10
Overview of legislative principles and measures

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Food safety concerns regarding the consumption of sewage-contaminated bivalve molluscan shellfish, particularly with regard to their role in outbreaks of typhoid, were expressed as far back as the 1890’s (Buchan 1910). Large outbreaks of typhoid associated with the consumption of contaminated bivalve mussels and oysters during the early part of the 20th century led to the establishment of national controls in both the United Kingdom and the United States. In England, the Public Health (Shell Fish) Regulations of 1934 allowed local authorities to make orders to control harvesting, or to stipulate further treatment of shellfish (both bivalves and gastropods), from areas deemed to represent a ‘danger to public health’. These Regulations, and their equivalents in other Member States of the European Union (EU), were superseded by the implementation of the Shellfish Hygiene Directive (91/492/EEC) which in turn has been replaced by EU Regulation 853/2004, which lays down the specific
hygiene rules for food of animal origin, and by 854/2004 which outlines specific rules for the organization of official controls on products of animal origin intended for human consumption. In the United States, the outbreaks led the Surgeon General to organize in 1925 a conference of relevant federal, state and industry bodies whose recommendations became the basis of the present National Shellfish Sanitation Program (NSSP) (US FDA 2008).

10.1 PRINCIPLE LEGISLATIVE SYSTEMS

The EU and United States systems mentioned above were developed for the purpose of promoting trade as well as for public health controls. In many countries outside these two trading blocks, controls may only be applied to enable export to one, other, or both of these, and produce for local sale may not necessarily be subject to any public health controls. This obviously creates a disparity in public health protection to the detriment of many, especially in less developed countries. In many countries there will be no public health controls on commercial bivalve mollusc production in the absence of any export drivers. In this chapter, reference will principally be made to the EU and the United States. Few countries have any public health controls in relation to the gathering of shellfish for personal consumption, one exception being Canada where such activity is subject to the same controls as commercial harvest (see chapter 12).

Many countries have either signed Memoranda of Understanding with the Food and Drug Administration (FDA) and/or agreements with the EU and have instituted controls that are intended to be equivalent to those of the United States or EU and enable producers in these countries to export to these important markets. The responsible authorities must be recognized as being capable of exerting the appropriate controls and there is the facility for inspection of both the authorities and individual producers. In the case of the EU the responsible authorities within the third country have to recognize individual establishments as complying and a list of these are communicated to the European Commission. The term ‘third country’ is used to define one which is not within the European Economic Area (EEA); this being comprised of Member States of the EU and certain European Free Trade Association (EFTA) countries. Some countries exporting to both markets have to fulfil the differing requirements of both systems.

The Food and Agricultural Organization (FAO)/World Health Organization (WHO) Codex Alimentarius Commission implements the Joint FAO/WHO Food Standards Programme which is intended to protect the health of consumers by co-ordinating action by various government and non-governmental bodies
and the preparation of standards and codes of practice. Codes of practice for the hygienic production of a wide range of foodstuffs, including seafoods, have been published by the Commission. The Codex Codes are viewed as the basis for international controls to ensure free trade. Working Groups of the Codex Committee on Fish and Fishery Products have recently produced revised codes of practice for various seafoods including finfish, crustacea and bivalve molluscs (Codex Alimentarius Commission 2009). The revisions to the codes of practice have included incorporation of the principles of hazard analysis and critical control point (HACCP).

The Codex Code of Practice includes an outline of the HACCP process, including a simplified flow diagram for the production of live molluscan shellfish, and sections containing more detail regarding the stages identified on the flow diagram. Each section gives the potential hazards and defects plus technical guidance as to how these might be addressed. Some of the content appears to be more closely related to those in the current EU Hygiene Regulations than those in the US NSSP. This is reflected by a less prescriptive approach to many aspects such as harvesting area controls and depuration requirements.

10.2 INTERACTION WITH OTHER LEGISLATION

In many countries there are interactions between shellfish hygiene legislation and other legislation aimed at controlling pollution. The latter will have the intent of limiting the amount of sewage (and other contamination, such as chemical) to which shellfisheries are exposed which would otherwise limit their utilization due to the requirements of the hygiene legislation. Reducing sewage pollution of shellfisheries at source is one of the most effective ways of reducing the risk of viral illness associated with shellfish consumption.

