This book, which has been authored by a range of international stakeholders, describes the science and associated societal issues which are driving both concerns and improvement in the management of shellfish harvesting waters world-wide. In this concluding contribution it is not the intention simply to summarize the discussion of preceding chapters. Rather, our remit is to identify:

- the principal causes of concern;
- the sources from which they derive;
- the shellfish species associated with potential disease transmission;
- the transmission pathways and their mitigation potential;
- the key elements of the ‘best management practice’ in shellfish monitoring programmes; and
- the extent to which the developing regulatory approaches reflecting this understanding could result in risk management and control.
Thus, we seek first to delineate the context for change in the management of shellfish harvesting waters and outline the potentially fruitful directions for future management and research.

It is worth noting that the health risks resulting from shellfish consumption have three drivers. The first is from pathogen contamination of harvesting waters. The second is from toxins derived from algal blooms driven by coastal nutrient enrichment. Both of these elements are caused by anthropogenic inputs to harvesting waters. The third driver is the presence of autochthonous pathogens, particularly *Vibrio* spp., which are a risk in warmer sea waters. There is an historical bias to research and investigations focused on the first driver and, to a large extent, this is reflected in this book. Each of the drivers is covered by, for example, Graczyk *et al.* in chapter 3 of this book, but the management approaches suggested by regulators and governments to date reflect the historical exploitation of temperate northern harvesting areas, where the first driver is the principal concern, and the evidence-base for remediation strategies targeted to the second and third drivers are much less well developed.

### 17.1 THE MANAGEMENT CHALLENGE

The shellfishery component of fisheries resource utilization comprises less than 10% of the seafood industry (by weight) world-wide and production is dominated by China which produces 68% of world-wide output value. As noted in chapter 1, some 84% of global bivalve production derived is from aquaculture. Thus, many of the environmental waters in which shellfish are grown are commonly in close proximity to anthropogenic pollution sources which will, at times, contain pathogens and nutrients derived from societal fluxes of human sewage and/or livestock waste. The ‘outcomes’ could be described as ‘alarming’ with over 85% of Norwalk-like virus (NLV) outbreaks, and all foodborne outbreaks of *Vibrio* spp. and *Plesiomonas shigelloides* in New York, USA between 1980 and 1994, associated with seafood consumption (see chapter 3; Wallace *et al.* 1999). In addition Graczyk *et al.* (chapter 3) note risks from ‘naturally occurring’ microbial pathogens in warmer nearshore waters such as *Vibrio* spp. which produce gastroenteritis which is much more severe than faecal–oral diarrhetic diseases of generally viral etiology. *V. vulnificus* can also cause infections resulting in fulminant primary septicemia (often with necrotizing cutaneous lesions) with a high mortality rate. Autochthonous algae also produce toxins when they break down, generally following periods of algal blooms caused by the interaction of anthropogenic nutrient enrichment and natural seasonal patterns of light and temperature changes in coastal waters.
Perhaps of most significance, however, is the fact that shellfish are commonly eaten uncooked particularly where they are sold as a premium product and marketed to stress their ‘pristine’ environmental source. Added to this is the now extensive, trans-continental shipping of shellfish providing the potential for effective pathogen transfer from areas of high disease endemicity to consumers with potentially low immunocompetence for potentially exotic pathogens.

Thus, there remains the ongoing potential for shellfish consumption both to complete the chain of faecal–oral infection where growing areas are impacted by wastewater and to provide the vector for endemic pathogens in warmer waters. This chain has, in most other food sectors, and in the potable water cycle, been specifically broken through hygiene interventions (for example pasteurisation of milk and chlorination of drinking water). These elements of the shellfish product and its environment conspire to produce a significant and continued health risk to the consuming population which is increasingly seen to have a global dimension. The potential management interventions charted in chapter 1 of this book, do no more than seek to prevent completion of the faecal–oral chain of infection and/or identify appropriate risk indicators for algal and autochthonous pathogen risks, thus, to limit illness in the consumer population.

