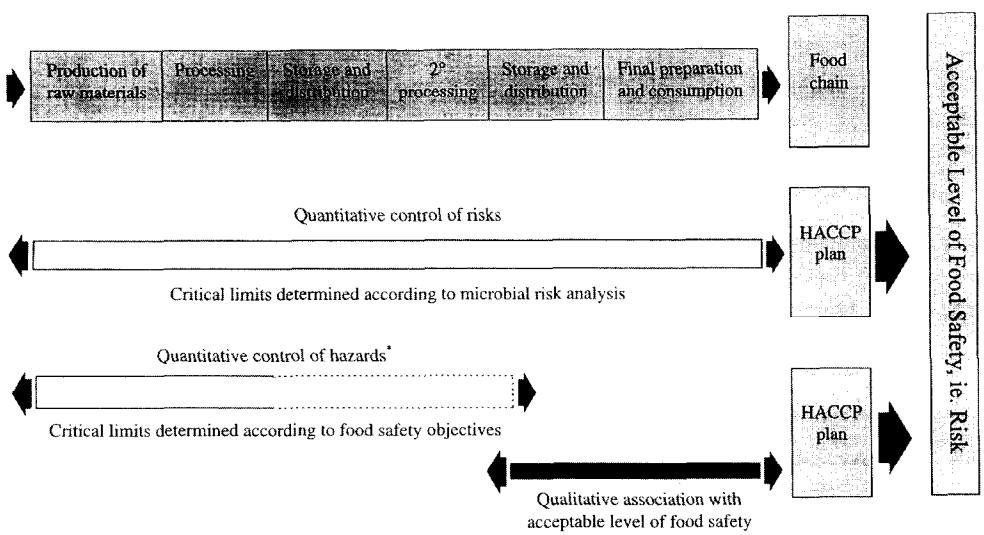

Fig. 1. Application of a quantitative approach to microbial food safety (* most common situation in international trade).

safety objectives (FSOs) (Fig. 1) for many segments of food production chains, subject to application of HACCP plans, is inevitable in the medium term. These HACCP plans will still contain critical limits for CCPs that are quantified according to the FSOs that are formulated as outputs for the particular segment of the food chain. Unlike the situation where HACCP plans are designed by genuine use of microbial risk assessment, the FSOs are likely to have only a qualitative association with acceptable levels of food safety.

The closer to the raw material production segment of the food chain that the HACCP plan applies, the more tenuous is the association likely to be between the FSOs for the HACCP plan and acceptable levels of food safety. Thus, the HACCP plan will quantitatively address the control of *hazards*, but not the control of *risks* (Fig. 1). This reality raises the question: Are HACCP plans implemented in such circumstances a genuine expression of HACCP principles, or do they more reflect a quantitative expression of GMP?

In this respect, it is noteworthy that the current draft revision of the Codex "Guidelines for the application of the Hazard Analysis Critical Control Point System" (Anon., 1995c) does not make an attempt to address the linkages between HACCP and risk assessment and/or FSOs. Avoidance of these issues will delay genuine application of HACCP principles.

6.3. Risk management

In parallel with establishing an internationally agreed approach to microbial risk assessment, there is a priority need to achieve consistency in risk management when determining an appropriate level of sanitary protection (i.e., acceptable level of food safety) across all food commodities. Reference to internationally agreed Codex standards and guidelines is obviously desirable to compare and assess an individual country's SP measures when they are in dispute.

Developing international guidelines for risk management arguably presents the greatest challenge in establishing and maintaining quantitative SP measures for food in international trade. The CAC must take rapid steps to address the problem of risk management for microbial hazards, especially where Codex committees have to translate risk assessment data into standards and guidelines. Currently, the consensus modality governing decision-making contains no formal elements of risk management with respect to what constitutes an acceptable level of microbial food safety. In general terms, Codex committees consider socio-economic and political issues as well as health and technical aspects when establishing standards and guidelines for control of hazards to human health in foods, and this complicates the issue of risk management according to the SP provisions of the WTO agreement.

In the short term, the lack of internationally agreed risk management frameworks for decision-making on acceptable levels of microbial food safety will likely limit determination of the equivalence of different national food hygiene programmes to *ad hoc* decisions made within the framework of bilateral agreements. It is likely that scientific inconsistencies in these decision-making processes carry the risk of undermining the intent and application of the WTO Agreement on a truly international basis.

7. Conclusions

Many observers have unrealistic expectations for microbial risk assessment in the short term; on the other hand, there are critics who suggest that adequate data will never be available to establish acceptable levels of microbial food safety. Both viewpoints do not pay due cognisance to the international drive for scientifically justified quantitative SP measures for the purposes of international trade, and the "newness" of the microbial risk assessment approach in contributing to the establishment of these measures.

Intrinsic to the WTO Agreement is the expectation that there will be increased international acceptance of food hygiene programmes individually designed by national regulatory authorities, as long as those programmes are risk-based, clearly specified, fully documented, scientifically valid and subject to audit as to their delivery according to specifications. Developing an infrastructure to achieve these equivalence objectives places much more responsibility on national regulatory authorities and Codex than in earlier times, and HACCP will be a primary

vehicle for achieving enhanced food safety goals in a cost-effective and efficient manner.

Even though appropriate scientific data will often be unavailable in the short term, the conceptual frameworks required for risk assessment will provide a systematic approach to meeting many of the current challenges arising from foodborne microbial hazards. Data gaps that prevent quantitative determination of food safety objectives and/or risk assessments will be identified and research will be targeted to fill these gaps. However, it must be emphasised that risk assessment alone is of limited usefulness unless risk management guidelines are available to establish acceptable levels of food safety. Only then can the risk assessment (or FSO) process be utilised to design HACCP plans that will deliver the chosen level of safety for a particular food.

Questions are likely to remain over the quality and sufficiency of microbial risk assessment (or FSO) data to resolve disputes when the level of protection (acceptable level of food safety) chosen by an importing country is under challenge. However, in our view, increasing use of microbial risk assessment and FSOs is inevitable with respect to establishment of SP measures for microbial hazards in food. As the risk assessment paradigm is increasingly applied and as decision-making criteria for risk management become established, more emphasis will be placed on predictive microbiology as a means of generating exposure data and establishing on-line monitoring parameters for HACCP plans. However, the greater the reliance on FSOs at the expense of genuine microbial risk assessment, the more difficulties will be encountered over international harmonisation of food safety programmes and judgements of equivalence.

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