In the United States, the Federal Water Pollution Control Act (Clean Water Act), as amended, requires that water quality is maintained for the purposes of the protection and propagation of shellfish (Anon 1948). This is undertaken by the Environmental Protection Agency which integrates the shellfish protection duties in with those for other water uses. This results in standards for sewage discharges and diffuse pollution measures. However, in the United States chlorination has been widely used to achieve bacterial indicator standards for sewage discharges and it is known that the viruses of interest with regard to shellfish public health are much more resistant to this compound than are the indicators (Tree et al. 1997). Using this approach to achieving compliance could actually increase the public health risk as the classification of harvesting areas will be artificially improved.
In the EU, the codified Shellfish Waters Directive 2006/113/EC (European Communities 2006) is intended to protect shellfish growing waters from pollution, and specifically to “safeguard certain shellfish populations from various harmful consequences resulting from the discharge of pollutant substances into the sea”. Most of the requirements of the Directive relate to physical (including temperature and salinity) and chemical parameters which may affect the ability of larval and juvenile shellfish to grow. However, there is a guideline value of 300 faecal coliforms per 100 ml of shellfish flesh and intravalvular fluid in 75% of samples. This is slightly laxer than the class A requirement under the EU hygiene legislation. As the Directive also requires Member States to establish programmes to meet its requirements, this has driven sewage improvement programmes within the EU although a large number of shellfisheries do not meet the faecal coliforms guideline value. Given that the hygiene legislation now concentrates on \(E.\ coli\) as a more specific indicator of faecal contamination (see chapter 6), there are often disparities in interpretation of the microbiological status of shellfisheries based on the hygiene requirements and the EU Shellfish Waters Directive. The latter will be subsumed into the Water Framework Directive from 2013 (European Communities 2000).

### 10.3 GENERAL PRINCIPLES UNDERLYING SHELLFISH HYGIENE CONTROLS

This chapter will address the general principles of legislative controls intended to control public health risks arising from the consumption of bivalve molluscs together with those controls more specifically aimed at the control of the risks associated with microbial contamination of faecal origin. Specific aspects relating to biotoxin, chemical and radiological contaminants will not be addressed; neither will the aspects of some countries’ programmes intended to control the risk arising from marine vibrios such as \(Vibrio parahaemolyticus\) and \(V.\ vulnificus\).

#### 10.3.1 Classification of harvesting areas

Classification is undertaken to provide an assessment of the likely level of contamination by pathogens of the bivalves harvested from the area. The microbiological status of an area is usually based on the results from a monitoring programme using faecal indicator bacteria (see chapter 6). A significant part of the assessment may also involve identification of potential contaminating sources...
(from sanitary surveys, see chapter 8). The assessment then dictates whether harvesting will be permitted from an area and, if so, what method and level of treatment may need to be applied to the bivalves prior to further sale.

10.3.2 Mitigation strategies

A primary mitigation strategy applicable to all classes of production area (and also to areas of relaying) is that of the application of short-term controls if the microbiological quality of the harvesting area does not conform to the requirements for the class in question. Such controls may include suspension of harvesting or the application of more severe treatment processes than normally required for the class of area (including relaying instead of depuration – see chapter 9). Suspension of harvesting needs to take into account the fact that faecal indicator bacteria and the pathogens of interest (especially enteric viruses) will clear from the shellfish at different rates and a return to normal status based on the indicators will not guarantee a return to the base level of risk of pathogen contamination. Depending on the degree of contamination, the shellfish species and the seawater temperature, removal of viral pathogens may take from about two weeks to more than two months.

The other mitigation measures involve post-harvesting treatments. The principles of depuration and relaying are detailed in chapter 9. Essentially, these processes are intended to provide the conditions whereby natural functioning of the bivalves will result in purging of microbial contaminants in artificial tanks (depuration) or the natural environment (relaying). Relaying may be undertaken for more extensive periods of time and thus may be used for more contaminated shellfish and, if the time is sufficient, this may result in the removal of enteric viruses. Heat-treatment, under specified conditions, is usually intended for moderately contaminated shellfish and the stipulated conditions should inactivate most non-spore-forming microbes, including enteric viruses. Development of heat-treatment specifications has centred on inactivation of hepatitis A virus, this being more heat resistant than most other pathogens of interest in shellfish-associated illness.