The central management challenge and many of the approaches available for achieving safe shellfish for human consumption have remained unchanged since the pre-historical beginnings of this resource utilization. However, the scientific and regulatory toolbox available to prevent disease transmission is growing apace with very significant developments coming from a diverse community of stakeholders.

17.2 NEW TOOLS AND APPROACHES

Perhaps the most significant element in the regulatory toolbox is the growing conceptual understanding of the complex interacting systems which produce the apparently random and chaotic changes in microbial and toxin levels in shellfish harvesting waters. This understanding principally derives from recent ‘drainage-basin’ paradigms adopted by environmental regulators first in North America with the Clean Water Act and subsequently in Europe with the Water Framework Directive (Anon 2000). These instruments replaced historical approaches based on equal regulation of individual discharges throughout a catchment. This produced equal treatment for dischargers but resulted in environmental and resource impairment where multiple ‘consented’ discharges could easily overwhelm the assimilative capacity of specific river reaches or receiving water bodies. The new paradigm focuses on the ecological and resource use requirements of the receiving water and all upstream discharges.
are managed in an integrated manner to prevent resource ‘impairment’ at the point of use.

Implementation of this developing regulatory model implies knowledge of:

i. the contribution of the various pollutant sources, in the case of shellfish harvesting water, principally quantitative microbial source apportionment;

ii. the spatial pattern of multiple inputs from within the contributing catchment where point and diffuse elements of particularly microbial pollutants may derive from animal and human sources, in addition to endemic pathogens;

iii. the fate and transport of pollutants as they pass through the complex set of hydrological, pedological and geological/sedimentary compartments within the catchment and nearshore systems; and finally,

iv. the processes driving the transport mechanisms operative within and between these complex interacting compartments which produce the highly episodic and seasonal variability in microbial and nutrient concentrations impacting on shellfish harvesting areas.

Detailed deterministic process understanding of these complex interacting systems is not, at present, available for catchment and nearshore microbial dynamics. However, the introduction of the new holistic regulatory approach has sparked a series of scientific initiatives which taken together are advancing knowledge in this area rapidly.

Initial responses designed to accommodate these holistic catchment concepts within a series of practical steps which could be taken on the ground by shellfish regulators can be seen in the design of a ‘sanitary survey’ as explained for New Zealand waters by Busby (chapter 13) and for Australian waters in Anon (2004). These represent the first regulatory attempts to recognize the complexity implied in bullets i to iv above whilst designing clearly defined stages in problem scoping through an initial sanitary survey and progress monitoring through annual reviews. Importantly, the extreme variability in faecal indicator concentrations and the periods of maximum risk are explicitly recognized in the sampling protocol for regulatory monitoring which requires microbial data acquisition to be undertaken during periods of adverse weather conditions.

Thus, for example, the New Zealand regulations are specifically designed to accommodate the spatial and temporal complexity through sanitary survey and temporally targeted sampling. This provides an innovative and intelligent, but practical, means of regulating the complexity implied in i to iv which is also reflected in United States regulations (chapter 7).
Further improvement to risk control beyond this immediate regulatory approach would require better process understanding of the complex catchment and coastal compartments outlined in i to iv. It is perhaps in this area where the impacts of the new regulatory paradigm will prove most significant in years to come.

Already new approaches have been developed to distinguish between animal and human microbial pollution using a suite of methods which have become known as microbial source tracking (MST). Santo Domingo and Edge (chapter 5) outline the application of these approaches to shellfish harvesting waters and chart a path to deciding which of the many approaches is most appropriate for specific situations. Delineation of animal and human sources impacting on specific growing areas is important because of the prominence of human-specific pathogenic viruses in historical shellfish-associated disease outbreaks (chapter 3), although zoonotic pathogens cannot be ignored (Macrae et al. 2005; Gourmelon et al. 2006; Levesque et al. 2006; Downey and Graczyk 2007; Graczyk et al. 2007; Leoni et al. 2007; Schets et al. 2007). There are major research efforts world-wide producing rapid advances in MST which is being used to inform regulatory decisions and practice often using MST approaches developed by the regulators themselves (Gawler et al. 2007). It should be noted that MST approaches currently afford only ‘qualitative’ information on likely contributing species (commonly either ruminant and/or human) and cannot provide precise quantification of the different contributing animal species to microbial loadings above a specific harvesting area (Stapleton et al. 2007). However, considerable potential exists for further development in this area which, if it could provide quantitative source apportionment, would prove extremely valuable in informing a sanitary profiling exercise.

