Chapters 11–13 of this monograph provided descriptions of the regulatory systems, responsible authorities and decision-making processes managing the bivalve shellfish industries in Scotland, Canada and New Zealand. These contributions gave us a valuable insight into how developed economies with significant shellfish industries approach their practical management responsibilities. In Chapter 10, Murray and Lee described how there are effectively two accepted approaches to bivalve shellfish regulation in use across the world – the United States approach via its National Shellfish Sanitation Programme (NSSP) and the European Union (EU) approach. Murray and Lee further pointed out that there are many countries that have no management schemes in place.

In the present chapter we will explore further the differences and similarities between the legislation in practice in Scotland, Canada and New Zealand, and then go on to look at the situation in a major multi-national coastal region which has nation states occupying a range of developmental scenarios (i.e. the Mediterranean) and in two of the world’s most rapidly developing economies.
This should provide the balance required in assessing what is desirable and what is achievable in management practice of bivalve shellfish industries, providing the reader with a more holistic view than merely restricting observations to systems in developed countries that have access to adequate resources.

14.1 APPROACHES TO SHELLFISH MANAGEMENT IN SCOTLAND, CANADA AND NEW ZEALAND – REPRISE

Management and regulatory procedures in the shellfish industries in Scotland, Canada and New Zealand were comprehensively dealt with in chapters 11, 12 and 13 respectively. These countries adhered closely to the previously described models (chapter 10) inasmuch as Scotland, as an EU member, faithfully applies the EU approach; Canada, with its close relationship to the United States, applies a variant of the United States NSSP approach and, most interestingly, New Zealand with its extensive shellfish export industry applies what is, in effect, a hybrid system, incorporating best practices from both the EU and the United States NSSP (chapter 13).

14.1.1 Responsible authority

In Scotland, the responsible authority for bivalve shellfish regulatory control is the Food Standards Agency Scotland (FSAS). Although the FSAS is a Government agency, it does not report to a specific minister and is free to publish any advice it issues in the form of guidance notes and advisory circulars. The FSAS delegates responsibility for some official controls to the Local Food Authority. Thus enforcement of the provisions is undertaken via a combination of central and local government, but the FSA retains overall accountability to the European Commission. In Canada, the Canadian Shellfish Sanitation Programme (CSSP) is jointly administered by three federal bodies. In New Zealand, the New Zealand Food Safety Authority (NZFSA) was established as a Public Service department on 1 July 2007 and reports directly to a government minister. Thus, these three countries have different reporting systems.

14.1.2 Shellfish production quantum

The pressures are different on the three countries discussed. In Scotland there are 186 classified shellfish harvesting production areas comprising 246 individual
harvesting sites. Six main species of bivalve mollusc are harvested, common mussels and Pacific Oysters dominating the aquaculture trade, clams and cockles the wild shellfisheries, a total of around 4000 tonnes with a value of around US$10M. In New Zealand there are 87 classified shellfish growing areas, most of these being aquaculture sites. Approximately 108 000 tonnes of bivalve molluscs are produced annually in New Zealand, 97 000 tonnes of which are Greenshell® mussels, *Perla canaliculus*, produced exclusively via aquaculture (2006 figures – total value US$200M). Around 80% of the bivalve molluscs produced in New Zealand are exported to more than 60 countries worldwide.

Canada has more than 1000 classified shellfish production areas with a combined coverage in excess of 21 000 km². In the year 2005, Canada produced US$146M worth of wild harvested bivalve molluscs, some 89 000 tonnes (predominantly scallops and clams). In that same year, the production and value of cultivated bivalve molluscs was around 38 600 tonnes (predominantly mussels and scallops) with an estimated value of approximately US$67M.

### 14.1.3 Categories of shellfish waters

In terms of classification outcomes, Scotland recognizes three categories of shellfish waters based on *E. coli* levels, namely: category A, where products can be put directly to market, category B and C where the product must go through either depuration, designated heat treatment or relaying prior to reaching the market place. These are standard EU categories. In New Zealand and Canada the United States approach prevails and defines: “remote approved”, “approved”, “conditionally approved”, “restricted” and “conditionally restricted” areas. The rationale behind the conditional and restricted categories is exactly the same in the three country systems – closures are applied on a restorable basis depending on factors that affect the shellfish and/or the shellfish water quality.

