Chapter 8

System operation

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8.1 TRAY LOADING

Different species vary in the maximum weight above them under which they are able to open and pump properly. It is therefore important to take this into account when loading trays or baskets. Table 8.1 gives the maximum depths stipulated in the UK for different species.

8.2 TANK LOADING

In general, it is preferable for the tank to be loaded prior to the seawater being introduced. This avoids the operator contaminating the seawater and enables the trays/baskets to be properly arranged without the possibility of the shellfish opening and ingesting disturbed material. The trays/baskets should be arranged in accordance with the design and approval requirements for the system (see Sections 5.2 and 5.3). Overloading systems will result in depletion of oxygen levels and high concentrations of metabolic end-products (such as ammonia) and reduced effectiveness of depuration.

Small tanks can be loaded manually. Larger tanks may be loaded using mechanical means – an example of this is shown in Figure 8.1. The need for the operator to stand in the tank to load (and unload) the shellfish should be avoided in order to avoid the risk of contamination of the system.

Table 8.1: Maximum depths per tray stipulated in the UK for different shellfish species

Latin name	Common name	Maximum depth
Crassostrea gigas	Pacific oysters	Double layer
Ostrea edulis	Flat oysters	Single layer overlapping
Mytilus edulis	Mussels	80 mm
Cerastoderma edule	Cockles	80 mm
Mercenaria mercenaria	Hard clam	80 mm
Tapes decussatus	Native clam	80 mm
Ensis spp.	Razor clams	Bundles of 12

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Figure 8.1: Mechanical system for loading and unloading tanks

If UV disinfection is used, the system should be filled via the UV unit. This means that the required level of initial disinfection of the seawater should be achieved during a single pass through the unit. In some systems, the plumbing arrangements do not allow this to be done. In this case, the correct volume of seawater is introduced to the tank (without shellfish present) and the initial disinfection is achieved by recirculation through the UV system for a minimum of 12 hours in order to ensure that the entire volume of seawater in the tank has passed through the unit. The shellfish are then added. However, filling via the UV unit is to be preferred.

From a regulatory aspect, maximum loadings may be specified to limit the shellfish:water ratio in the system in order to ensure maintenance of adequate dissolved oxygen concentrations and to prevent build-up of excessive amounts of metabolic products such as ammonia. This will usually be a function of the maximum loading per tray and the number of trays. The maximum loadings stipulated in the UK for the standard design systems are given in Table 8.2. In Morocco, the maximum density authorised by the competent authority is 30 kg/m^2.

There is a recommendation in the US NSSP of a tank seawater volume of at least 6 400 litres per cubic metre of shellfish for hard clams (*M. mercenaria*) and eastern oysters (*Crassostrea virginica*) and 4 000 litres per cubic metre of shellfish for soft clams (*M. arenaria*). In New Zealand, the minimum value of 6 400 litres per cubic metre of shellfish is specified for cockles and oysters unless a lower value is determined, and approved, on the basis of depuration process studies at the time of commissioning while the minimum values for other species have to be based on such procedures.

Table 8.2: Maximum loadings stipulated in the UK for the standard design systems

System type	**Mussels** *Mytilus* species and hybrids	**Cockles** *Cerastoderma edule*	**Oysters**[1] *Crassostrea gigas* and *Ostrea edulis*	**Clam** *Tapes philippinarum* and *Tapes decussatus*	**Hard clam** *Mercenaria mercenaria*	**Razor clam** *Ensis* spp.
Small-scale 550–600 litres	90 kg	30 kg	750	56 kg	72 kg	40 kg
Medium-scale[2] 2 000–2 500 litres	750 kg	110 kg	4150	500 kg	650 kg	145 kg
Large-scale[2] 4 000–4 500 litres	1 500 kg	220 kg	12 000	1 000 kg	1 300 kg	290 kg
Bulk bin[3] 1 100 litres Bin	300 kg	-	-	-	-	-
Vertical stack 650 litre sump total 16 trays	240 kg	80 kg	2 000	168 kg	216 kg	105 kg

[1] The loading for oysters is specified in terms of the number of animals.

[2] The capacity of the medium and large scale systems depends on which type of approved trays are used.

[3] The bulk bin system has only been fully verified for use with mussels.

Shellfish that are not fully immersed will not depurate and so, after loading with shellfish and filling with seawater, it should be checked that there is the minimum recommended depth of seawater above the shellfish.

8.3 BATCH OPERATION

Depuration consists of an all in/all out process for each system. No shellfish must be added to, or removed from, a tank or any part of an interconnected system during a cycle. An interconnected system is one where more than one tank shares the same recirculating water supply or the flow-through supply from one tank comes from another). Where the water flow through single tanks in a system can be isolated from each other, drain down can be carried out at different times once the required depuration period has been completed and the tank to be drained has been isolated from the others. If any disturbance to the system or water flow occurs during a cycle, all shellfish must be replaced in the system and the entire cycle restarted.

