Driving forces and risk management

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Bivalve shellfish are widely distributed and have been exploited as a source of food for thousands of years, archaeologists regularly finding shellfish middens near ancient human habitation. This role as a food source has also led to human illness caused by infectious agents transmitted from human or animal sources through shellfish consumption (see chapter 3). Such illness can occur in populations dependent on shellfish as a subsistence protein source, or in populations far from the point of origin consuming this product as a result of intra-regional or international trade. Whilst most recognized illnesses transmitted this way are seen as nuisances, they can be deadly, especially to humans with previously compromised immune systems.

Shellfish are filter-feeders and as a result they can concentrate pathogenic microorganisms from the environment, even from waters that meet regulatory standards. Outbreaks of diseases in humans due to contaminated shellfish have been reported in both developed and developing countries. The microbial agents associated with shellfish-related illnesses can be of bacterial, viral, or protozoan
origin. Such a diversity of microbial agents represents a considerable challenge from a monitoring standpoint and for scientists trying to develop comprehensive exposure prediction models. Whilst illnesses associated with eating contaminated shellfish are well recognized (including gastroenteritis, hepatitis and toxin-related poisoning), in most cases the actual etiological agents are unknown. However, it is assumed that viruses are responsible for the majority of cases of unknown etiology. Viruses have also been responsible for sizeable outbreaks. Indeed, the largest outbreak reported so far is the epidemic of hepatitis A (HAV) in China in 1988 in which 288,000 people were affected after eating raw or improperly cooked clams (Butt et al. 2004a, 2004b).

Outbreaks of gastroenteritis due to bacterial pathogens can also be significant, although in many cases these cannot be attributed to faecal pollution. For example, outbreaks associated with shellfish contaminated with Vibrio parahaemolyticus have been reported from Japan, USA and other countries. In Japan, between 1996 and 1998, there were 1710 incidents and 24,373 cases of V. parahaemolyticus (FAO/WHO MRA 02/02) and reported food poisoning cases due to this organism outnumbered those due to Salmonella spp. Between 1997 and 1998, more than 700 cases of illness due to V. parahaemolyticus, the majority of those related to raw oyster consumption, were reported from the USA. Emergence of cases due to the pandemic serotype of V. parahaemolyticus O3:K6 in the United States has led to greater attention on the pathogenic microorganisms that may be transmitted to humans through shellfish.

Monitoring of shellfish flesh or shellfish waters for the presence of pathogens and indicator organisms are two of the strategies available for public health protection (see chapter 6). Each of these strategies can be challenging. In chapter 13, Busby explains how the 2004 amendments to the regulations in New Zealand suggest monitoring both growing waters and shellfish flesh.

4.1 SCOPE OF THE MONOGRAPH

From a public health perspective, food safety is the overall goal and there are two distinct areas where interventions to this end can take place, either pre- or post-harvest. Pre-harvest, water quality management is the focus whereas post-harvest quality management depends on the nature of the particular processes undertaken. This monograph focuses exclusively on water quality management and pre-harvest processes. In effect, post-harvest processes are the remit of food safety and post-infection issues belong in the realm of health care and treatment.

Further, in the context of water quality management, the primary risk factors are pathogens (human, animal, naturally occurring), toxic algae and chemical contaminants. This volume concentrates on infectious disease risks posed by
microbial contaminants rather than toxins. It is acknowledged that management of environmental bacterial pathogens (of non-faecal origin like *Vibrio* spp.) as well as algal toxins is extremely difficult as their levels are impacted by environmental factors as well as nutrient fluxes. There is undoubtedly more scope for management interventions in the case of human and/or animal derived pathogens which form the focus of the monograph.