### 14.1.4 Sanitary surveys and annual review

As to be expected, Canada, Scotland and New Zealand all underpin their bivalve shellfish regulatory regimes with extensive sanitary surveys. Although the terminology applied may differ, all three systems utilize effectively the same methods and data sources. In addition, all undertake annual reviews of approved areas; for example the Canadians apply a rigorous, comprehensive survey based on 15 sampling runs performed at random dates over a calendar year. In addition, there are annual reviews of approved areas plus a complete re-evaluation of each approved site at least triennially. Scotland is in the throes of setting up sanitary survey reports for all existing and new fisheries which will
take the final form of a sampling plan for the area. Annual review also features highly in Scotland’s plans. In these, a minimum of nine samples is required, taken in separate months, between January and December to maintain an area classification. The NZFSA consider the risk assessment approach, which is a sanitary survey, to be a critical component in establishing the evidence base for shellfish safety. For potential new growing areas a minimum of 30 water and 30 shellfish flesh samples are required to be analysed from samples reflecting a variety of environmental conditions over a minimum 12-month period. They too produce an annual review of the sanitary survey and include the bacteriological data taken under adverse environmental conditions.

14.1.5 Monitoring programmes

The monitoring programme in Canada is immense – a 21,000 km area of harvest waters translate into more than 1500 sampling stations. That notwithstanding, it is also the case that the majority of Canadian waters are currently not monitored due to factors as variable as resource availability, distance and climate. As stated previously, the CSSP basically applies the United States Food and Drug Administration (US FDA) bacteriological parameters comprising faecal coliforms in shellfish waters but not in the shellfish flesh. In Scotland, the EU legislation is strictly adhered to requiring determination of E. coli levels in shellfish flesh. In New Zealand, the drive to minimize closures to ensure security of supply to 64 export partners lead in 2004 to an overhaul in its procedures to ensure consistency in dealing with so many partners. Since the 1970s, New Zealand had based its regulatory approach on US FDA protocols which are still evident in the current system, but this has now included some EU practice modified by the particular New Zealand perspective. Thus, in effect both the US FDA shellfish waters and the EU shellfish flesh protocols apply. Analytical methods were varied slightly to reflect those favoured in Europe. The most difficult questions were what level of E. coli to apply to the shellfish flesh and should levels in the flesh apply to the classification as well as the NSSP water quality levels or in support of them? It was decided that E. coli levels in shellfish should be used for classification purposes and that the same median and percentile approach as used for water quality should be used for shellfish quality – a sort of belt and braces approach.

14.1.6 Other aspects – communication, mitigation and liaison with stakeholders

Examination of chapters 11, 12 and 13 clearly indicate that, for virtually all aspects of the regulatory regime, each country takes appropriate steps to
engage with the relevant stakeholders. For example, public shellfish harvest areas are subject to public notices and press campaigns if any harvesting restrictions apply. Although far from foolproof, this approach demonstrates a clear intent to alert casual collectors to the existence of real hazard conditions. In the same way there are well-documented consultation processes, clear liaison with industry, local, regional and international collaborations. Where triggers are exceeded, clear actions that are to be taken are identified in all countries.

Not all the actions are identical, not all the processes follow the identical set of pathways, nor would they be expected to with different approaches to the central pillar of monitoring between the countries. Adopting a consistent approach to monitoring would help smooth out problems oscillating around complementarities of data, but that is for discussion in chapter 17.

14.2 A SURVEY OF CURRENTLY ACHIEVED MANAGEMENT PRACTICE IN SELECTED LOCATIONS

The approaches towards microbiological monitoring of shellfish for the presence of pathogens/indicators vary in different countries, largely determined by capacity. Resource rich developed regions and countries such as the EU and the United States have systems where either shellfish or harvesting waters are monitored. In these cases the EU or US FDA methodologies are the two accepted predominant management approaches (Lees 2000). In other countries, depending on resources, capacity and other factors, a spectrum of management responses exist. The subsequent sections will go on to examine some of those responses to provide a more complete perspective on achievable management strategies for bivalve fisheries around the world. The examples will outline a well articulated but poorly implemented system in an expanding economy (China), a regional perspective from the Mediterranean and the situation in a country with a well-developed science and research base that apparently lacks a clearly defined system (India).

14.2.1 Controls on cultivated bivalves in China

China produces about 11 million tonnes of bivalves annually through commercial aquaculture programmes (China Fishery Statistical Yearbook 2006), which is about 70% of total world production, and 95% of these products are consumed domestically.
China has made great efforts in the past decades, developing a series of regulations and national standards to control the safety of aquatic products. However, the lack of systematic management and effective control procedures over the entire process of bivalve production is a major problem for Chinese administrators and producers. For example, there is a lack of consistent monitoring programmes for chemical residues and other pollutants in bivalves, unclear stipulations on the responsibilities of different stakeholders, such as the responsibilities for site opening/closure and producer responsibilities for food safety events, and an incomplete early warning and recall system. Additionally, harvesting area classification is still an ongoing project.