Process and black box modelling of microbial concentrations in catchment and nearshore systems is the second area of significant investigation which has received impetus from the new regulatory paradigm. Catchment microbial modelling is a new and emerging discipline with some operationally useful black box models (Kay et al. 2005) which lack the process components to inform management decisions on appropriate control strategies and growing efforts to develop process-based, deterministic catchment models (Jamieson et al. 2003; Jamieson et al. 2004a; Jamieson et al. 2004b; Jamieson et al. 2005a; Jamieson et al. 2005b; Ferguson 2005; Ferguson et al. 2003a; Ferguson et al. 2003b; Oliver et al. 2005a; Oliver et al. 2005b; Oliver et al. 2006; Oliver et al. 2007). As this research area develops, operational microbial deterministic models will become available to the regulatory community and will provide predictive capacity for the implementation of both sanitary surveys and mitigation measures which are identified for priority action to achieve regulatory compliance (Kanso et al. 2005; Kay et al. 2007; Qian and Reckhow 2007).
Nearshore hydrodynamic and water quality modelling of microbial concentrations is certainly a more mature science with well established methods and approaches (chapter 16). Parallel statistical modelling developed in response to the WHO Guidelines for Safe Recreational Water Environments (WHO 2003) is also discussed and under development in several countries (Crowther et al. 2001; USGS 2003, 2006, 2006). Perhaps the largest significant weakness in both nearshore modelling approaches is the lack of good calibration data which characterises the dynamic and highly episodic patterns of microbial concentration experienced in nearshore waters. It is also apparent that, often, the model developers with high level skills in mathematics, hydraulics and environmental physics do not fully appreciate the nature of microbiological data and specifically the inherent imprecision in microbial enumerations which are used to provide the often sparse calibration data for complex numerical modelling exercises. Without such an appreciation, which can only derive from inter-disciplinary working, spurious precision in predicted values is too easily assumed which can lead to ill-informed and inappropriate expenditures and/or choice of harvesting areas. In part, this may derive from the different disciplinary perspectives of the hydrological modelling and microbiological communities, the former concerned with accurate hydrological flux prediction and the latter with characterisation of peak risk episodes. Thus the definition and estimation of imprecision needs integrated attention of these two communities. It is interesting to note that Gourmelon et al. (chapter 16) explain the use of telemetric real-time data acquisition for warning trigger activation rather than assuming the predictive reliability of deterministic modelling in this area.

As the combined catchment and coastal modelling agendas converge and the modelling tools become more precise and truly 'predictive', they will provide reliable predictive tools able to inform and drive the future management, regulation and remediation of impaired harvesting areas.

17.3 THE DEVELOPING AGENDA

Regulation and management of shellfish harvesting waters is at a challenging and very fluid stage because there is a growing understanding of the processes driving the physical systems operative within linked catchment and nearshore environments. These produce short periods of high risk to microbial shellfish flesh ‘compliance’, and associated health risk caused by elevated microbial concentrations caused by episodic transport processes driving concurrent fluxes from the sewerage system (Kay et al. 2008) and/or agricultural diffuse sources (Wilkinson et al. 2006; Kay et al. 2008). Traditional regulatory systems involving monitoring regimes with regular sampling intervals (or even pseudo-random
sampling within a period, such as a month) are unlikely to characterize the brief periods of peak risk to the consumer. Indeed, monitoring at regular time intervals is systematically biased not to characterize episodic peak risk periods. The New Zealand approach, involving targeted monitoring during peak risk periods, can be seen as an initial recognition of this variability and it seeks to ensure public health protection through the adjustment of sample collection. However, this implies resource availability for pro-active, opportunistic sampling and analysis by the regulatory community and/or reliable predictive modelling to underpin regulatory use of surrogates such as rainfall.