8.4 CONDITIONS FOR DEPURATION

The conditions for depuration should follow the principles given in Section 3, be in accordance with local legislative requirements and, where appropriate, be agreed with the local control agency following a formal verification process.

In general, for systems based on flow-through or recirculation, at least 1 change in the seawater per hour is recommended. However, the actual value will depend on the system design (including the shellfish:water ratio) and the species being depurated.

8.5 DEPURATION PERIOD

A wide variety of depuration periods are used around the world, from as short as a few hours to as long as several days. It is important to note that the rate of removal of faecal coliforms or *E. coli* is not necessarily directly related to the rate of removal of pathogens. This especially applies to some of the viral pathogens and marine vibrios. Tailoring depuration periods very closely to the bacterial indicator content of individual batches (which may not relate directly to the pathogen content of that batch) and the theoretical or observed depuration rates of those indicators is therefore spurious. There has been some general tendency towards a period of 48 hours and, in a well-designed and operated system, this should ensure the removal of most sewage-derived bacterial pathogens and give approaching two-thirds reduction of viral pathogens such as Norovirus. Extension of depuration time (e.g. to 5 days) should enhance removal of the viral pathogens, given that the temperature and other conditions are satisfactory (e.g. 18 °C for *C. gigas* in northern Europe).

From a regulatory aspect, a minimum of 42 hours is specified in the UK and 44 hours in the US NSSP. In New Zealand, the stipulated minimum period is 48 hours unless the authority recognizes that the end point requirements will be consistently met by a shorter period. Even in such a case, a minimum of 36 hours is specified although it is also recognised that some species may require longer than 48 hours. Shorter periods than these are used in some countries where a minimum period is not specified by the competent authority and where the industry targets the period primarily at the removal of faecal indicator bacteria. For example, depuration periods of 18–24 hours are commonly used in Italy and in some cases the period may be significantly shorter than this.

8.6 DRAIN DOWN

The water in the tank should normally be drained in the same direction as the normal flow in order to avoid re-suspension of settled faecal material. For the same reason, the rate of draining should be approximately the same as the flow rate during operation. If the normal water take off level (e.g. suction bar) is above the lowest level of shellfish, then an auxiliary lower drainage port should be opened when the water is nearly at that level.

8.7 MONITORING

Monitoring of temperature, salinity and flow rate should be undertaken at least three times during each depuration cycle: at the beginning, in the middle and at the end. If any of these parameters are not within the stipulated ranges (defined by, or as agreed with the local control agency or as given in the Hazard Analysis and Critical Control Point (HACCP) plan then it should be adjusted as appropriate and timing of the process restarted from the beginning.

UV monitoring recommendations are given in Section 6.2. For other seawater disinfection procedures, a test kit should be used to ensure that the appropriate level of disinfectant has been achieved at the start of the contact time for each batch of seawater. The contact time should be recorded. Following disinfection, the residual level of disinfectant should again be determined to ensure that it is below the required levels.

It is important that any method used to determine the concentration of disinfectant is suitable for use with seawater as the salts in this can interfere with some chemical reactions. It is also important to make sure that any method used is suitable for use with the range of concentrations to be expected (normal and abnormal).

Free chlorine is usually measured by a colour reaction with N,N-diethyl phenylene diamine (DPD). Total chlorine is usually measured with the same method after release of bound chlorine by the addition of potassium iodide. Accurate determination requires the use of a meter to determine the level of colour produced by the reaction. Approximate values may be determined by the use of a kit where the resulting depth of colour is compared with a chart.

Ozone is usually added automatically to meet a preset redox potential measured using an appropriate meter. However, the concentration actually achieved in the water undergoing disinfection should be determined occasionally using a chemical method while the residual concentration in the seawater used for depuration should be checked regularly. Both checks may be undertaken using a colour reaction. Two methods for this include bleaching of indigo trisulfonate and a methyl substituted form of the DPD reagent used for chlorine analysis. As with chlorine determinations, kits are available for simple visual comparison while large plants with on-site laboratories may use instrumental measurement to get a more accurate result. A photograph of a kit used in a depuration centre for the measurement of residual ozone is shown in Figure 8.2.

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Figure 8.2: Example of a kit for the measurement of ozone

A suggested record form is given at Appendix 3.

Chapter 9

Post-depuration handling

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As with pre-depuration handling, this should avoid recontaminating shellfish, undue shock or vibration to the animals or exposure to extremes of temperature.