14.2.1.1 Legislative mechanisms

More than 20 major national standards have been issued during the past 11 years, either governing the hygiene of the products or prescribing water quality criteria and monitoring methods, and these include:

- GB2744-96 – Hygiene Standard for Marine Bivalves;
- GB 2742-1994 – Hygiene Standard for Oysters;
- GB/T4789.1, 2, 3, 4, 5, 7, 10-2003 – General Principles for Foodstuff Microbiological Test and Foodstuff Microbiological Test series, including total bacterial colony counts, *Salmonella* spp., *Shigella* spp., *Vibrio parahaemolyticus*, and pathogenic staphylococci;
- GB3097-1997 Sea Water Quality Standard;
- GB11607-1989 Water Quality Standard for Fisheries;
- GB12763.4-91 The Specification for Oceanographic Observations of Chemical Parameters in Sea Water;
- GB12763.6-91 The Specification for Oceanographic Observations of Biological Parameters in Sea Water; and
- Note: GB denotes ‘National Standard of the People’s Republic of China’.

14.2.1.2 Monitoring protocols

Microbiological monitoring of Chinese shellfish waters is undertaken using thermotolerant or faecal coliforms as determinants. Monitoring is also undertaken for biotoxins including Diarrhetic Shellfish Poison and Paralytic Shellfish
Poison and heavy metals such as Cu, Cr, Hg but these do not feature in this monograph.

For the assessment of microbiological water quality, total and faecal coliforms are measured using either multiple tube fermentation or membrane filtration methods according to the relevant national standards (i.e. GB17378-1998). The indicator levels are assessed against the following levels: total coliforms ≤ 500 /L, faecal coliforms ≤ 140 /L.

Monitoring of the actual shellfish product, the flesh, is undertaken with a similar range of parameters. For the microbiological components these include total counts of colony forming units (cfu), total coliforms, *Salmonella* spp., *Shigella* spp., *V. parahaemolyticus* and pathogenic staphylococci, all determined by the most recent editions of national standards for testing shellfish: total counts, GB/T4789.2-2003; coliform group, GB/T4789.3-2003; *Salmonella* spp., GB/T4789.4-2003; *Shigella* spp. GB/T4789.5-2003; *V. parahaemolyticus*, GB/T4789.7-2003; pathogenic staphylococci, GB/T4789.10-2003. In terms of compliance, total bacterial counts in bivalve flesh must not exceed 10^5/g; total coliforms 300 MPN/100 g and there must be zero *Salmonella* spp. in 25 g flesh.

### 14.2.1.3 Requirements for depuration and dispatch centres

Requirements for these processes include a range of factors, including tap water, depths of drains, flow of water, and sanitary conditions.

Purification centres must have their own laboratories or be able to access a laboratory equipped with necessary facilities, so that the effectiveness of the purification process can be determined through microbiological tests. Purification centres must record data regularly, including the source of the live bivalves and their quality, harvesting date, duration of purification and relaying, the health condition after purification, dispatch details or consignment after purification.

### 14.2.1.4 Implementing the legislation

Samples of live or processed bivalve products must be tested before sale. Depuration is recommended for live samples that could not meet the official standards and farming areas will be closed (for an appropriate period) if biotoxin levels are above the limits, or products on sale withdrawn if biotoxin or other safety indices are above the regulatory limits. An official report is produced after testing each sample and sent by mail or fax to the farmers or processors who are then responsible for taking any remediation measures. Serious violations or actual harm done to human health will incur penalties and may result in withdrawal of the license (or permit for production) as detailed in the Temporary Regulation on Monitoring and Management for Hygiene of the Bivalve
14.2.1.5 Responsible authority

Monitoring the environmental and sanitary quality of shellfish waters is undertaken by local fisheries’ environmental monitoring stations, according to GB3097-1997. The Local Oceanic and Fisheries Bureau is the competent authority responsible for enforcing the law. Quality and safety of bivalve products on the market are supervised by the local Health Bureau or Bureau of Quality and Technical Supervision (for domestic commodities) and entry–exit Inspection and Quarantine Bureau (for export commodities). The latter two are under the supervision of the General Administration of Quality Supervision, Inspection and Quarantine of People’s Republic of China (AQSIQ).

There is a complexity of management systems in China for the quality of aquatic products. Different levels of Oceanic and Fisheries Bureaus report to the Bureau of Fisheries of the Ministry of Agriculture for management of aquaculture activities, while they also report to the State Oceanic Administration for issues such as sea area allocation and the issuance of utilization licenses. As for the marketing of fish products, both the local Health Bureaus and Bureau of Quality and Technical Supervision have the right to demand withdrawal of unhealthy products (more usually a confiscation in this case) and closure of relevant fishing/cultivation areas for a certain period of time. However, for export to third countries, the different levels of entry–exit Inspection and Quarantine Bureaus are in charge of the inspection and testing.

Although not law enforcement bodies themselves, companies such as Intertek Testing Services and SGS-CSTC Standards Technical Services Co., Ltd. are often commissioned to provide the third party accreditation for aquatic products being exported to foreign countries. Their work has become an integral part of quality control system in China, and their test results enjoy an adequate legal status.