The nature of microbiological data capture will always introduce an information lag between sample acquisition and management information being available to the regulatory and public health communities. Real-time measurement of surrogate variables, such as salinity and turbidity, linked to parallel telemetric data transmission is one approach available (chapter 16) to provide near-real-time management information on episodic risk. However, this does not involve actual microbiological information. Acquisition of this type of microbiological data has formed a central component of the US EPA’s research agenda for both bathing waters (Wade et al. 2003; Haugland et al. 2005; Wade et al. 2006) and shellfish harvesting areas (chapter 3). In this work, a considerable effort has been devoted to the development of rapid methods (generally quantitative polymerase chain reaction-based) of faecal indicator enumeration, rather than direct virus and other pathogen quantification which has proven problematical in both water and flesh matrices (Croci et al. 2007; Schultz et al. 2007). However, there are likely to be significant developments in near-real-time direct pathogen enumeration as well as enhanced indicator quantification in the next few years (Brands et al. 2005; Rizvi et al. 2006; David et al. 2007; Gabrieli et al. 2007; Maekawa et al. 2007; Phan et al. 2007; Saitoh et al. 2007; Schultz et al. 2007) which will shorten the current lag in the availability of management information from a few days to a few hours.

Acquisition of any ‘spot’ determination from a sample of the environment will always be a snapshot in time and very many such ‘snapshots’ are required to characterize the highly dynamic microbial risk pattern evident in shellfish harvesting waters. It is here that accurate predictive microbial modelling can make its major contribution. The potential exists to predict the level and duration of the key peak risk episodes which has two principal advantages for the regulatory community. First, it can guide sampling programmes to the most appropriate periods of data acquisition and suggest appropriate periods when harvesting would be inappropriate for defined treatment interventions (chapter 9). Second, truly deterministic and process-based modelling tools can guide remediation strategies through the understanding afforded of the range of
interventions covering point source disinfection, through agricultural best management practices (BMP) at the field scale (chapter 15). Realistically, the availability of such tested tools are further into the future but the experience of other related modelling communities addressing, for example, catchment derived nutrient fluxes, offers considerable encouragement to the shellfish regulator.

17.4 CONCLUSIONS – CURRENT STATE OF PLAY AND WAY FORWARD

Whilst speculation on potential developments is interesting and important, we suggested a series of questions above which this chapter now addresses. The most intensively researched and managed driver as defined above remains the enteric pathogens which are concentrated in shellfish flesh and cause significant illness outbreaks world-wide. They derive mainly from human sewage disposal, although zoonotic pathogens from agricultural activity and autochthonous ‘natural’ pathogens cannot be discounted. Filter-feeding bivalve molluscs are the principal species of concern particularly where they are lightly cooked or consumed raw. The transmission pathways involve complex catchment to coastal systems and mitigation involves an integrated spectrum of practices covering both point source control of treated effluent discharges and agricultural BMPs to attenuate flows from diffuse agricultural sources.

Best practice in current monitoring programmes is increasingly seeking to target peak risk episodes and intelligently adjust sampling regimes to acquire data during such periods. However, there will always be compromises where sampling resource is limited and the regulator must seek to characterize pathogen risk from a relatively small number of samples in which faecal indicators are commonly enumerated. The emerging tools of:

- rapid methods for near-real-time indicator and pathogen enumeration;
- real-time monitoring of surrogate parameters and telemetric data transmission; and
- predictive modelling using both statistical (black box) and deterministic (white box) approaches offer potential for:
  1. more appropriately targeted regulatory sampling;
  2. continuous risk assessment particularly in periods where physical samples have not been collected; and
  3. predicting the impacts of different remediation and BMP scenarios implemented at the catchment scale.
Thus, there is considerable immediate potential for better regulation and improved public health with significant additional gains likely in this area as the developing tools become available to underpin a sustainable use of shellfish resources world-wide. It would therefore seem timely, fitting and logical to begin to realise that potential without delay to achieve those health gains in a consistent and collaborative way.

17.5 REFERENCES