9.1 UNLOADING

The water in the depuration system should be drained to below the level of the bottom layer of shellfish before any are removed in order to avoid disturbance and reingestion of sedimented material. Depending on the design and size of tank and containers (trays, baskets, etc.), the shellfish may be removed manually or by a mechanical lifting mechanism.

After unloading, the residual seawater should be drained away and any remaining solid material removed or washed out. The inside of the tank should be scrubbed with a cleaning solution suitable for use in food production (this might be subject to local rules): sodium hypochlorite solutions are often used for this purpose. The tank should then be rinsed thoroughly with potable water or clean seawater in order to remove any traces of the cleaning agent. All remaining rinse water should be drained away before the tank is used again. Every few cycles, the plumbing should be flushed through with the cleaning solution and then meticulously flushed with potable water or clean seawater. This prevents build-up of dirt and slime in the pipes.

9.2 WASHING/DEBYSSING

The shellfish must be rinsed with potable water or clean seawater after depuration in order to remove any adhering solid material such as faeces. This operation may be undertaken in the tank after draining or after the shellfish have been unloaded. At no time must any of the shellfish become immersed in the wash water – adequate drainage must be provided.

Mussels that have been provided with the correct physiological conditions during depuration will embyss and the threads will need to be removed before packing by the same process as used prior to depuration. Preferably, a separate item of equipment should be provided, especially for large-throughput plants. For small plants, the same item of equipment may be used pre- and post-depuration providing all shellfish and

Figure 9.1: Sorting and packing table

other material is removed after pre-depuration use and the equipment is thoroughly cleaned.

Figure 9.1 shows a vibrating table with rinse spray used for post-depuration sorting and packing of mussels.

9.3 PACKING

Packing operations should take place in a separate part of the plant to that used for the other operations and preferably physically separated from those areas (Figure 9.2). Materials for packing should be of food-grade, even though, with most species of shellfish sold live, the packaging should not come directly into contact with the edible parts. Packaging materials may be mesh nets, trays with or without covers, or plastic bags. Local or international regulations (for exported product) may dictate the type of packaging used. The packaging should allow any liquid lost from the shellfish during storage to escape so that the shellfish do not sit in a pool of liquid. Oysters are generally packed with their concave shell downwards.

Depending on the throughput of the plant, commercially available packing machines may be used. These may be set for specific amounts (weights) of shellfish for each pack. Where such machines are used they should be cleaned on a regular basis. For some species of shellfish, e.g. oysters, buyers may require the shellfish to be graded (e.g. by size, weight) and such grading will take place prior to packing. Again, where this grading is undertaken by machine, this should be cleaned regularly.

Local or international regulations may also dictate the type of pack label that is acceptable and the details to be included on the labels. The label itself and the printing thereon needs to be waterproof and the label should stay fixed to the pack during subsequent transport and handling procedures. The labelling itself will often include the species of shellfish, date of packing, shelf-life or use-by date and the approval number of the

M.GI.B SRL, MESOLA (FE), ITALY

Figure 9.2: Post-depuration bivalve sorting and packaging

packing centre. In the EU, the label must indicate the country of origin (for some specific codes are allotted) and the shelf-life or use-by date can be replaced by the phrase "these animals must be alive when sold". To assist cross-referral to records in the depuration centre, it is useful to include a batch number that indicates the cycle/system (and possibly tank) to which the packed product refers. For commercial purposes, the labels may contain the name of the firm or other details. Examples of labels are shown in Figure 9.3.

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Figure 9.3: Labels attached to the packaging of depurated products

9.4 STORAGE

Packed shellfish awaiting transport (or direct sale from the plant) should be kept in a clean area (or cold room) under temperature controlled conditions, normally 2–10 °C depending on the species in question. This area should be separate to the areas of the plant dealing with the processing prior to the packing stage and may be part of, or lead off, the packing area itself.

9.5 TRANSPORT

Transport should not expose the shellfish to contamination, crushing or extreme vibration in order that the quality and viability of the product is maintained. Transport

should be undertaken in vehicles that are lined with easily cleanable materials. The shellfish themselves should be kept off the base of the vehicle so that any liquid lost from the packs drains away from the load. The temperature should be controlled, normally within the range 2–10 °C depending on the species in question. As with pre-depuration storage and transport, local regulations may stipulate other temperature ranges. International trade, or even slow methods of transport for local markets, may result in potentially long periods between packing and arrival at the final destination and this will increase the difficulty in maintaining the optimum temperature during transport.

Chapter 10

Microbiological monitoring

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The ultimate measure of success of depuration relates to its ability to remove the microbial contaminants for which it is carried out while keeping the bivalves live and of good quality. Microbiological monitoring therefore provides the basis on which to judge that this has occurred. However, such monitoring is usually based on faecal indicator bacteria and these are removed more easily than many of the pathogens (especially the viruses) (see Section 3.5). Such monitoring does not, therefore, provide a definitive measure of the safety of the depurated product.