Before considering the package of interventions available, three key questions need to be answered: Which contaminants? Which shellfish? Which parts of the transmission sequence? The answer to the first question has been discussed in the preceding paragraphs – bacterial and viral contaminants. The answer to the second question is similarly succinct, the shellfish of interest are filter-feeding bivalve shellfish predisposed to transmit bacterial and viral pathogens. The answer to the third question is more complex as there are many stages where interventions could occur. For the purposes of this monograph, the focus on the transmission sequence is from land- or water-based contamination of water (fresh or sea) to harvest of contaminated product (including harvest for subsistence, recreational, non-market or local sale, or commercial harvest).

### 4.2 MANAGEMENT OPTIONS AND INTERVENTIONS

#### 4.2.1 Sources of potential sewage contamination

As is generally the case, point sources of contamination are readily identifiable and include treated water effluent; stormwater runoff; combined sewer overflow (CSO); livestock slaughterhouse and processing effluent; overflow from manure lagoons. Coastal regions are often highly populated and commonly have further seasonal influxes. Wastewater treatment becomes an issue, particularly in times of any seasonal population highs. The presence, quantity, survival and infectivity of human pathogens in the wastewater and agricultural run-off that may pollute shellfish waters is of key importance.

As noted in chapter 1, non-point sources are more difficult to both identify and quantify because of their diffuse delivery mechanisms and because they include contaminated freshwater inflow or coastwise movement of contaminated waters; runoff from pasture or cropland; untreated sewage; seepage from septic tanks; seepage from landfills; and release from contaminated sediment that may be disturbed in a variety of ways. In addition, intermittent sources of faecal material include recreational or fishing boat waste; large ship bilge dumping; seasonal tourist concentration; livestock or wildlife migration.

The key goal is to focus on identifying contaminant sources and means of transmission to shellfish and then selecting options to interrupt the cycles.
In some cases, identification of primary sources can be performed using sanitary surveys. Understanding of landscape and land use is also critical. In other cases, more sophisticated microbial source tracking methods are needed to more accurately determine the relative importance of different faecal pollution sources (USEPA, 2005 and fully discussed in chapter 5).

4.2.2 Current management responses

One of the most widely used management approaches is the regular microbiological monitoring of shellfish harvesting areas/shellfish tissues and classifying the areas. Shellfish harvested from areas with <14 faecal coliforms (geometric mean) per 100 ml water are designated by United States Food and Drug Administration (USFDA) as “approved”, while in the European Union (EU), samples of shellfish with <230 E. coli or <300 faecal coliforms per 100 g of flesh are classified as category A. Shellfish from these areas can be used for human consumption without further processing. Shellfish harvested from areas with higher faecal coliform or E. coli counts are to be used only after depuration, relaying or heat processing (see chapter 9). In both the EU and the USA, commercial depuration is subject to legal control and purified shellfish are required to comply with end product standard for shellfish sold live. However, human volunteer studies in Australia (Grohmann et al. 1981) and natural outbreak studies in United Kingdom and USA (Lees 2000) suggest that depuration may fail to eliminate enteric viruses from contaminated shellfish and that compliance with E. coli or faecal coliform standard does not guarantee absence of viruses. This is further confirmed by a number of studies that show that viruses are eliminated at a much slower rate compared to faecal coliforms (Schwab et al. 1998).

In the case of bacterial pathogens like V. parahaemolyticus the pathogens are generally present at low levels (<10^2/g) and the infective dose is >10^5 (Sanyal and Sen 1974). Therefore, one of the management options to prevent human illness is to prevent bacterial growth in oysters by rapid chilling of the oysters immediately after harvest.

Cooking shellfish is another alternative for public health protection. Millard et al. (1987) demonstrated that the HAV virus could be inactivated by more than 4 log_{10} infectious units by raising the internal temperature of shellfish (cockle) meats to 85–90°C for one minute. However, data for other viruses, including norovirus is lacking. Since norovirus is believed to be responsible for the most common gastrointestinal illness associated with shellfish consumption, heat inactivation data for this virus would be useful. The major problem in getting this data is that noroviruses cannot be cultivated. Studies of Slomka and
Appleton (1998) indicate that feline calicivirus is inactivated more readily than hepatitis virus. Though adequate cooking will reduce the risk of human infection with viruses, a study in the USA of a multi-state outbreak of norovirus gastroenteritis associated with oysters, suggested that home or restaurant cooking offered little or no protection (McDonnell et al. 1997).

