RISK ANALYSIS AS A PREREQUISITE FOR FLEXIBLE, VALIDATED AND EFFECTIVE POST MORTEM INSPECTION PROCEDURES

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INTRODUCTION

Until the 1980's, control of hazards in raw meat generally depended on traditional principles of meat hygiene, with few attempts to draw quantitative associations between particular inspection activities and their outcomes in terms of human health. However, the last ten years has seen modernisation of meat inspection and meat hygiene programmes as an increasingly important regulatory and commercial goal. There are increasing demands for scientific validation of existing specifications, and calls for development of meat hygiene systems that are both efficient and cost-effective. In parallel, consumer groups are increasingly vocal on what they perceive is an unacceptable level of food-borne disease associated with the consumption of red meat products.

Meat inspection programmes are primarily engaged to ensure that meat is "safe and wholesome". In the case of raw meat, this is only a qualitative measure of freedom from hazards to human (and animal) health. Ante- and post mortem meat inspection cannot guarantee freedom from all clinically or grossly-detectable abnormalities, and monitoring programmes have limited ability to detect all randomly-occurring violative levels of chemical hazards. More importantly, some level of inadvertent microbiological contamination is inevitable in the slaughterhouse / processing environment.

Notwithstanding these problems, meat inspection programmes can perform at a high level in protecting consumers against health hazards that may be transmitted by raw meat. What is now needed is formal scientific analysis to quantify levels of performance, along with recognition of the notion of hazard reduction rather than hazard elimination with respect to particular classes of "hazards". The newly-emerging discipline of health risk analysis provides this opportunity.

RISK ANALYSIS

Risk analysis is an applied science and the three main elements are risk assessment, risk management and risk communication. Risk assessment is the primary scientific process and is regarded as the estimation of the likelihood (probability) and severity (magnitude) of harm or damage resulting from exposure to hazardous agents or situations. Scientific value judgements and policy choices are inevitably involved at some decision points in the risk assessment process and these "risk assessment policy" issues should have clear policy guidelines. Risk management is concerned with development and selection of policy options for the purpose of decision making, and the implementation of the regulatory programme that is developed from the risk assessment. A range of methodologies are available for risk analyses involving human values e.g. threshold, comparative, or balancing risk standards. The results of risk assessment and risk management need to be effectively communicated both within and between regulatory authorities, and to the public.

HAZARDS IN MEAT

Raw meat represents a mixed system in terms of "hazards". The general principles of risk analysis apply to all classes of hazards, but different application of risk assessment methodology is needed to evaluate eachdifferent class (Hathaway, 1993a). The performance of the inspection programme often is an integral part of these assessments.

Chemical residues and contaminants of potential public health importance may be introduced at any stage in the meat production system and detection of violative levels of this class of hazards requires specific monitoring programmes. Risk analysis of chemical hazards will not be discussed in this paper.

Gross abnormalities detectable by post mortem inspection are a second class of "hazards" and consist of those of potential public health (and animal health) importance, and those aesthetic defects that are unacceptable to the consumer. In many on-line inspection situations it is difficult to differentiate between true safety hazards and aesthetic "hazards". A risk analysis of a post mortem meat inspection programme made up of a large number of procedures is concerned with the performance characteristics and scientific justification for the different procedures. The needs of industry, e.g. facilitation of processing efficiency, a low level of wastage, and integration of regulatory and commercial goals, should also be considered.

Some level of microbiological contamination of the carcass and offals is an inevitable consequence of slaughter and dressing, and this represents a third class of hazards. There is now a qualitative recognition amongst meat hygienists that inadvertent microbiological contamination rather than chemical residues and grossly-detectable abnormalities is the most important source of public health hazards that may be associated with raw meat. A more systematic regulatory approach is required if this source of hazards is to be kept to "the lowest practicable level possible" and this will require some form of microbiological risk assessment, either on a qualitative or quantitative basis. To date, the development of an appropriate risk assessment model has been inhibited by lack of information and lack of a detailed conceptual framework (Hathaway, 1993a).