10.3.3 Responsibilities

In general, the hygiene legislation in each country will identify a central competent authority which is responsible for the implementation of the legislation and ensuring appropriate enforcement. Local authorities may be tasked with specific duties such as sampling and practical enforcement. Most legislation in this area puts specific duties on the shellfish industry for ensuring compliance and the
official enforcement duties are principally intended to act as an audit on the industry. In countries with devolved administrations, including states in the United States, regional or local authorities may act directly as the competent authority for regional/local laws. The EU Regulations, effective from 1 January 2006, have direct application in all Member States but there is still the need for these to be applied and enforced on a national, regional and local level. In some cases, individual Member States may introduce national measures in order to apply hygiene rules as allowed for by Community law. In the main these will be used to deal with particular national issues and to enhance public health protection and regulation. In addition, some aspects such as penalties for non-compliance, have to be put into national legislation as the EU does not provide a framework for this.

10.3.4 Traceability

In general, shellfish hygiene control systems incorporate procedures whereby traceability is intended from one stage to the next in the production chain. The means by which this is achieved, and the level of control exerted, varies between the different systems. In general, as for other foodstuffs, both forward and backward traceability (as appropriate) should be possible at any point in the chain. This ensures that if problems are identified in a production or relay area post-harvesting (such as a pollution event), a product can be recalled and if an outbreak of illness occurs, the relevant treatment and packaging premises and production or relay area can be identified for further investigation. In the EU, such documents have to be kept for 90 days in order to allow traceability in the event of an outbreak of illness due to an organism with a prolonged incubation period. Furthermore, these documents have to contain certain prescribed details. In general, commingling of batches should be avoided, if this is allowed in some instances (for example in the EU, batches of the same species and class can be mixed) then full traceability will be lost.

10.3.5 Communication

Effective application of shellfish hygiene controls relies on good communication between the various authorities and between the authorities and the various parts of the industry involved in the production chain. This communication may or may not be specified in legislation: in Europe there is an explicit requirement for food businesses to advise their competent authority where a consignment may present a risk to health. In the case of classified production areas, the central competent authority is required to hold and publish a definitive list and to bring this to the attention of all interested parties. However, effort is required on the part of all
involved to make sure that information is transferred to those who need to receive it. Specifically, the authorities rely on the industry to identify potential new production and relay areas and new depuration or heat treatment plants. The latter are subject to formal processes of approval and so the industry cannot legally trade in the absence of formal application, approval and provision of a unique approval number. Standard application forms are provided for the industry in some member states to facilitate the provision of such information to the relevant authority. The industry also needs to be made aware of any incidents or changes of status in production and relay areas or of potential outbreaks of shellfish-associated illness.

10.3.6 Funding

In general, funding for the official shellfish hygiene controls is provided by central and local authorities while the industry is expected to fund those aspects of control for which it is responsible (such as end-product testing). In some systems the industry is also expected to make a contribution to, or largely cover the costs of, the official controls. The new EU Food Hygiene Regulations (see below), make allowance for the competent authority to make a charge on industry for the funding of the monitoring programme and for ‘excessive’ official controls relating to the expenses incurred during control of large incidents. However, in general there are usually significant hidden costs of the official controls that fall to public funding.

10.4 EU LEGISLATION

Current EU legislation on live bivalve molluscs (which also covers gastropods, echinoderms and tunicates) are included in hygiene legislation concerned with all food of animal origin. Regulation (EC) No 853/2004 (European Communities 2004a) covers the hygiene rules to be applied by harvesters/businesses and Regulation (EC) No 854/2004 (European Communities 2004b) those for official controls to be applied by the competent authority. The controls only apply to commercial production. This legislation replaces controls which were previously applied under Directive 91/492/EEC, the Shellfish Hygiene Directive, as implemented in national legislation in each Member State. Casual gathering of shellfish for home consumption is not subject to any EU hygiene controls. Member States are responsible for passing their own legislation implementing the Regulations. The UK national legislation implementing the Regulations was put in place in January 2006. Details of the implementing legislation may vary between the Member States and in some instances these variations have caused significant differences in the form and extent of controls. In some areas the Regulation does not specify requirements in detail and this will increase the opportunity for
variation in interpretation of the requirements between Member States. Where any differences or local specifications apply, these will be highlighted in the appropriate sections. Reference will also be made where appropriate to potential significant differences in application in other Member States.

Control within each Member State is the responsibility of the competent authority; the body or bodies which undertakes veterinary checks. In the United Kingdom the Food Standards Agency (FSA) has competency for the monitoring of harvesting areas and the enforcement of these at central level. Local enforcement is the responsibility of the local food authority which consists of local authorities and port health authorities. These also undertake the official control sampling of harvesting areas on behalf of central government. In the United Kingdom both the Official Controls Regulation 854/2004 and the hygiene rules Regulation 853/2004 are to be implemented by a single set of Regulations.

