Risk Analysis and International Standards for Meat Hygiene

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ABSTRACT

There is a markedly increased desire for quantitative data on the risks associated with consumption of meat and meat products, and traditional meat hygiene requirements are coming under increasing scientific scrutiny. Application of risk analysis on a broad front is an important prerequisite to achieving improved meat hygiene goals on a global basis. As the risk assessment paradigm is increasing applied and guidelines for risk assessment become established, internationally-accepted criteria for risk management decisions on acceptable levels of health protection present a further challenge.

INTRODUCTION

In a contemporary food safety environment, satisfying the need for inspection and hygiene measures that are scientifically justified, effi and equitable requires a risk-based approach. Although food safety risk analysis has been applied on an *ad hoc* basis for many years, are now a number of reasons for the emergence of a more formal discipline:

(1) Greater public concern over real or imagined food-borne hazards to health

(2) Inclusion of risk assessment principles in national legislation, and new legislative conditions that facilitate product liability claims

(3) The increasing need for food control systems to represent efficient and cost-effective use of government funds

(4) Trade agreements that require scientific validation of sanitary measures utilised by national governments.

Countries exporting a large proportion of their agricultural produce have a particular interest in a risk analysis approach. As w meeting the challenges of their domestic food safety environment, they must also meet the food safety expectations of importing countrie this context, food safety programmes for meat and meat products are arguably the most complex of any food commodity group application of food safety "risk analysis" in different countries suffers from a diversity of approaches. This paper will explore several are application where international agreement on methodological approaches will result in efficient and scientifically-justified meat hy programmes that enhance consumer protection.

FOOD SAFETY RISK ANALYSIS

There is still considerable confusion over a food safety risk analysis vocabulary. The definitions agreed by the Codex Committee on Ge Principles (Anon., 1996a) provide a basis for developing a brief explanation.

Recognition of the difference between "hazard" and "risk" is a primary issue. A hazard is a biological, chemical or physical agent i condition of, food with the potential to cause an adverse health effect. In contrast, risk is a function of the probability of an adverse h effect and the severity of that effect, consequential to a hazard(s) in food. Understanding the association between a reduction in hazard food in a particular segment of the food chain, and a reduction in the risks of adverse health effects in the exposed consumer population, particular importance in development of food safety controls.

The three components of the risk analysis process are risk assessment, risk management, and risk communication. Risk assessment is th primary scientific process and represents an evaluation of the probability of occurrence (likelihood) and severity (magnitude) of known o potential adverse health effects resulting from human exposure to food-borne hazards. The risk estimate that is generated may be expresse in quantitative or qualitative (i.e. categorical representation) terms. A risk assessment should contain four analytical elements: hazard identification, exposure assessment, hazard characterisation (which may include a dose/response assessment) and risk characterisation.

Risk management is concerned with weighing policy alternatives in light of the results of risk assessment and, if required, selecting implementing appropriate control options. Decisions on acceptable levels of risk should be determined primarily by human h considerations, and arbitrary or unjustified differences in these levels should be avoided (Anon., 1997). Other factors which may influ decision-making include technological feasibility, economics and social concerns. Risk management policy options categorising diffe approaches to acceptable levels of risk include:

- "Zero-risk" policies eg. implicit in *de minimis* and acceptable daily intake approaches
- Risk balancing policies eg. cost-benefit, as-low-as-reasonably-achievable (ALARA)
- Risk threshold policies eg. where specified levels of risk are deemed acceptable
- Risk comparison policies (including precedence)
- Procedural approaches eg. utilising negotiation or consensus building.

Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk manag consumers and other interested parties.

GENERAL ASPECTS OF MICROBIOLOGICAL RISK ASSESSMENT

Although hygiene programmes must address biological, chemical and physical hazards in meat and meat products, this paper is prim concerned with microbiological hazards. There is an emerging consensus that microbial pathogens of gastrointestinal origin are by fa most important source of public health risks resulting from consumption of meat and meat products. In this context, the pathogens ranke recent epidemiological reviews as being of most significance are : *Salmonellae, Campylobacter, Escherichia coli* O157:H

monocytogenes and *Toxoplasma gondii* . With the exception of *T. gondii*, it is likely that almost all foodborne transmission of these pathogens of gastrointestinal origin originates from unseen microbiological contamination of the carcass and viscera during slaughter and dressing. In respect of raw food commodities such as fresh meat, microbiological risk assessment will mostly be concerned with evaluating different levels of contamination that are incurred from the harvesting and processing environment.