10.1 PROCESS VERIFICATION

Physical assessment of a depuration system as satisfactory and ensuring maintenance of factors affecting physiological activity in the right range for the species in question does not always lead to the system providing satisfactory bacterial reductions. Therefore, local regulations may require that the effectiveness of the system be demonstrated in practice before it is used for depuration of product intended for the marketplace. Such requirements differ markedly. It is usually based on the bacteriological testing of samples from the loaded system pre- and post-depuration and determining whether the reduction in the concentration of faecal indicator bacteria (either faecal coliforms or *E. coli*) is satisfactory. In Europe, the requirements vary between countries and in some standard design systems may only require a single satisfactory verification cycle prior to full approval although non-standard designs may require very thorough validation. Under the US NSSP, product from unverified systems is subject to positive release based on end-product criteria for single cycles while verification is achieved by showing that the general performance over 10 consecutive cycles is satisfactory. The NSSP verification criteria are shown in Table 10.1. Plants which have not achieved full verification over 10 cycles, where a new source of shellfish is used, or where failure of the verification criteria has occurred, the shellfish post-depuration must meet the following criteria:

i) Geometric mean (from three samples) of soft clams not to exceed 110 faecal coliforms/100 g and no single sample to exceed 170; or
ii) 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.

Table 10.1: US NSSP criteria for verification of depuration plant performance

	Faecal coliforms per 100 grams	
Species	**Geometric mean**	**90th percentile**
Soft clams *Mya arenaria*	50	130
Hard clams *Mercenaria mercenaria*	20	70
Oysters	20	70
Manila clams *Tapes philippinarum*	20	70
Mussels	20	70

10.2 ONGOING MONITORING

The microbiological monitoring is usually not undertaken as a primary control in itself, or even as routine monitoring of critical points in the process. Rather, it is done to check that the process is producing the required outcome given the other controls and monitoring procedures that are in place. Usually, the microbiological monitoring will include pre- and post-disinfection analysis of the seawater and pre- and post-depuration analysis of shellfish.

Microbiological monitoring should be undertaken at a frequency stipulated by the local control agency or resulting from the outcome of the HACCP study (see Section 11). The frequencies recommended below are those that should be considered in the absence of those requirements. Where there is more than one tank per system, samples should be randomly taken from at least one tank chosen randomly.

An example record form is given at Appendix 3.

10.2.1 Seawater

The seawater entering the depuration tanks should be monitored for faecal indicator organisms on at least a weekly basis. Samples should be taken aseptically and sent to an accredited laboratory for testing for faecal coliforms and/or *E. coli* using a suitable method(s) (e.g. ISO 9308, part 1, 2 or 3). Neither of these faecal indicator bacteria should be detectable in 100 ml of the disinfected seawater.

10.2.2 Shellfish

On a regular basis, pre- and post-depuration shellfish from the same batch should be tested. The pre-depuration test confirms that the microbiological content of the harvested shellfish is that expected from the classification status of the harvesting area, as well as identify the microbiological load to be reduced by the process, while the post-depuration sample indicates whether depuration has been successful. The results of pre-depuration samples will depend on the microbiological status of the harvesting area. Single post-depuration samples should not exceed 230 *E. coli* (300 faecal coliforms) per 100 grams. Local regulations may require lower post-depuration results than this and a properly designed and operated system should be capable of consistently producing levels of ≤80 *E. coli* (100 faecal coliforms) per 100 grams. A suitable method for the laboratory to use is ISO TS 16649-3 – a standard operating procedure based on this method is given in Appendix 7.

In some countries there are additional requirements for depurated shellfish. For example, in Japan, in addition to the *E. coli* standard of 230 per 100 grams, the bacterial count should be no more than 50 000 per gram and the MPN for *V. parahaemolyticus* should be no more than 100 per gram.

Chapter 11

Hazard Analysis Critical Control Point (HACCP)

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HACCP is a system which identifies, evaluates and controls hazards which are significant for food safety (CAC, 2003). It is a science-based and systematic tool that assesses hazards and establishes control systems which focus on prevention rather than rely mainly on end product testing. It not only has the advantage of enhancing the safety of the product but, because of the means of documentation and control, it provides a means of demonstrating competence to customers and compliance with legislative requirements to the authorities.

11.1 BASIC PRINCIPLES OF HACCP

The *Codex Alimentarius* Commission has adopted the basic texts on food hygiene, including HACCP, in 1997 and 1999 and the guidelines for the application of HACCP were revised in 2003 (CAC, 2003).