Shellfish imported into the EU from a third country must have been produced under conditions which are at least equivalent to those stipulated by the Regulations. Countries outside the European Economic Area may apply for equivalence under which they can trade with the EU on the same basis as Member States. The Commission will then verify the controls applied by the third country to fulfil the relevant requirements and will publish a list of those centres within the country that are deemed to satisfy the controls. Where health problems and/or the presence of pathogens have been identified in third country imports, the Commission may impose particular controls until it is satisfied that any deficiencies have been rectified.

The following sections will concentrate on the requirements of the Shellfish Hygiene specific Annexes of Regulations 853/2004 and 854/2004. Regulation 854/2004 Annex II applies to live bivalve molluscs and by analogy to live echinoderms, live tunicates and live marine gastropods. It stipulates controls at all stages of production from monitoring of the quality of harvesting areas through to placing on the market. A large proportion of the content of the Regulations, as they relate to shellfish, is directed at addressing the health problems caused by sewage contamination.

Where shellfish are to be further processed by cooking, canning, or other means, they must meet the requirements of live bivalve molluscs prior to such processing. The controls under the Regulations stipulate:

- classification of production and relaying areas;
- monitoring of classified production areas and relaying areas to determine the degree of faecal pollution according to defined \textit{E. coli} parameters, which results in the designation of each production area to one of three classes;
10.4.1 Classification of production and relaying areas

Prior to classification, there is a requirement to undertake a study to determine the sources of organic pollutants, the way that they vary with season and the way that contaminating effects are modified by the bathymetry and hydrodynamics within an area. This essentially constitutes a sanitary survey. Classification itself then requires demonstration of compliance with criteria for *E. coli* in shellfish flesh. The levels are given in chapter 6. These determine whether areas are classified as A, B or C. Shellfish harvested from class A areas can be sold for human consumption without further treatment. Those from class B areas must be depurated or relayed in class A areas and those from class C areas must be relayed for an extended period of time (up to two months) or subjected to an approved heat-treatment procedure.

10.4.2 Monitoring of production and relay areas

These areas have to be periodically monitored for microbiological quality, toxin producing plankton, biotoxins and chemical contaminants. There is also a need to check the origin and destination of bivalve molluscs from these areas. Sampling plans have to be prepared for this monitoring and these have to ensure that the monitoring is both representative and reflects geographical and temporal variation. The default sampling frequency for biotoxins is defined as weekly during periods of active harvesting, unless a risk analysis shows that a reduced frequency is justified.

10.4.3 Decisions after monitoring

If monitoring shows that the relevant standards are exceeded, or even if not, there might be a risk to human health, in which circumstance the production area has to be closed to prevent harvesting. An alternative is to re-classify the area appropriately. The methods for this are explained in chapter 11.

10.4.4 Additional monitoring requirements

Any classified production area that is closed or subject to special conditions in relation to harvesting has to be policed in order to ensure that bivalves from such
areas do not end up on the market. There is also a requirement for verification checks to be made at the end-product stage. This is in addition to the requirements for testing by the food business operators themselves.

10.4.5 Recording and exchange of information
The competent authority has to maintain a list of classified production and relay areas and to provide this to interested parties such as those involved in the bivalve mollusc trade. Those interested parties have to be informed when there is a change in the hygiene status or extent of a production area.

10.4.6 Food business operators own checks
Food business operators are required to undertake their own checks in depuration and dispatch centres. Results of these internal checks may be taken into account in determining the classification of production areas, and in any decision to close or open such areas, providing that the sampling and analysis have taken place in accordance with agreed protocols, and that the laboratory has been designated by the authority and is accredited to acceptable standards.

10.4.7 Controls on harvesting, storage and transport
10.4.7.1 Harvesting
Shellfish must be harvested from areas that conform to the criteria for class A, B or C as determined by the microbiological monitoring described above and then subjected to any appropriate processing dictated by the classification. The competent authorities may prohibit the harvesting on health grounds from areas that meet the specified monitoring requirements. Temporary closures may be undertaken where particular contamination events have occurred; in the United Kingdom these are known as Temporary Closure Notices (TCNs) and are made by the local food authority. In general, in the United Kingdom such TCNs are used for sewage contamination, such as in the case of emergency discharges arising from equipment breakdown at a sewage plant.