14.2.1.6 Implications of non-compliance

At present, an oral or written warning is the usual measure to be taken when non-compliance occurs. Subsequently TRMMHBCE can impose further penalties, including:

- For Class Three waters (see 14.2.1.7 for details of shellfish water classifications), if it is difficult to improve the water quality in a short time, or in case of long-term pollution, the fisheries management
authority (local Fisheries Bureau) should close the relevant farm, or ban the on-going shellfish cultivation activity, and forbid harvesting.

- For areas that are temporarily classified as Class Three waters due to occasional pollution incidents, including red tides, temporary closure will be implemented. The fisheries authority will demand that the monitoring stations follow the pollution incident closely, allowing for re-opening of the farms only when the pollution disappears and no residue of pollutants and biotoxins are detected.

- No harvesting of bivalves is permitted in temporarily closed areas. Cultivating or harvesting bivalves in long-term closed Class Three waters, and collecting bivalves in temporarily closed areas without permission are illegal, and the collected products will be destroyed.

- For those bivalves collected in temporarily closed areas without permission which had poisoned consumers after consumption of the products, the activity of harvesting and sale will be banned immediately; the products will be destroyed, the illegal income confiscated, and a fine of one to five times of the illegal income will be imposed. If no illegal income has yet been generated, a fine of between 1000 and 50 000 yuan will be imposed (US$140–6900). For those who have caused severe harm to consumers’ health, further liabilities and penalties are likely.

- Institutions and individuals who engage in bivalve purification and relaying should meet with hygiene requirements and produce shellfish that is up to food safety standards; upon violations, a warning for correction will be in place, and a fine of up to 5000 yuan (US$690) will be imposed; failure to correct or other serious violations will result in the withdrawal of the sanitary license.

- Institutions and individuals who discharge wastes into the shellfish cultivation areas and bring about environmental pollution or bivalve contamination, will be accused according to Item 42 of Marine Environment Protection Law of the People’s Republic of China (effective as of 2000).

14.2.1.7 Assessment for classification of harvesting areas – legislative backdrop

The TRMMHBCE is currently the most complete regulation in China governing bivalve production. This regulation stipulates the hygiene requirements for bivalve cultivation (including cultivating and harvesting areas), depuration, relaying and dispatching. For example, defining the competent authority
(hierarchical Fisheries Management Authority), licensing of cultivation establish-
ments, cultivation area classification into three categories, enforcement procedures (closure and re-opening of farms in Class Three water areas), and monitoring regimes is clearly defined or listed in items 3–7. There is also a preliminary requirement on traceability of bivalve products (items 9 and 15).

As listed in TRMMHBCE, bivalve shellfish production areas can be classified into three types, based on results of water quality and the sanitary quality of bivalve products (correlating with the US FDA rather than the EU approach):

(1) **Class One**: Water environmental quality and bivalve sanitary quality accord with relevant national standards. The shellfish cultivated or caught in this area can be put on the market directly for human consumption.

(2) **Class Two**: Water environment is slightly polluted and levels of some pollutants exceed the regulated standards in shellfish meat. But the bivalves produced in this area can meet relevant national standards for sanitary quality after purification or relaying. The bivalves cultivated or collected in this area can be put on the market for sale after purification or relaying.

(3) **Class Three**: The water environment and the shellfish are seriously polluted, and the bivalves produced in this area are unable to meet relevant national sanitary standards with available treatment measures. The bivalves thus produced are forbidden for human consumption.

In addition, there is also a draft of Shellfish Harvesting Area Classification compiled by researchers in the Yellow Sea Fisheries Research Institute, Chinese Academy of Fishery Sciences (YSFRI). In this draft standard, the criteria for harvesting area classification are based on the purpose and hygiene requirements of bivalve production. The classification criteria and details are listed in Table 14.1. To date, this is unpublished.

An on-going Harvesting Area Classification project (2007) is governed by the Fisheries Bureau of Ministry of Agriculture. Shellfish waters are classified into three categories according to microbiological index (number of *E. coli*) following the guidance of GB4789.3-2003 – Test of Coliforms in Foodstuff.

- **Class One**: number of *E. coli* <300/100 g meat, bivalves harvested in this area can be put to market directly and consumed without cooking;
- **Class Two**: *E. coli* 300–6000/100 g meat, bivalves harvested in this area can be put to market directly with advice to consume after cooking; and
• Class Three: \( E. coli > 6000/100 \text{ g meat} \), bivalves harvested in this area can be put to market after purification, reducing the number of \( E. coli \) to Class Two levels.