Microbiological contamination of raw meat can obviously result from gross pathology as well as from slaughter and dressing. The possibility of microbiological cross-contamination resulting from gross pathology must always be considered in risk analysis of abnormalities detectable at post mortem inspection.

RISK ANALYSIS OF ABNORMALITIES DETECTABLE AT POST MORTEM INSPECTION

Maintenance of continuous post mortem inspection consumes the large majority of regulatory resources in most meat inspection programmes, but it's performance has not been evaluated in a modern epidemiological context and data on the outcome of it's application in terms of public health are rarely available. The procedures are not usually differentiated according to the geographical origin and class of livestock presented for slaughter, and rarely have mechanisms to incorporate the on-farm status of the slaughter population (Harbers et al., 1991). Similarly, feedback to farmers to improve the health status of the slaughter population is often inadequate.

RISK ASSESSMENT

In broad terms, the major "hazards" detectable at post-mortem meat inspection are identified during observation of tissues. Following removal of the most important hazards, incremental benefits decrease as the level of inspection intensity increases. The optimum usage of post-mortem inspection occurs when the incremental gain in benefits (in the broadest sense) equals the incremental increase in costs. Thus the optimal use of post mortem inspection resources does not eliminate all hazards, but removes all potentially important hazards and ensures that any residual hazards are minor in nature and exist at a prevalence that constitutes a "negligible" risk to the consumer.

A health risk assessment is typically divided into four activities which have primarily been developed for evaluating chemical hazards. Specific adaptation of these activities is required when evaluating post mortem inspection procedures (Hathaway, 1993a):

1. Hazard identification: All "hazards" (public health, animal health, and aesthetic defects) that could be present in the tissues of interest and that could be detected by organoleptic inspection procedures need to be identified.
2. Hazard characterisation: The dose/response relationships that are developed from laboratory animal trials to assess chemical hazards are inappropriate for the characterisation of gross abnormalities detectable at post-mortem meat inspection, therefore all hazards that may be present in raw meat and which can be detected by post-mortem inspection procedures are considered. "Severity" can be used to rank hazards according to level of concern and this commonly includes concurrent consideration of: the severity of health effects in the individual, the frequency of cases, and the cost (treatment, control, monitoring).
3. Exposure characterisation: Exposure of the human population to "hazards" in meat that should have been detected by the procedures under investigation is very dependent on the particular processes and conditions that apply prior to human consumption. Despite this, the "worst-case" exposure characterisation must assume that the consumer will be exposed to all hazards that are capable of being detected by organoleptic meat inspection but which escape the inspection procedures in place. Thus the establishment of the performance attributes of individual procedures (sensitivity, specificity and non-detection rate) allows a quantitative characterisation of exposure.
4. Risk characterisation: A consideration of the difference between non-detection rates for all identified hazards for each procedure, together with a scientific assessment of the consequences of each difference, provides the basis for the risk characterisation. In the case of tissues that are not destined for human consumption, the only hazards of significance are those that serve as an indicator function for other tissues, or those which may have implications for animal health.

The risk assessment model is dependent on extensive field trials, carried out under commercial production conditions. Selection of sampling parameters are risk assessment policy decisions that are primarily scientific value judgements. Samples must be representative of the population to which the conclusions are to relate and must include enough samples to enable definite conclusions to be reached as to the consequences of any change in inspection procedures. The level of residual risk that is not addressed by the model also depends on

sample size. A sample size of 30,000 has the capability of limiting the chance of non-detection of an unidentified hazard to less than 1:10 000 with 95% confidence, and this would represent a practical compromise between the desire to detect all abnormalities that could possibly occur at very low prevalences, and the practicality of conducting large-scale field trials.

An appropriate trial design for evaluating the performance of different inspection procedures is an essential element of the risk analysis (Harbers et al., 1992; Hathaway and Richards, 1993). If possible, all tissues should be inspected by each of the procedures to be compared (full matching). In a processing environment where line speeds are high, it may only be possible to apply one procedure to the tissues not rejected by the other (negative matching). This latter design forgoes some statistical power and can be artificially rigorous, however evaluation of many inspection procedures involves comparisons between different intensities of inspection (e.g. visual examination, compared with visual examination plus palpation) rather than comparisons between alternative inspection procedures. Negative matching is a practical and reliable design in such cases.