Compliance with the geographical limits of classified harvesting areas and the correct identification of the origin of batches (see section 10.4.11 on Documentation) rely greatly on the co-operation of harvesters with some auditing by the authorities. In the United Kingdom, the food authorities are often aided in such matters by other bodies with responsibility for controls on shellfish stock conservation, the latter more often having access to suitable boats and
other equipment. Verification of practices in mariculture areas tends to be easier than that of the harvesting of wild stocks.

### 10.4.7.2 Storage and transport

These activities may take place both before and after processing and/or packing: if processing is by heat treatment, smoking, or similar means, then the requirements of the Hygiene Regulations relating to Fishery Products will apply. General hygiene controls apply to avoid contamination. There are specific stipulations precluding immersion in more contaminated water after harvesting or any form of immersion after leaving the dispatch centre (see below), both of which could negate the effects of other controls. The comparable controls in the United States include specification of storage and transport temperatures in order to limit the multiplication of bacterial pathogens. No such specifications are given in the European Regulations.

### 10.4.8 Standards for depuration, relaying and heat treatment

#### 10.4.8.1 Depuration

Purification centres have to be approved by the competent authority. The regulations contain a mixture of general and specific requirements given regarding purification systems and processes. The general nature of much of the requirements has led to wide variations between EU Member States regarding depuration system requirements and practices. The requirements are also less stringent than those which applied in many European countries under domestic legislation preceding the Shellfish Hygiene Directive (which applied before the EU Hygiene Regulations), for example in Denmark and France.

This particularly applies to the period of purification. No particular period is specified in Regulation 853/2004. It is, however, stated that the period must be sufficient for the shellfish to meet the microbiological end-product standards and that it should be adjusted, where necessary, to meet the extent of contamination of the incoming product. Historically, many EU Member States had standard stipulated minimum depuration periods, usually in the region of 48 hours, and some removed the standard requirement when the Shellfish Hygiene Directive (91/492/EEC) was introduced. This, together with broad interpretations of the other requirements in ways that do not conform to good practice based on best current technical knowledge, has led to the situation in some Member States where purification of class B shellfish may fail to produce shellfish that will consistently meet the *E. coli* and salmonella end-product standards. In the United Kingdom, a standard 42-hour depuration period has been maintained and
conformance with this and other prescribed operating conditions results in virtually all post-purification testing showing compliance with the bacterial end-product standards. In Italy, a 48-hour purification period is stipulated for shellfish imported from third countries (Italian Republic, 1993).

The frequency and type of microbiological testing of shellfish before and after purification and any testing of the seawater used for depuration will be determined by the operator’s HACCP plan. The final product will need to meet the standards described below in section 10.4.10.

10.4.8.2 Relaying

For class C shellfish relaying is an alternative to heat treatment and for class B shellfish an alternative to depuration. Where class C shellfish are relayed in class B areas they will still require depuration after the necessary relay period. Specific stipulations are given in Regulation 853/2004 regarding the identification of relay areas, their separation from production areas, and the operation of a batch system, in order to enhance control of the process. The competent authorities can determine the minimum water temperature which is deemed necessary for effective removal of contaminants. As with purification, the period required is specified by the criteria of the faecal indicator bacteria. There is an additional requirement for class C shellfish to be relayed for at least two months irrespective of this, although the competent authority can agree to a shorter period if a risk assessment shows this to be justified. This is another aspect of the application of the EU hygiene controls where there has been a difference in implementation between Member States: in some, relay of class C shellfish may take place in class A or B waters (with subsequent depuration in the latter case), whereas in others relaying is only permitted in class A waters.

10.4.8.3 Heat treatment

Approved heat-treatment methods are recognized alternatives to relaying for class C shellfish and depuration for class B shellfish. The methods are specified in Regulation 854/2004 as:

(1) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90°C and maintenance of this minimum temperature for a period of not less than 90 seconds;

(2) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160°C and the pressure is between 2 and 5 kg/cm², followed by shelling and freezing of the flesh to a core temperature of –20°C; and
(3) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (1). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.

10.4.9 General hygiene standards

These controls are prescribed to ensure that transport facilities and buildings and equipment used in purification and dispatch centres do not contribute to contamination of shellfish and are readily cleanable, thus reducing such risks further. Dispatch centres are facilities undertaking final washing, grading and wrapping of products ready for human consumption. Such centres must also be approved by the competent authority.