**Table 14.1** Draft standards for harvesting area classification in China

<table>
<thead>
<tr>
<th>Items</th>
<th>Class One</th>
<th>Class Two</th>
<th>Class Three</th>
</tr>
</thead>
<tbody>
<tr>
<td>Floating materials</td>
<td>No oil film, foam, and other floating materials on the water surface</td>
<td>Oil film, foam, and other floating materials on the water surface</td>
<td></td>
</tr>
<tr>
<td>Colour, smell, and taste</td>
<td>No abnormal colour, smell, and taste in the seawater</td>
<td>Abnormal colour, smell, and taste in the seawater</td>
<td></td>
</tr>
<tr>
<td>Suspended materials (mg/L)</td>
<td>Those added by human activities ( \leq 10 )</td>
<td>Those added by human activities &gt; 10</td>
<td></td>
</tr>
<tr>
<td>Faecal coliforms/L</td>
<td>( \leq 700 )</td>
<td>( \leq 10,000 )</td>
<td>&gt; 10,000</td>
</tr>
<tr>
<td>( E. coli /L )</td>
<td>( \leq 140 )</td>
<td>( \leq 2000 )</td>
<td>&gt; 2000</td>
</tr>
<tr>
<td>Pathogen</td>
<td>No pathogens</td>
<td>Some pathogens</td>
<td></td>
</tr>
</tbody>
</table>

Source: Yellow Sea Fisheries Research Institute, draft working standard, 2004

**14.2.1.8 Sampling regimes**

According to item 3 in the Annex of TRMMHBCE, the water quality of the cultivation areas and shellfish hygiene indices should be tested monthly from May to October and bimonthly from November to April. During times of harmful algal bloom occurrence, testing should be done daily. However, in practice, this rule is not followed closely. Some cultivation areas are rarely monitored; other areas may be sampled and tested only four times per year. However, it is intended that in the future the standard is enforced and the sampling frequency will be on a regular monthly basis.

**14.2.1.9 Local competent authorities and licensing of “depuration and dispatch centres”**

According to TRMMHBCE, the local competent authority should be the hierarchical Fisheries Management Authorities. These are the provincial and municipal Oceanic and Fisheries Bureaus, which are the integrated subordinates of the State Oceanic Bureau and Fisheries Bureau of the Ministry of Agriculture of China.

Although a complex process, it is generally agreed that the Oceanic and Fisheries Bureaus of different levels are in charge of regulating the process, especially the division, allocation and licensing of aquaculture areas. However,
criteria such as the Harvesting Area Classification have not been consistently enforced in many cultivation areas so far.

14.2.1.10 Current infrastructure – reference and monitoring laboratories

There are two national reference laboratories for the testing of aquatic products, including the National Centre for Quality Supervision and Test of Aquatic Products, which is affiliated with the YSFRI. The output of these laboratories is collated on an annual basis.

Microbiological, biotoxins and other contaminants are routinely tested for in foodstuffs in a hierarchy of national, provincial and municipal level Health Bureaux (supervised by the Ministry of Health), and Bureaux of Quality and Technical Supervision and entry–exit Inspection and Quarantine Bureaux (under the supervision of AQSIQ). In addition, there are approximately 18 food quality laboratories affiliated with the Ministry of Agriculture that test for microbiological indices and other contaminants in agricultural products, including aquatic products.

The eligibility rate of Chinese export foodstuff is higher than 99%. In addition to legislation and enforcement improvements, such as implementing the Harvesting Water Classifications, the Government of China has also been working on marine environmental protection and remediation. Pollution control programmes have been carried out in major sea cultivation areas, and special environmental monitoring institutes like the Centre for Supervision and Test of Fishery Ecological Environment in the Yellow/Bohai Seas (MOA) have been set up, which has the legal right of producing testimony in lawsuits concerning pollution of shellfish cultivation waters.

14.2.1.11 Summary of the situation in China

There is a legislative system safeguarding the food quality of cultivated bivalves in China. An overall regulation (TRMMHBCE) was enacted in 1997, which deals with the overall procedures from cultivation to placing on the market of bivalves in China. However some revisions would help meet the needs of the industry of today. Relevant national standards are also used for operational guidance.

There are also a whole set of regulations supervising the processing of fish products. Since most bivalve products on domestic markets are sold alive or without much processing, these regulations are generally applied for export, and are duly enforced by the hierarchical entry–exit Inspection and Quarantine
Bureaux. These regulations always embrace the same standards and ‘test limits’ of the destination countries, by emphasizing the establishment of accredited management regimes (such as HACCP and good practices), and generally up to EU and US FDA standards. It is a legal requirement that all the processors obtain a licence from their local entry–exit Inspection and Quarantine Bureaux and receive routine inspections and those who export to third countries must obtain EU or US FDA certificates. The entry–exit Inspection and Quarantine Bureaux checks the performance of all the licensed processors monthly and official examinations under the supervision of a jury is held biannually.