The HACCP system can be applied from production to consumption and it consists of the following seven principles:

Principle 1: Conduct a hazard analysis
Identify the potential hazard(s) associated with each stage of depuration; assess the likelihood of occurrence of the hazard and identify the measures for their control;

Principle 2: Determine Critical Control Points (CCP);
Determine the points, procedures or operational steps that can be controlled to eliminate the hazard(s) or minimize its (their) likelihood of occurrence;

Principle 3: Establish critical limit(s)
Establish critical limit(s) which must be met to ensure that the CCP is under control;

Principle 4: Establish a system to monitor control of the CCP
Establish a system to monitor control of the CCP by scheduled testing or observations;

Principle 5: Establish corrective action(s)
Establish the corrective action(s) which must be taken when monitoring indicates that a particular CCP is not under control;

Principle 6: Establish procedures for verification
Establish procedures for verification which include supplementary tests and procedures to confirm that the HACCP system is working effectively;

Principle 7: Establish records and record keeping
Establish documentation concerning all procedures and records appropriate to these principles and their application.

11.2 APPLICATION OF THE HACCP PRINCIPLES TO SHELLFISH DEPURATION

Prior to the application of HACCP to a depuration unit, that unit should be operating according to the *International Recommended Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev.4 2004). Annex 1: *HACCP System and Guidelines for its Application* should be consulted for further information to assist with the design of a specific HACCP plan.

Management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

If the necessary expertise is not available on site for the development and implementation of an effective HACCP plan, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. HACCP literature and especially depuration HACCP guides can be valuable and may provide a useful tool for businesses in designing and implementing the HACCP plan.

The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate.

The application of HACCP principles consists of the following tasks as identified in the logic sequence for the application of HACCP (CAC, 2003).

A HACCP plan is a document that describes how a depuration plant will apply the above seven principles in its particular depuration establishment. The following sequence for the preparation of a specific HACCP plan is recommended by the Codex Alimentarius (Figure 11.1). It is applied hereafter for shellfish depuration considering only process critical control points and assuming that sanitary CCPs (hygiene practices, cleaning and disinfection, etc.) are implemented as per regulatory requirements.

1. Assemble a HACCP team
The HACCP team should have access to all information necessary for their work. The present manual is a good source of information to the HACCP team to identify the hazards and the control measures.

If the necessary knowledge and skills is not available at the depuration establishment, the team can be assisted by local public health officers, independent expert(s), fisheries extension officers and/or fish inspection officers.

For example, a HACCP team of a hypothetical depuration plant can be formed by:

- The Unit's Safety supervisor with a degree/training in food science/food safety, good experience in shellfish depuration and a special training in HACCP application to depuration
- The Unit's Personnel supervisor with a degree/training in food hygiene, experience in seafood industry and a special training in HACCP application to depuration
- The Unit's equipment maintenance
- An advisor on shellfish safety and regulatory requirements