10.4.10 End product standards

Live bivalve molluscs sold in the final state for human consumption have to meet the following requirements:

(1) they must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid;

(2) they must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:
   (a) for paralytic shellfish poison, 800 ug/kg;
   (b) for amnesic shellfish poison, 20 mg domoic acid/kg;
   (c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 ug okadaic acid equivalents/kg;
   (d) for yessotoxins, 1 mg yessotoxin equivalent/ kg; and
   (e) for azaspiracids, 160 ug azaspiracid equivalents/ kg.

EU Regulation 2074/2005
(1) *E. coli* ≤230/100 g;
(2) *Salmonella* spp. not detected in 25 g.

It is recognized in the Regulations that scientific progress may result in the application of tests for viruses rather than relying only on faecal indicator bacteria as a guide to freedom from microbial contaminants. Occurrences of
large viral outbreaks ensuing from intra-community trade in live oysters prompted a review of documentation requirements (see below) and the establishment of a network of European and National Reference Laboratories for the microbiological aspects of shellfish hygiene.

### 10.4.11 Documentation ("paper trail")

The documentation specified in Regulation 853/2004 is intended to provide a means whereby the origin of shellfish and any subsequent processing can be determined in the case of illness associated with shellfish. This provides a means whereby the responsible authorities can undertake appropriate checks of the harvesting area, approved centres and other factors which have been involved with such a batch of shellfish.

Each harvested batch of shellfish destined for a purification centre, dispatch centre or fishery products establishment must be accompanied during transport by a registration document containing a number of items of information regarding the harvester, the date and place of harvesting, the species and approximate quantity, and the approval number and destination of the batch. The responsibility for completing these documents lies with the harvester.

In order to improve traceability, required as a result of problems encountered during investigation of intra-community outbreaks, the registration document requirements were amended and the document must now contain details of the health status of the production area. The registration documents for relayed shellfish must also include information on the length of relay. Where a registration document is to accompany a batch of shellfish from a purification centre to a separate dispatch centre, the duration of purification must be recorded.

In some EU Member States, there is a requirement for fishermen to keep record in a logbook of the co-ordinates, place and class of harvested shellfish as well as the appropriate information being included on the registration document. This provides an additional check on the information given on the movement document.

Packages of shellfish leaving a dispatch centre (or combined purification/dispatch centre) must be provided with a health mark identifying factors including the dispatch centre (by means of a unique number), country of dispatch, species, day and month of wrapping. The health mark must also include either a warning that the shellfish must be alive when sold or a date of durability. Where the shellfish are not in individual consumer-sized packages, the health marks must be retained by the retailer for at least 60 days following the “splitting” of a consignment.
The connection between the health-marked shellfish and the movement documentation showing harvesting details should be provided by the documentation within the purification or dispatch centre. The establishment of such a connection may be complicated by the allowance of the mixing of batches from different areas of the same health status: traceability in such situations will essentially stop at the purification/dispatch centre.

10.4.12 Imports from third countries

The requirements for equivalence were referred to in general terms in section 10.1. These are explicitly defined in the EU 853/2004. A recent list of countries deemed equivalent under Community law have been published by the Commission (European Communities, 1997a, amended by European Communities, 1997b). The equivalence requirements under the EU Shellfish Hygiene Directive also apply to imported processed shellfish that must meet the requirements of that Directive prior to processing (i.e. bivalves, echinoderms, tunicates and marine gastropods).

10.5 UNITED STATES NATIONAL SHELLFISH SANITATION PROGRAMME

10.5.1 United States legislation

United States controls are exerted at the federal and state levels. The FDA is the prime federal agency responsible for regulating seafood safety. The power for such regulations derives from the Federal Food, Drug and Cosmetic Act (US FDA 1989) and the Public Health Service Act (US PHSA 1944) and these control interstate trade. The National Marine Fisheries Service of the Department of Commerce undertakes a Voluntary Seafood Inspection Programme. Other federal agencies are also involved in seafood safety programmes. State authorities are responsible for intra-state controls and play a significant part in the co-operative National Shellfish Sanitation Programme (NSSP).