However, the current Chinese legislation and enforcement regime is rather different from the requirements of US FDA or EU directives governing the quality and safety, and marketing of cultivated bivalve products. Small companies and farmers in China are usually not effectively supervised and monitored, due to the lack of resources for internal quality control and a somewhat fragmented supervisory system administered by the local food authorities. However, larger companies, particularly those involved in processing, are generally well controlled by internal as well as external (governmental) regulations. Indeed, one thing noteworthy for these larger companies is that most of them have introduced US FDA or EU standards under their own initiative and have already obtained US FDA certificates for export of their products. For example, about 90% of processors in Shandong Province have obtained FDA certificates, of whom FDA takes a selective check annually. In addition about 50–60% of processors in Shandong have obtained EU certificates, of which the EU may take a selective check at any time.

### 14.2.2 Mediterranean states

This section draws very heavily and often directly on a recent report produced by United Nations Environment Programme (UNEP) Mediterranean Action Plan – Assessment of the State of Microbial Pollution of the Mediterranean Sea, published in June 2007. This document went through a separate process of peer review and we are indebted to Dr George Kamizoulis, Senior Scientist, WHO/EURO Project Office Coordinating Unit for the Mediterranean Action Plan for making the report and its output fully available to us.

As a general rule, in Mediterranean countries, individual growing areas are classified according to European standards for those countries belonging to the EU. The rest of the Mediterranean countries follow their own national guidelines or the European standards or appear to have no policies or processes. Some potentially productive growing areas remain prohibited for harvest because of inadequate state resources to conduct the requisite sanitary surveys.
The key features of national legislation and related measures concerning the quality of shellfish waters and shellfish in the various Mediterranean countries are summarized in the following paragraphs. Unfortunately, the picture is not complete, as information from some countries was not readily available to the report’s authors.

14.2.2.1 Mediterranean states that are also EU member states

Seven nations fall into this category – France, Spain, Italy, Greece, Slovenia, Cyprus, and Malta. The first four countries all regulate their shellfish industries based on the Water Framework Directive (2000/60/EC) and the European Food Standard Regulations 854/2004.

There may also be old national practices that continue. For instance, France still operates an administrative standard for shellfish growing waters (that has no statutory standing) into four categories as follows:

- **A**: Satisfactory, 0 *E. coli* per 100 ml seawater
- **B**: Acceptable, 1–60 *E. coli* per 100 ml seawater
- **C**: Doubtful, 61–120 *E. coli* per 100 ml seawater
- **D**: Unsatisfactory >120 *E. coli* per 100 ml seawater

In Greece, apart from the guide standard of 300/100 ml flesh and intervalvular fluid for faecal coliforms, the law also sets a mandatory standard of 700/100 ml. Shellfish satisfying the guide value are acceptable for human consumption, those satisfying the mandatory value are subjected to depuration. The microbiological quality of shellfish produced in small quantities for the Greek local market (up to 100 kg per day) is governed by health regulations stipulating that shellfish sampled in the market should not exceed 5 faecal coliforms/ml of flesh to be considered suitable for consumption. Shellfish containing between 6 and 16 faecal coliforms/ml of flesh require depuration before consumption, while those containing more than 16/ml are considered unsuitable for consumption. There are currently 24 officially monitored shellfish production zones in Greece.

In Spain, depurated shellfish destined for consumption must comply with the following microbiological standards:

- Aerobic microorganisms: up to 100 000/g
- *Escherichia coli* up to 500 per litre flesh and intervalvular fluid
- *Salmonella* spp. absent in 25 ml flesh and intervalvular fluid
- Streptococci (Group D) up to 100/g
- *Vibrio parahaemolyticus* up to 100/g
Italy follows the EU guidelines (854/2004) for shellfish. Shellfish-growing waters are still classified into approved zones and conditioned zones, with the following standards:

- **Approved zones**: Seawater should not contain more than two *E. coli* per 100 ml. Up to 7 per 100 ml seawater is tolerated in not more than 10% of the samples, provided that the shellfish themselves come up to the required standards. Shellfish should not contain more than four *E. coli* per ml of flesh plus intervalvular fluid, and *Salmonella* spp. must be absent in 25 ml flesh plus intervalvular fluid.

- **Conditioned zones**: Seawater should not contain more than 34 *E. coli* per 100 ml. Up to 49 per 100 ml are tolerated in not more than 10% of the samples. Shellfish should not contain more then 39 *E. coli* per ml of flesh plus intervalvular fluid.

Depurable species are only cleared for direct consumption if they originate from culture areas in an approved zone. Depurable species originating from (a) natural breeding grounds and (b) culture areas in conditioned zones are subject to mandatory depuration prior to consumption. Those originating from natural breeding grounds in conditioned zones must be cooked prior to consumption. Non-depurable species are cleared for direct consumption if they originate from approved zones, or from culture areas in conditioned zones, otherwise they are subject to mandatory cooking. Under Italian Law, Class A zones also have a requirement for *Salmonella* spp. and *Vibrio* spp. (0 in 25 g flesh plus intervalvular fluid). Stabilization zones are also included, with the same standards as for Class A zones.