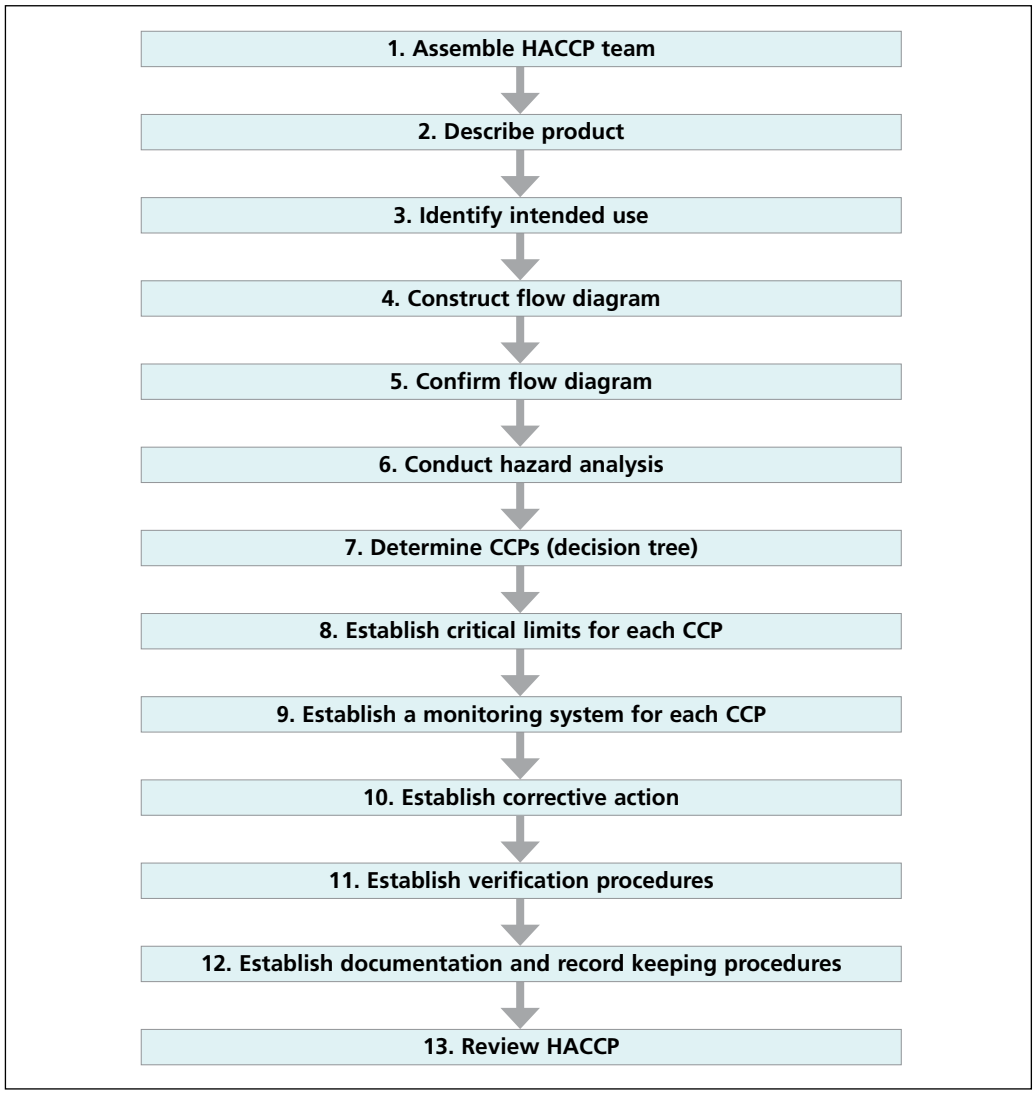

Figure 11.1: Summary of how to implement a HACCP analysis

2. Describe product

A full description of the product should be drawn up, including relevant safety information such as: harvesting area, depuration technique storage conditions, conditions and methods of distribution. The description should at least include the following items:

– Name of the product
– Shellfish species (common and/or scientific name)
– Type of depuration
– Preservation method (live, fresh chilled in ice)
– Packaging method (plastic boxes, polyurethane boxes, other)

An example of product description can be as follows:
"Live oysters (*Crassostrea gigas*) harvested from (locality), depurated for at least 44 hours, using UV disinfected water". The depurated oysters are packed in mesh nets and sold live to retailers and to restaurants.

3. Identify intended use

The intended use should be based on the expected uses by the end user or consumer. It is important to identify if the product is to be used in a way which increases the risk of harm to the consumer, or if the product is particularly used by consumers who are especially susceptible to a hazard. In specific cases, e.g. institutional feeding, vulnerable groups of the population may have to be considered.

For example, a description of the intended use can read as follows: The live oysters (*Crassostrea gigas*) are purchased by restaurants, transported in refrigerated trucks, stored at temperatures of 5 to 10 °C and served live to the customers.

4. Construct flow diagram

A flow diagram should be constructed by the HACCP team (e.g. Figure 11.2). The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specific operation.