The NSSP exerts voluntary controls on the interstate trade in bivalve molluscs. The FDA has a key role in the administration of the programme, formulating regulations and overseeing state controls. State agencies are responsible for passing and implementing state laws and regulations consistent with the National Programme. The state agencies are then responsible for applying these controls within their own states, with the FDA undertaking audits of their effectiveness of compliance with the programme. Industry co-operates
by ensuring that shellfish are only accepted from recognized sources. The Interstate Shellfish Sanitation Conference consists of officials from federal and state agencies and industry and reviews the performance of the programme. The FDA produces a manual, subject to periodic revision, which specifies the criteria for compliance with the programme (US FDA 2008). The FDA also uses these criteria to establish Memoranda of Understanding with other countries wishing to export shellfish to the United States.

10.5.2 Classification of harvesting areas

Controls on the microbiological quality of harvesting areas are undertaken via the testing of water rather than of shellfish as in the EU Directive. Thus all species occurring within a single area will have the same classification. There are effectively five classes of waters (see also chapter 6). Shellfish from approved waters can be sold directly on the market without prior treatment. Shellfish from restricted areas may only be sold after depuration or relaying. These two classes therefore correspond to class A and B respectively of the European Shellfish Hygiene Directive. Conditionally approved or conditionally restricted areas are known to be subject to periodic pollution and during, and for a period of time after such events, particularly periods of heavy rainfall, the area will be closed. Shellfish from prohibited areas may not be sold for consumption. Any class of area may be subject to closure by the state authorities if pollution dictates. Within harvesting areas prohibited areas are defined around sewage outfalls or other sources of contamination. Separate control criteria are given for marinas that may be subject to particular types of intermittent pollution.

Classification of harvesting areas depends on a shoreline survey of the area to identify potential sources of pollution, an analysis of meteorological, hydrographic and geographic factors affecting the area and bacteriological analysis of water samples. This information has to be updated annually and re-evaluated every three years. A full survey has to be undertaken for each area at least every 12 years. Minimum numbers of water samples are prescribed for each of these evaluations, a number of which have to be taken under conditions which are determined to yield the worst results. Water samples are either tested by an MPN method which is specified by the American Public Health Association (APHA 1970) or by a membrane filtration method.

If shellfish-associated illnesses are linked to a particular harvesting area, or if pathogenic organisms are isolated from shellfish samples from a harvesting area, then the classification of the area has to be reviewed and, if necessary, amended. The other essential components of the NSSP also have to be reviewed for possible deficiencies.
The NSSP gives state authorities the option of clearing adult and developing shellfish from prohibited areas in order to prevent illegal harvesting. Seed shellfish, as defined by the authority, which are taken from a prohibited area must be grown on in an aquaculture area for at least six months prior to harvesting for human consumption.

10.5.3 Harvesting and transport

General hygiene rules are stipulated for the harvesting process to prevent contamination of product. Harvesters have to be licensed by the responsible authority and such authorities are responsible for undertaking patrols of the various categories of harvesting areas.

Time limits are specified by which shellfish not intended for wet storage or depuration must be placed under temperature control. These time limits are intended to prevent proliferation of bacterial pathogens. More stringent temperature controls apply if the waters have been associated with V. vulnificus infections.

Stipulations are given that boats involved in the shellfish trade (harvesting or others) should not dispose of sewage into harvest areas. Failure to comply with this requirement resulted in a large outbreak of viral illness (Kohn et al. 1995).

10.5.4 Holding, shucking, heat shocking and packing

General hygiene stipulations are given for these operations together with requirements for the quality of water used for wet storage and control of temperatures during processing and, packing and storage.

10.5.5 Depuration

Plans for plants have to be approved by the authority before construction. Specifications regarding the location and construction of plants and equipment are given and also for the seawater used (dissolved oxygen, coliforms, salinity, temperature, pH), sorting and cleaning of shellfish prior to depuration, loading of shellfish (tank/trays) and flow of water. The minimum depuration period allowed is 48 hours.

A control plan for the plant has to be prepared by the authority and plants have to be inspected and certified prior to operation and at intervals thereafter, the plants have to have a satisfactory supervisory system and have to keep records regarding both the source shellfish and the depuration process. The process to be undertaken has to be specified and approved and tested to
demonstrate compliance with the recommended removal efficiency for removal of faecal coliforms. Ongoing verification criteria for depuration systems (based on analysis of results from ten process batches) are given in Table 10.1. Where full verification has not been achieved for a plant or new source of shellfish, or where failure of the criteria has occurred, the shellfish post-depuration must meet the following criteria:

1. geometric mean (from three samples) of soft clams not to exceed 110 faecal coliforms/100 g and no single sample to exceed 170/100 g; or
2. geometric mean (from three samples) of other clam species, mussels, or oysters not to exceed 45 faecal coliforms/100 g and no single sample to exceed 100/100 g.