The statistical choice for comparison of the outcomes of different inspection procedures is also a risk assessment policy decision. Some studies have used tests of statistical significance to decide on equivalent performance but although superficially attractive, they provide only limited information. The most rigorous approach upon which to base risk management decisions is to consider the worst cases included in the confidence intervals for the non-detection rates for each procedure (Hathaway and Richards, 1993).

The risk assessment model should quantify the precise non-detection rates that accompany different post-mortem inspection procedures for a specific class of livestock, and provide the basis for the establishment of an acceptable defect level based on an assessment of the likely public health, animal health and aesthetic risks. It will be clear from the above discussion that the exposure characterisation is an integral part of a risk assessment. Unfortunately, comprehensive data on exposure of human populations to meat-borne pathogens, generated from epidemiological or clinical studies, are rare. Additionally, exposure to abnormalities not detected by a particular procedure is very dependent on the particular processes and conditions that are applied to the raw meat prior to human consumption. These problems can be somewhat alleviated by construction of a detailed scenario set, and calculation of the likelihood of each possible risk scenario by different statistical methods. PC software programmes such as @RISK (Palisade Corporation, New York) are now available for this purpose. As yet, there are no published examples of application of this level of methodology for exposure characterisation.

RISK MANAGEMENT

With the realisation that even high-intensity routine post mortem inspection procedures are neither 100% sensitive nor 100% specific, risk management decisions will focus in the first instance on the comparative performance of the different procedures (particularly non-detection rates) under test. The detection of any abnormalities of potentially severe human health, animal health or aesthetic importance is an obvious prerequisite of any inspection regime but application of high-intensity procedures to detect all abnormalities of trivial importance is not defendable if resources are to be proportionally allocated according to areas of greatest risk.

As an example, as-low-as-reasonably-achievable methodology (ALARA) adopts "zero risk" as an ideal but balances the ideal against "reasonable" cost limits on the resources needed for the obtained level of safety. ALARA does not demand the exact quantification of risks and benefits in terms of a single denominator, and would be sensitive to the uncertainties that are implicit in public health risk analyses. As such, ALARA is a reasonable compromise between the often unachievable demands of "zero-risk", and the practical and social / political difficulties of a quantitative risk-cost-benefit approach (Brunk, 1992).

If there is to be comprehensive application of a risk analysis model for abnormalities detectable by post mortem inspection, the food safety responsibilities of all parties (producer, processor, regulator and consumer) should be evaluated at all key points in the meat production chain. This may introduce organisational, legal or commercial limitations in terms of desired regulatory activities. Development of on-farm systems that document the food safety responsibilities of the producer of slaughter pigs are well advanced in the Netherlands (Snijders et al., 1993), and such systems will lead to risk-based post mortem inspection programmes that take on-farm health status into consideration. The critical role of the consumer in contributing to risk in the handling and preparing of fresh meat for consumption, and the role of the regulator in communication of the risks associated with end-use, provide further examples.

RISK COMMUNICATION

Evaluation of risk by the public is often wider than that of the "experts", and is more likely to include concurrent consideration of issues such as voluntary / non-voluntary exposure, familiarity, fairness, and the possibility of alternatives. Covello (1992) makes the important observation that in the public view, efforts to make a risk fairer, more voluntary, and controlling mechanisms more inclusive of the public, can be as important in determining an acceptable level of risk as are efforts to reduce the level of the risk. This illustrates the integral role of risk communication in risk analysis and it is clear from recent experiences on a world-wide basis that regulators must modify the public's desire /perception of "zero-risk" for raw meat, as well as any unrealistic expectations of the effectiveness of regulatory action. There is an obvious need for open and effective instruments of communication (both internal, and external to the regulatory agency), as well as a consistent and politically-effective regulatory policy.