4.2.3 Source protection

Management practices that remediate the source of contaminated water are of great value to the ultimate goal of preventing shellfish contamination. Such measures include locating sources of contamination away from water bodies. Waste material can then be collected and treated prior to entry into fresh or coastal waters. Wherever possible, dedicated efforts should be made to treat all sewage discharged to water bodies, to redesign sewage transport systems to eliminate CSOs and to redesign or re-site manure lagoons to prevent catastrophic overflows. In addition, development of new contaminating sources should be discouraged at sites that could threaten the integrity of shellfish waters.

Natural buffers or filters (such as wetlands, mangroves, settling ponds, riparian or littoral filters) could be created/restored between contaminant sources and at-risk waters. Such a strategy should include controls over wastewater or bilge dumping from commercial and recreational vessels in the vicinity of shellfish waters.

It is essential that management efforts between watersheds and/or river basins and coastal zones are co-ordinated. This will require communication between local, state, and federal agencies and defining regulatory standards that can achieve both water and shellfishing goals. Additionally, management approaches will benefit from incorporating multidisciplinary perspectives (such as hydrology, ecology and microbiology). This philosophy should extend to nation states with adjacent waters.

4.2.4 Source management

Once the raw water has been contaminated, management options may switch to managing the water, increasing the focus on and speed of decay of potential pathogens. Methods to achieve this could include enhancing dilution by increasing mixing; promoting adsorption to sediment; introducing bacteriophages after known contamination events; introducing non-contaminating flocculants; and installation of artificial shellfish beds/towers prohibited from harvest to clean the water. In reality, such interventions are largely speculative and untried and have varying likelihood of success in a real-world situation.
4.2.5 Shellfish management

As the end-point of the primary production process, the shellfish themselves provide the most accessible and effective management options. First amongst those options is defining no-take zones, by creating a general coastal survey or zone map to identify areas not likely to be suitable for shellfish harvest (such as areas not naturally supporting shellfish; areas with insufficient nutrient and water flow; and waters close to densely populated areas, ports or coastal industries). Second in the hierarchy of responses is to conduct an in-depth sanitary survey of current and likely future harvest sites, ensuring that such areas are sited away from known contaminant sources. This could lead to opening and closing of areas based on monitoring and management of contributing factors (particularly rainfall) highlighted in the sanitary survey (see chapter 8).

Once sites have been identified for future exploitation or historically exist, the application of monitoring tools is a logical next step. Thus, where possible, waters should be monitored for multiple contaminants in conjunction with shellfish flesh monitoring for those actual contaminants detected by water quality monitoring. This would inform harvest, relaying or depuration activities until the shellfish flesh no longer shows contaminant or any such contamination is at some acceptable level.

The final and most effective option is to control consumption, although for casual collections that is virtually impossible.

4.3 RISK MANAGEMENT

4.3.1 Risk management components

Monitoring and surveillance activities are fundamental to understanding the human health risks associated with contaminated shellfish. An additional tool available to risk managers is quantitative risk analysis (QRA) which is applied in a four step process as described by McBride (2004), namely hazard assessment, exposure assessment, dose–response analysis and risk characterization. The concentration of pathogens (hazard assessment) and the nature and degree of exposure (exposure assessment) varies according to the individual, location and situation. A risk profile can be calculated based on the distribution of these variables. QRA relies on information from other studies, including monitoring and surveillance and scientific literature. The risk characterization can be used to modify and refine management efforts, thereby leading to more effective public health practice. Details of the methodology can be found in several texts, including Haas et al. (1999), Haas and Eisenberg (2001).
As indicated earlier, the manager’s armoury is considerably enhanced by site selection tools, including sanitary survey, modelling and monitoring in an attempt to reduce risk at source. Identification of key parameters in site selection processes that could improve safety considerations is an important function.