### Table 10.1 United States NSSP criteria for verification of depuration plant performance

<table>
<thead>
<tr>
<th>Species</th>
<th>Faecal coliforms per 100 g</th>
<th>Geometric mean</th>
<th>90th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft clams</td>
<td></td>
<td>50</td>
<td>130</td>
</tr>
<tr>
<td><em>Mya arenaria</em></td>
<td></td>
<td>50</td>
<td>130</td>
</tr>
<tr>
<td>Hard clams</td>
<td></td>
<td>20</td>
<td>70</td>
</tr>
<tr>
<td><em>Mercenaria mercenaria</em></td>
<td></td>
<td>20</td>
<td>70</td>
</tr>
<tr>
<td>Oysters</td>
<td></td>
<td>20</td>
<td>70</td>
</tr>
<tr>
<td>Manila clams</td>
<td></td>
<td>20</td>
<td>70</td>
</tr>
<tr>
<td><em>Tapes philippinarum</em></td>
<td></td>
<td>20</td>
<td>70</td>
</tr>
<tr>
<td>Mussels</td>
<td></td>
<td>20</td>
<td>70</td>
</tr>
</tbody>
</table>

Source: US FDA, 2008

### 10.5.6 Documentation

All stages of the production of shellfish, from harvest to final packing have strict requirements for appropriate marking of batches and identification of the harvester, processing establishment, and all other components through which the shellfish have passed. Separation and identification of independently harvested batches has to be maintained through the production system, unless accommodated by a management plan which minimizes such mixing and specifies how identification of source will be maintained. The information is cumulative and does not apply to separate stages of the harvesting and processing chain. This would seem to have advantages over the EU system in which it may be difficult to make adequate links between the separate items of documentation involved in the production process.
10.5.7 Control of laboratories

Laboratories taking part in the bacteriological examination of water samples for classification purposes and shellfish samples for end-product testing are inspected under the control of the FDA. The FDA also undertakes distribution of split samples to such laboratories under the Shellfish Laboratory Quality Assurance Program (Peeler et al. 1995).

10.6 CONTROLS OUTSIDE THE EU AND UNITED STATES

Those countries that export to one or other of the EU and United States will need to satisfy the relevant requirements of the importing bloc, this being either direct application of the controls which apply in the EU or United States, or which are recognized as being equivalent to these. There is usually a need for the competent authority in the exporting country to show that it has the ability to apply and enforce the requirements.

In countries such as Canada and New Zealand that export to both the EU and United States, the regulatory and enforcement system will need to be acceptable to both. In practice, rather than applying two different systems, such countries have tended to develop modifications of one or other, or hybrids of the two, that are not only acceptable to the importing authorities but may have unique features and advantages. Further details on the systems applied in Canada and New Zealand are given in chapters 12 and 13. In these countries, the hygiene controls are also applied to products for domestic consumption but this is not necessarily the case. In many countries that do not export to the EU or United States, there are no hygiene controls on commercial shellfish production.

10.7 CONCLUSIONS

Due to the large amount of international trade in shellfish, many countries have controls based on either the EU or United States standards for hygiene of seafoods and some may have to satisfy both. Addressing the problems of the inconsistencies between the two systems may be progressed via a body such as Codex Alimentarius, but such consolidations need to be undertaken without “generalisations” which may dilute the effectiveness of each system and may also lead to inconsistencies in the interpretation and application of the controls in different countries. The EU and United States hygiene requirements for imports of shellfish may also lead to significantly different standards for shellfish.
exported from a number of developing countries and those that are applied to shellfish produced for consumption within those countries.

Ultimately, public health legislation, and its enforcement, needs to be judged on its effectiveness in controlling and preferably reducing the incidence of infection associated with the products in question. This requires the acquisition of good epidemiological data and a mechanism for ongoing scrutiny of such data. Evaluation of information from individual outbreaks can yield valuable additional information regarding any possible causes and enable the identification of possible improvements in legislation and/or enforcement. Reduction in the incidence of viral illnesses associated with consumption of bivalve molluscs will necessitate improvements in technology, both laboratory and processing, as well as the appropriate use of legislation.

10.8 REFERENCES