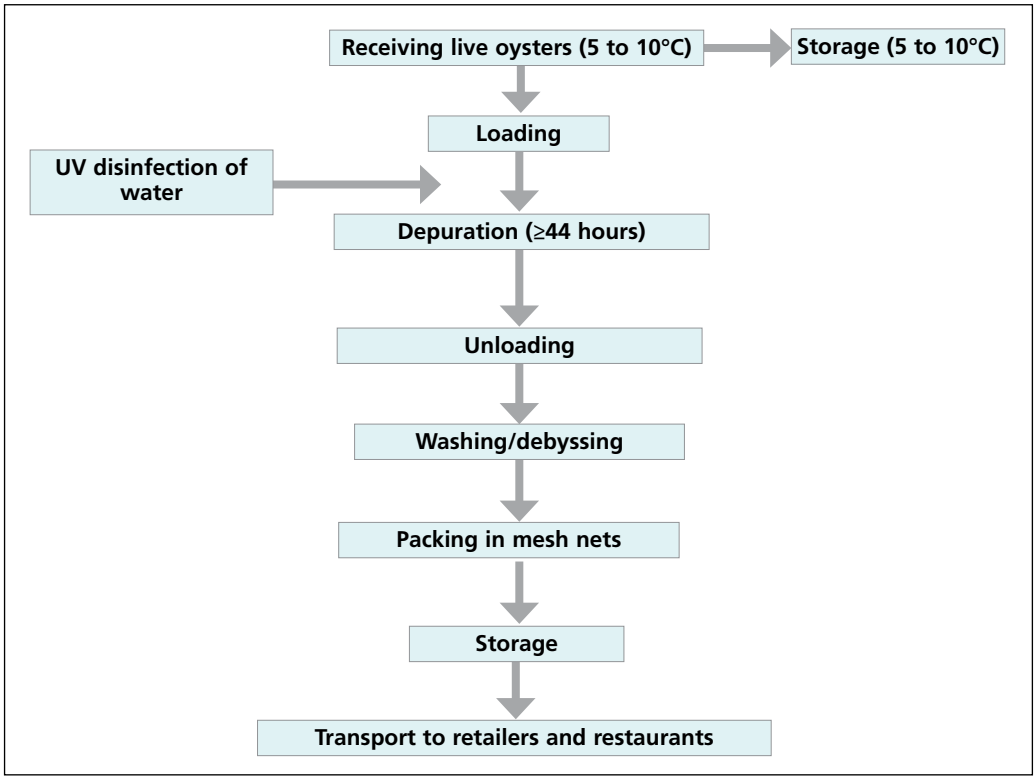

Figure 11.2: Example of a shellfish depuration flow diagram

5. On-site verification of flow diagram

The HACCP team should confirm *in situ* the production operation against the flow diagram during all stages and hours of operation and amend the flow diagram with information such as correct durations, temperatures, etc., where appropriate.

6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (see Principle 1)
The HACCP team should list all hazards that may be reasonably expected to occur during depuration, transportation until the point of shellfish consumption.

A hazard is defined as a biological, chemical or physical agent in, or condition of food, with the potential to cause an adverse health effect.

The HACCP team should next conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential for the production of a safe depurated bivalves.

Hazard analysis is the first HACCP principle and one of the most important tasks for the application of the HACCP system. An inaccurate hazard analysis would inevitably lead to the development of an inadequate HACCP plan.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of microorganism of concern;
- production or persistence in bivalves of toxins, chemicals or physical agents; and
- conditions leading to the above

The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard. More than one control measure may be required to control a specific hazard (s) and more than one hazard may be controlled by a specific control measure.

Consideration needs to be given whether any elements of the process itself will introduce potential hazards. With regard to depuration, these may include disinfectant compounds such as chlorine or ozone used to produce clean seawater and any by-products formed during their use.

Using the information provided in this manual, a hazard analysis for the live oysters delivered to retailers and restaurants, used here as an example (see page 54), is summarized in the HACCP plan (Table 11.1). It includes, among other HACCP information, the hazards identified and the measures selected to control these hazards.

7. Determine Critical Control Points (CCPs)
A CCP is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (Figure 11.3) recommended by the CODEX which indicates a logic reasoning approach.

There may be more than one CCP at which control is applied to address the same hazard. Likewise, several hazards can be controlled at a single CCP.

The application of the decision tree should be flexible according to the type of operation. Other approaches than the decision tree may be used for the determination of CCPs. If a hazard has been identified at a step where control is necessary for safety, and if no control measure exists at that step or at any other, then the product or the process should be modified at that step, or at an earlier or later stage, to include a control measure.