4.3.2 Monitoring milieu

One of the current imponderables in the shellfish safety debate is whether it is better to monitor shellfish flesh or water column quality. Added to that is the lack of confidence in currently accepted indicators to adequately reflect risk to human health whether derived from shellfish flesh or the water column. The challenge to scientists is to understand the impacts of water quality on the quality of shellfish flesh. As a minimum this would entail calibration of indicator levels between the two systems. The resolution of these issues would considerably enhance the confidence of risk managers in the depuration and relaying processes.

In terms of the risk management process, having access to real-time data on water quality and/or shellfish quality to inform decision making in a timely fashion would be a huge advance. Source tracking becomes increasingly important – attributing pathogens to human or animal sources, particularly in a timely fashion, will provide enhanced quality of information on the likely hazard posed by a specific type of contamination (see chapter 5).

As an example, multiple strains of norovirus have been implicated in foodborne outbreaks, and agricultural inputs can contribute significantly to norovirus levels. This is an upcoming area for discussion in the context of shellfish and water. We are only just beginning to understand human and animal viruses after huge investment in time and resources and we are relatively unaware of many animal viruses. As an illustration, there are many animal noroviruses recognised but these have been little studied to date. We should not make assumptions – animal sources may be important reservoirs of new pathogenic variants that could be transmissible through shellfish consumption. The issue of animal–human transfers also should be scoped in this context.

4.3.3 The commercial imperative

Very little focus appears to be on the responsibility for the additional cost burden associated with an enhanced set of safety mechanisms around shellfish consumption. It can be safely assumed that the primary responsibility for additional costs will lie with the producers in the first instance. Inevitably these costs will subsequently assimilated by consumers. It is not realistic to assume
that additional costs will be a positive driver for a safer shellfish harvest management process – rather the reverse.

This cost factor leads into the response of the food industry to any changes that may be prefaced in this monograph. Undoubtedly a key driver is that of trade in bivalves as a food commodity (as discussed by Pawiro in chapter 2) – a driver that often appears to compete with health protection. Risk managers have a responsibility to focus on the health protection issues rather than the trade dimension. Casual gathering is an extremely difficult area to control and one that certainly complicates public health controls. The tensions between commercial exploitation and casual exploitation need to be explored and the inherent difficulties in controlling casual collecting must be recognised. If necessary, a range of models need to be constructed to accommodate all options – one size does not fit all.

4.3.4 The challenge

It is important to establish a framework to work within when analysing a complex issue such as this – fundamental controls must be delineated and the surrounding framework established from there. This will, in turn, allow scientists to attempt to resolve the key questions: Are current risk management strategies effective? Are they so ineffective that there is need for a paradigm shift or could they be made more effective by incremental modifications? These are matters that we will return to in chapter 17 following their exploration within the subsequent sections.

4.4 OPTIONS FOR THE FUTURE

At the end of this monograph we expect to be able to understand more fully whether there is an underlying requirement for a new management and regulatory framework for the safe management of shellfish and harvest waters. This brief chapter has outlined the driving forces behind the current need for a regulatory framework, but has also hinted at shortcomings in existing frameworks. It should be noted that both socio-political, as well as economical factors, will play important roles. In all considerations, however, public health should be regarded as the principal goal.

4.4.1 Primary conflicts

It is generally accepted that there is a need to classify growing sites, but little agreement on what methods to employ: either by water column classification (easier, cheaper, but implies a clear understanding of the relationship between
contaminants in water and shellfish quality which is often lacking); or by shellfish flesh contamination (more expensive, destroys product, but measures actual risk, and is often required by importing countries). Adding to this is the use of different standards by different countries which can impact on international trading.

It is impossible to test harvest waters or shellfish flesh for all possible contaminants and so indicators are sought. However, authorities generally agree that faecal coliforms and \textit{E. coli} are not effective indicators because their presence does not correlate with pathogen presence in flesh and their presence does not correlate well with viral pathogens in either the water environment or the shellfish flesh.