In Slovenia, water quality control processes for shellfish breeding are contained in the 1988 Slovenian Decree on Preventive Vaccination, Diagnostics and Research in the Relevant Field. The standard for acceptable shellfish waters is 10 faecal coliforms/100 ml flesh, based on a fortnightly sampling frequency.

There are no legal standards for shellfish water quality in either Cyprus or Malta. In Malta public health legislation deals with shellfish for consumption and no shellfish products can be sold unless the trader is holding a permit issued by the Superintendent of Public Health. As of June 2007 there were no valid permits issued in Malta for the sale of fresh shellfish, although there was activity governing shellfish imported for human consumption. There are no officially designated shellfish growing areas in Cyprus. Any shellfish harvested originate from unofficial shellfish growing areas and are consumed locally.
14.2.2.2 Other Mediterranean states

_Algérie_
There is no information for official shellfish growing areas or regulation and control procedures running in Algeria.

_Bosnie et Hercegovine_
Standards for shellfish growing waters in Bosnia are based on EU standards, however no effective surveillance programme exists.

_Croatie_
In Croatia, shellfish water is classified in the articles of the Water Classification Decree of 1981, where four classes of coastal sea water are delineated based on both microbiological and physicochemical parameters. In terms of microbiological standards, the Croatian standard deems as acceptable a concentration of total coliforms of not greater than 100 cfu/100 ml for shellfish harvest waters.

_Egypt_
There are no specific statutory standards or criteria under Egyptian law regarding the microbiological quality of shellfish waters or shellfish flesh. However, shellfish waters are examined at regular annual intervals. These data are then apparently evaluated according to international (global) and European standards. Enforcement is through internal administrative procedures emanating from the Ministry of Agriculture as lead Government department. However, there is no official monitoring programme as most of the shellfish are consumed locally.

_Israël_
As shellfish are not grown or harvested in Israel, there are no requirements for any related standards.

_LEBANON_
There is no information available on shellfish harvesting, production or monitoring for Lebanon.

_The Libyan Arab Jamahiriya_
Apparently, there are no national standards currently in force for shellfish waters in the Libyan Arab Jamahiriya. However, pending the development and adoption of new standards, which are currently being finalized, the Libyan Arab
Jamahiriya is observing the standards adopted by the Contracting Parties of the Mediterranean Action Plan in 1987.

**Monaco**
There are no official shellfish growing areas along the Monaco coastline.

**Montenegro**
No data is available on shellfish waters or monitoring in Montenegro.

**Morocco**
Microbiological quality standards and criteria for shellfish waters in Morocco are based on French (and therefore EU) legislation. There is, however, little information readily available on the implementation of that legislation or any monitoring programmes.

**The Syrian Arab Republic**
No data is available on shellfish waters or monitoring in the Syrian Arab Republic.

**Tunisia**
Tunisia has 16 traditional shellfish growing waters classified into three categories:

- **Sanitary zones:** Shellfish flesh up to 300 faecal coliforms per 100 ml; *Salmonella* spp. absent in 25 g; water up to 2 faecal coliforms per 100 ml.
- **Conditioned zones:** Shellfish flesh up to 3900 faecal coliforms per 100 ml; water up to 34 faecal coliforms per 100 ml.
- **Unsanitary zones:** Shellfish flesh above 3900 faecal coliforms per 100 ml; water above 34 faecal coliforms per 100 ml.

Whenever a site is found to be contaminated, it is closed and then re-opened again when the water quality and/or shellfish flesh improves and meets acceptable conditions.

**Turkey**
The Aquatic Products Law came into force in Turkey in 1971, was amended in 1995, and contains general conditions and regulations for coastal protection and production of aquatic products. This law regulates the discharges to fish and shellfish production areas and sets acceptable values in receiving waters.
The Ministry of Health is responsible for the coordination of activities related to aquatic products at both national and international levels.

The Turkish Quality Control System for fishery products was introduced in 1998 and has been developed under the Fishery Law, the Fishery products regulations and EU Directives (91/493/EEC, 91/492/EEC, 79/223/EEC and 94/356/EEC) and the FAO Standard (Codex Alimentarius). There are two classes and four regions in Turkey (1999/767/EC Decision); Two in A class (live bivalve sand molluscs-91/492/EEC) and two in B class. The harvesting season generally runs from 1 September to 1 May. The difficulties in applying a monitoring programme include the lack of a clear limit for some parameters and consistency of sampling in bad weather conditions. The annex to the regulations defines limits on activities and substances. The microbiological limits for harvesting waters are:

- total coliforms not to exceed 70 per 100 ml;
- faecal coliforms not to exceed 10 per 100 ml; and
- *E. coli* not to exceed 2 per 100 ml (extendable to 7 per 100 ml).