In developing new approaches to control or elimination of cross-contamination with pathogens of gastrointestinal origin, it is important to recognise that there is an increasing body of data that documents the limited contribution of post mortem inspection to control or elimination of pathogens of foodborne public health importance. Obviously, the hazards arising from grossly-detectable abnormalities can be subjected to a risk assessment approach (Hathaway, 1993).

In risk assessment of meat and meat products, the contamination levels of the raw material entering the food chain dictate the character of the initial microflora but this can be markedly modified by subsequent events. Construction of detailed scenario sets describing all steps from production and processing through to intended end-uses of a food describe exposure, and targeted research is required to accumulate appropriate microbiological data. Predictive modelling of the fate of microbial hazards in meat produced according to a specified process is playing an important role in this respect. Because of the variability inherent in much biological data, Monte Carlo simulation modelling that generates probabilistic risk estimates offers considerable promise (Van der Logt and Hathaway, 1997). However it is important to acknowledge that application of microbiological risk assessment approaches in the near-term will more commonly utilise qualitative approaches rather than mathematical models.

A plethora of meat hygiene requirements, mostly based on good manufacturing practice (GMP), are in place to limiting food-borne illness attributable to microbiological contamination. These requirements have largely evolved from general principles of hygiene, are usually described in qualitative terms, and are rarely formulated relative to a quantitative assessment of risks to human health. Microbiological standards have only been incorporated in codes of practice where epidemiological evidence has demonstrated a "significant" risk to public health e.g. for cooked, refrigerated, ready-to-eat products.

In the case of fresh meat, national regulatory authorities are well aware that unless robust risk assessments (and risk management decision-making criteria) are available, new standards based on fixed numbers of microorganisms may result in excessive wastage of what are essentially wholesome commodities. In the absence of a history of animal modelling and "safety evaluation" according to a notionally zero risk baseline as is the case with chemicals, it is acknowledged that the general objective of microbiological risk analysis is to facilitate reduction of microbial hazards to "the minimum which is technologically feasible and practical" (Anon., 1995).

In respect of chemical hazards in food, a risk assessment approach provides the opportunity to broaden the understanding of acceptable daily intakes, maximum residue levels and their public health significance (Hathaway, 1997). Guidelines for chemicals in foods will inevitably have to address the differences between "safety evaluation" and a genuine risk assessment approach.

INTERNATIONAL STANDARD SETTING

Application of a risk analysis approach is now pivotal to developing standards for the international food trade. In promoting a risk analysis approach, a Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues (Anon., 1995) has developed a generic model for carrying out a risk assessment, and has provided general recommendations for systematic application of risk assessment principles in the elaboration of Codex standards. A Joint FAO/WHO Expert Consultation on Risk Management and Food Safety (Anon., 1997) has developed general principles for risk management and recommendations for their application.

Risk analysis also has a central role in the multilateral food safety work of the World Trade Organisation (WTO). The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) states "Members shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations".

Codex "standards" (standards, guidelines, and related texts such as Codes of Practice) are essential benchmarks for the SPS work of the WTO. Sanitary measures of a Member government that are based on Codex standards will be considered justified and in accordance with the provisions of the WTO. Where different measures have equivalent outputs, the measures chosen to achieve required levels of protection should be those least restrictive of trade. The SPS Agreement also recognises the fundamental right of Members to protect themselves at a level they deem necessary. However, Members are expected to justify any higher levels of protection by utilising risk assessment techniques and other scientific analysis as appropriate.

Notwithstanding the increasing availability of risk analysis principles and frameworks, a number of challenges are inherent in their application to international standards for meat and meat products. In addition to the current limitations in microbiological risk assessment methodologies, many GMP-based codes of practice and inspection procedures have not been critically evaluated as to their impact on foodborne risks to human health. The complexity of available sanitary measures for slaughter, dressing, inspection, storage and processing, and their interactions in achieving desired levels of control of a wide range of hazards, accentuates the limitations of the information pool on foodborne risks.

APPLICATION OF HACCP

Given the increasing importance of HACCP in meat hygiene programmes, successful application requires formal recognition of the essential linkages between design of HACCP plans and risk analysis.