EXAMPLES OF APPLICATION IN NEW ZEALAND

New Zealand is a major producer of lambs for the international market and the lamb meat production system is unique: average carcass weights and slaughter ages are considerably less than in other countries, large homogeneous groups of lambs are usually sent direct to the slaughterhouse, and the slaughter population has a very high health status. A major study to evaluate traditional post mortem inspection procedures for the viscera of lambs was carried out and this involved more than 963,000 comparative evaluations in 37 export slaughterhouses (Hathaway and McKenzie, 1991). Notwithstanding the international inconsistencies in ovine meat inspection codes, a significant number of traditional procedures were demonstrated to have no scientific basis when routinely applied to the viscera of lambs slaughtered in New Zealand. The failure of inspection of most lymph nodes to enhance any judgements based on routine (and usually

detailed) inspection of primary organs was a striking finding. Further risk analysis studies are being undertaken for the viscera of adult sheep, and the carcasses of lambs and adult sheep.

Other risk analyses have been undertaken for post mortem inspection procedures for: the lymph nodes, umbilicus and heart of very young slaughter calves; the masseter muscles and hearts of adult cows; and the lymph nodes of cattle and farmed deer with respect to reactors and non-reactors to the tuberculin test. In all cases, scientifically-unjustified post mortem inspection procedures and/or judgements have been identified (unpublished data). In conjunction with the risk analyses in sheep, extensive studies are being undertaken to determine the risk factors associated with different levels of inadvertent microbiological contamination incurred during slaughter and dressing. These latter studies will facilitate development of an integrated risk analysis model for all sources of microbiological contamination of raw meat.

INTERNATIONAL ACTIVITIES

Regulatory aspects of the international trade in raw meat will increasingly depend on harmonised approaches to risk analysis. An important aspect of the recent work of the Codex Alimentarius Commission (CAC) is the recognition that priority attention be given to risk analysis wherever it is appropriate to apply this discipline in the development of standards and guidelines for food safety (Hathaway, 1993b). With the intent that national measures be based on international standards and guidelines wherever possible, the GATT Uruguay Round draft Decision on Sanitary and Phytosanitary Measures (SPS) also relies heavily on the principles of risk analysis.

The Codex Committee on Meat Hygiene was recently reconvened to redraft the meat hygiene codes of practice, and the new codes were adopted at the 20th Session of the CAC in July, 1993. In a departure from the solely prescriptive approach usually taken by Codex food commodity committees, the new codes provide for flexibility in the development and application of each hygiene programme for raw meat, as long as meat hygiene goals are adequately met by the regulatory agency and industry. It is readily accepted that in the absence of detailed scientific research, regulators often have to implement meat hygiene requirements that are based on current knowledge and practice (Principle 2). However, an important principle developed in the Codes is that risk analysis based on accepted scientific methodology should be undertaken wherever possible so as to improve current knowledge (Principle 3) and to ensure scientifically-justified meat hygiene regulations (Principle 8).

A number of national and international organisations have published methodological guidelines for risk analysis of chemical hazards but no such guidelines are yet available for risk analysis of hazards that are grossly-detectable at post-mortem meat inspection. National initiatives in somecountries have led to changes in domestic programmes but the widely-recognised need to accept the equivalence of different national programmes where warranted, and harmonise international requirements for trade, currently suffers from the lack of recognised risk analysis models. It is noteworthy that the GATT SPS text effectively describes boundaries for risk management (e.g. must not discriminate and must be consistent with the chosen appropriate level of protection) but there is no development of actual risk analysis mechanisms.

CONCLUSION

Risk analysis should allow regulatory authorities to gain the knowledge necessary for the proportional allocation of all inspection resources according to their maximum ability to reduce meat-borne hazards, and justify the particular commercial requirements placed on industry with respect to meat hygiene. Even if adequate scientific data is unavailable in the short term, the methodological frameworks required for risk analysis will induce a systematic approach to meeting the current challenges arising from hazards of raw meat. With the alignment of national regulatory agendas, an additional benefit will be the establishment of internationally-harmonised standards and specifications that are consistent and science-based. The predominant position of routine post mortem inspection in meat inspection programmes dictates that risk analysis of abnormalities detectable at post mortem meat inspection be recognised as a priority.

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