### 14.2.3 India – a system under development

Shellfish culture is not yet effectively organized on a commercial basis in India and most of the shellfish consumed is harvested from natural beds and consumed locally. The Indian Marine Products Export Development Authority (MPEDA) has initiated a monitoring programme wherein mussels are monitored for faecal coliform counts and presence of biotoxins, but its extent and regulatory worth is unknown. This is surprising for a country with such an active academic community and a responsible approach to regulatory regimes.

Surveillance and monitoring notwithstanding, research into microbial contamination of shellfish populations in India has taken place and is continuing. Deepanjali *et al.* (2004) conducted a two-year study on the prevalence of pathogens, *V. parahaemolyticus*, *V. vulnificus*, choleraemic *V. cholerae* and of indicator bacteria (faecal coliforms) in oysters from two estuaries along the coast of Karnataka. In addition, presence of enteric viruses and coliphages were also monitored. This study focussed on two estuaries close to Mangalore -. Mulki and Sasthan. There was no correlation between the levels/presence of *tdh*⁺ *V. parahaemolyticus* and presence/levels of faecal coliforms. Faecal coliforms were detected in all shellfish samples while *tdh*⁺ *V. parahaemolyticus* was observed in only 10.2% of samples. Choleraemic *V. cholerae* was not detected in oysters during the two year study. This suggests that *V. cholerae* O1/O139 may not be common in the environment in this region.
Another important human pathogen that is likely to be associated with shellfish is \textit{Salmonella} spp. Studies with clams from markets in India indicate that 20\% are positive for \textit{Salmonella} spp. (Kumar et al. 2003). However, in tropical waters rich in organic matter, \textit{E. coli} and \textit{Salmonella} spp. could persist for a long time and even multiply (Winfield and Groisman 2003). Studies in India show that most of the seafood associated \textit{Salmonella} spp. infections belong to the serotype \textit{S. weltevreden} (Kumar et al. 2003). However, in the United States, \textit{S. weltevreden} is rarely found in human cases. In contrast, studies in Thailand reveal that \textit{S. enterica weltevreden} is the most common serovar associated with human Salmonellosis (Bangtrakulnonth et al. 2004). Thus the clinical significance of \textit{Salmonella} serotypes isolated from aquatic environments need to be studied further.

These findings, albeit quite rudimentary, suggest that the introduction of a monitoring programme in India would help to protect consumers from risks associated with consuming contaminated bivalves.

\subsection*{14.3 CONCLUSIONS}

This chapter is a brief illustration on the inconsistent approach to the management of bivalve shellfish destined for human consumption. It confirms that resources and commercial circumstances dictate the nature and extent of the regulatory response. Thus, we have a significant number of well-resourced countries where there is no appreciable management response to the issue because the shellfish are either not harvested or generally harvested and consumed locally. The commercial imperatives appear to come in two broad categories. First, internal markets within a country will lead to some resource allocation and some control processes to safeguard domestic consumers. Second, if the shellfish are to be exported to other countries, then there will likely be a much greater allocation of resources required as there will likely be far more comprehensive controls to satisfy. The existence of lucrative export markets, for instance for the New Zealand shellfish industry, brings with it financial rewards but also the requirements to meet exacting food safety requirements for the export customers. Thus it is predominantly the commercial demand for the shellfish that dictates the allocation of resources for monitoring and control. Where there are sufficient resources, there is still limited consistency and no real attempt to harmonize approaches unless there is a real commercial imperative such as meeting the demands of different export markets (as in New Zealand, see chapter 13).

Within a naturally defined region such as the Mediterranean, practice varies enormously on a scale from no management through to full, careful
implementation of EU legislation. Then we have countries such as China and India on remarkable economic development trajectories who either have a wonderfully complex but poorly implemented set of management controls (China) or have at best an understanding of the issue that is largely ignored (India). In effect, the Chinese response can be seen to clearly demonstrate the paradox created when the export markets demand an exacting regulatory set of controls and get them, thus making the associated costs an essential part of the business. The internal market within China largely avoids the same levels of control as they are seen as an additional and unwelcome cost to internal consumers.

The system needs harmonizing and re-structuring in such a way that countries can proceed along a pathway that increasingly develops their capacity to accurately monitor health risks. Whilst the logic of responding to the market place is clear, all consumers deserve the same degree of protection. Thus, the casual collectors and those they supply should be as safe from infectious disease as are the export customers. Applying fairly unsophisticated sanitary surveys alone, right up to monitoring on a regular basis for the right indicator in the right milieu – flesh or water – using best available analytical techniques, all on a consistent basis, should be a common goal.

14.5 REFERENCES


Temporary Regulation on Monitoring and Management for Hygiene of the Bivalve
Cultivation Environment (TRMMHBCE). Ministry of Agriculture of People’s