The newly revised Codex standard on application of HACCP defines HACCP as "a system which identifies, evaluates, and controls hazards which are significant for food safety" (Anon,, 1996b). This definition does not effectively establish a distinction between the control of hazards and the control of risks. However, any hazards considered must be of "such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food". Similarly, application of a decision tree to identify critical control points (CCPs) includes consideration of the question "could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable level(s)"? Thus the concept of an acceptable level of risk is implied but not elaborated, yet consistent decisions on CCPs and critical limits will largely rest on application of a practical and systematic risk analysis process (Notermans *et al.*, 1995).

In achieving the recommendation that "quantitative methods of risk assessment should be developed for biological hazards to facilita improve application of HACCP" (Anon., 1995), the setting of food safety objectives (FSOs) for the particular segment of the food ch which a HACCP plan is being applied would appear unavoidable (see below) (Hathaway and Cook, 1997). An example of a FSO fo slaughter and dressing might be "to minimise transfer and redistribution of microbiological hazards from the gastrointestinal tract and h the carcass, according to specified microbiological targets".

In general terms, it is contended that application of genuine HACCP-based systems should provide improved food safety assu compared to those provided by adherence to GMP, and/or should provide greater benefit/cost ratios for particular food safety characte than those achieved by GMP. Thus the enhanced food safety control offered by genuine HACCP systems should not be compromised inclusion of "CCPs" that represent undifferentiated GMP requirements. This appears as a common problem in a number of the g HACCP plans that have been published.

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

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

JUDGEMENT OF EQUIVALENCE

Differences in meat hygiene programmes inevitably exist between countries, and are often a result of a different spectrum / prevale foodborne hazards and different production systems. Determining the equivalence of food safety control measures in different coun becoming a critical issue in the international trade in food. The WTO SPS Agreement specifically requires that if requested by an exp country, an importing country will consider claims of equivalence for a food control programme, with the burden of obje demonstrating equivalence resting with the exporting country.

A framework for the determination of equivalence of meat hygiene programmes requires the development and application of principles and guidelines in a systematic manner. Due to the complexity of meat hygiene programmes, the basis for comparison dependent on the particular component of the control programme being assessed, and should be at the highest level of generality allows effective comparisons to be made.

The analytical decision-making process for judgement of equivalence at the "macro" (infrastructure) level will rely primarily on qual evaluation of systems, and judgements at the "micro" (procedure and product) level will rely primarily on quantitative evaluation of the and wholesomeness of the product. Judgements are dependent on the expected food safety outcomes of a control system and this re formulation of appropriate FSOs.

FSOs may be described in qualitative or quantitative terms, including formulation according to a chosen level of protection (acce level of risk). When there is insufficient information to adequately evaluate differences in inspection capability and product safety in ter foodborne risks to human health, these differences should be evaluated in terms of the level of control of the hazards of concern qualitative judgement as to the likely outcomes in terms of risks to human health. In doing so, consideration should be given to compe levels of control of the hazards of concern by other components of the particular food safety programme. Validation in respect of FSOs becomes a key issue in judgement of the equivalence of HACCP-based food safety control programmes. Decision trees can im judgements.

Agreement is also required on formal structuring of some aspects of analytical decision-making related to "other legitimate factors protection of human health and fair practices in trade", and the extent they can be taken into account (Anon., 1997). Codex "stand provide essential international benchmarks, and the Codex system is striving for a well-documented risk analysis process in the elaborati standards so that governments can determine their position when deciding on the national applicability of Codex standards, and their determining equivalence (Hathaway, 1997).

CONCLUSION

The application of risk-based approaches have the potential to substantially improve the scientific elaboration of meat hygiene standard allow an overall assessment of risks and benefits in meat hygiene programmes. The transition from systems based on traditional princip meat hygiene and a "command-and-control" regulatory involvement to Company-driven, quality assurance-based systems utilising food risk assessment and HACCP is already in train, and will be markedly influenced in exporting countries by the provisions of the WTO Agreement. Current initiatives (and the WTO SPS Agreement) are firmly focused on the outputs of the food control system rather prescriptive aspects of process inputs and the means of delivery, as long as the sanitary measures that are applied achieve the required le health protection.

As the risk assessment paradigm is increasing applied and guidelines for risk assessment become established, internationally-acc criteria for risk management decisions on acceptable levels of health protection present a further challenge. Risk assessment alone limited usefulness unless risk management guidelines are available that establish acceptable levels of food safety, and allow meani judgements of equivalence of meat hygiene systems in different countries.

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