### 4.4.2 Requirements of control mechanisms

The exploitation of shellfish as a food source by man requires societal controls to limit infectious diseases caused by pathogens to which shellfish are exposed. The usual note of caution should be applied when considering casual gathering and their limited response to regulatory and control mechanisms.

The minimum requirement regarding the appropriate combination of management options is that they establish a system to identify and manage sources of contamination. That system must be accompanied by the development of regimes to monitor contaminants in water prior to harvest and in shellfish flesh prior to consumption. Evaluation of implemented management practices could be introduced to assess pollution control effectiveness and to further confirm the identification of the primary faecal pollution source(s).

Once shellfish have been contaminated, there must be access to clearly described protocols to purify them, undoubtedly based on existing relaying and depuration processes. In terms of surveillance, it is also essential to have well established methods available so that the regulator can track shellfish from outbreak back to harvest site.

None of these processes are easy and will require a concerted campaign to raise awareness amongst producers/harvesters and consumers. That will in turn more readily enable controls on shellfish harvest to be more easily enforceable if any measures are built on a sound evidence-base. Additionally, in an ideal world there would also be movement towards harmonised systems to ease or support international trade.

### 4.4.3 Requirements of science

To ensure that the regulatory and control bodies have good science upon which to base legislation poses significant challenges to the scientific community.
To accomplish that, science needs to provide means to resolve fundamental issues. Thus we must be able to track contaminants back through system to source, which implies accurate techniques to detect and measure contaminants in water and/or flesh. These detection techniques will be particularly valuable if they are developed with a view to providing data in “real time”. Emerging developments in microarray, nanotechnologies and bioinformatics will provide the opportunity to simultaneously determine the presence of indicators, pathogens, and source identifiers, increasing the accuracy of risk assessment models and hence usefulness of environmental monitoring (Santo Domingo et al. 2007). Until then, the imponderable of identifying suitable proxies for contaminants, indicators, must be resolved if the contaminant of concern cannot itself be readily identified or measured.

Regulators must be armed with the tools to identify events or conditions that could change waste/contaminant system interactions with the receiving waters and so could affect open/closed harvest practices. The obvious example here is the effect of rainfall: Can we make valid predictions on the likely effect that known amounts of rainfall within a catchment may have on contaminant levels in shellfish beds? In this context, science is challenged to develop models to predict system response to a contamination event and thus, for example, to proactively close harvest areas.

Obviously these technologies, as they are developed, will be equally applicable to the evaluation of methods of shellfish contamination mitigation, i.e. relay and depuration.

4.5 CONCLUSIONS

It has been clearly established that the harvest of shellfish for human consumption is accompanied by significant risk to human health from, amongst other things, pathogenic microorganisms associated with faecal waste. What is obvious is that health impacts and monitoring of these impacts is relatively underdeveloped. Different countries or regional alliances look to different regulatory tools to cope with the risks, such as the EU Water Framework Directive and the US Clean Water Act and the concept of riparian retirement as applied in New Zealand. Earlier chapters in the monograph (see chapter 2) discussed the increase of world trade in bivalve shellfish. That in turn demands more and better collaborations nationally and internationally, which will consequentialy ease trade negotiations.

Challenges exist for regulators and scientists, not least to determine the relative threat posed by different organisms, thereby enabling priorities to be set and defining a hierarchy of the really important organisms to govern responses.
This can, in turn, inform the wider public health picture – possibly linking water based recreation issues with those of shellfish and shellfish harvest waters. It may be that, for example, we can learn valuable lessons for shellfish water management from recreational water management as discussed by Kay et al. in chapter 15. What is obvious is that a consensus exists for change to better reflect the actual risks and thus to protect the consumer.

Subsequent chapters in the monograph will address the issues that have been raised in this brief chapter. This will lead to a rounded appraisal and, if appropriate, a framework for change, based on a well reasoned approach will be recommended in the final chapter.

4.6 REFERENCES