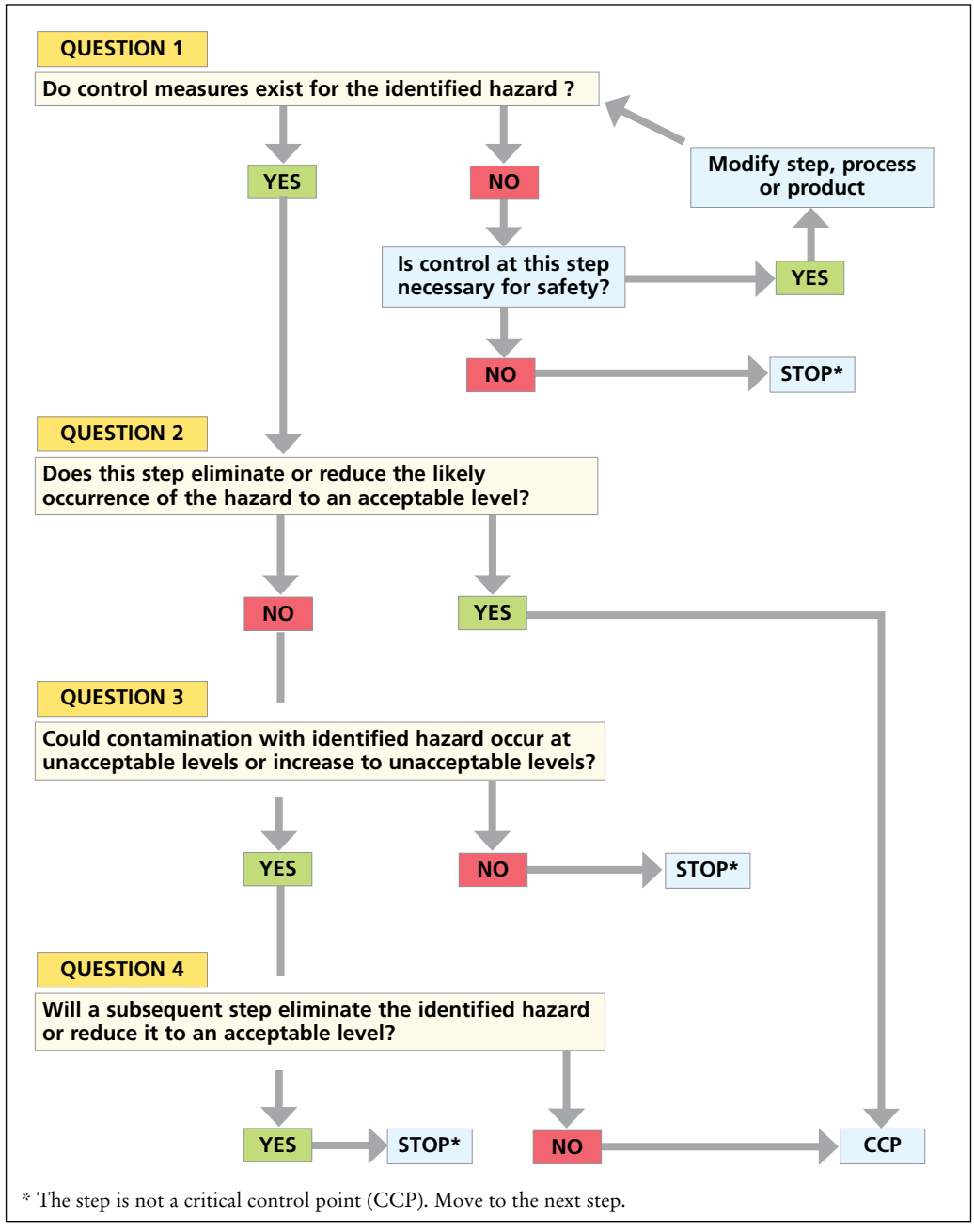

Figure 11.3: Decision tree for the identification of critical control points

As described elsewhere in this manual, depuration as currently commercially practised will not reliably reduce pathogenic marine vibrios, biotoxins or chemical contaminants from potentially hazardous concentrations to those where the product can be considered safe for consumption. CCPs for these hazards must recognise this – they will invariably focus on ensuring that product is received from areas where concentrations in the shellfish are below statutory or recommended safe limits. Current controls on harvesting areas will not ensure that harvested shellfish will be free from pathogenic viruses although the occurrence and concentration will tend to be lower from areas of better water quality, e.g. NSSP approved status or EU class A. Additionally, depuration as currently practised will not ensure removal of viruses but may, if performed according to best practice, reduce the concentration of these. Both of these considerations need to be taken into account when identifying CCPs and applying them within the HACCP plan.

Following is an example of the application of the decision tree to decide whether receiving raw material is CCP for the hazard presence of biotoxins and the hazard presence of salmonella and viruses.

Step 1: Receiving live oysters

Hazard 1: Presence of pathogenic bacteria and viruses

Control measure(s):

1) Purchase live oysters only from a licensed harvester who has harvested them from an approved B area and has tagged the containers or has proper purchase records

Is step 1 a CCP for the considered hazard or not?

Question 1: Do control measures exist for the identified hazard? Yes (measure described above)

Question 2: Does this step eliminate or reduce the likely occurrence of the hazard to an acceptable level? Yes. By applying the control measure 1 described above, we avoid purchase of oysters which can not be rendered safe for human consumption by depuration.

Conclusion: This step is a CCP for the obtention of safe live oysters after depuration

Hazard 2: Presence of biotoxins

Control measure(s):

1) Purchase live oysters only from a licensed harvester who has harvested them from an approved area and has tagged the containers or has proper purchase records

Is step 1 a CCP for the considered hazard of biotoxins or not?

Question 1: Do control measures exist for the identified hazard? Yes (purchase only from licensed suppliers)

Question 2: Does this step eliminate or reduce the likely occurrence of the hazard to an acceptable level? Yes. By using only licensed harvesters that collect only from approved areas we avoid depurating oysters containing biotoxins.

Conclusion: This step is a CCP for the considered hazard

This exercise shall be conducted at each step and for each hazard to identify CCPs. In the present example, the CCP identified using the decision tree are summarized in Table 11.1, along with other useful information.

8. Establish critical limits for each Critical Control Point (CCP)

Critical limits are defined as criteria that separate acceptability from unacceptability. A Critical limit represents the boundaries that are used to judge whether an operation is producing safe products as a result of proper application of the control measures. In other words, critical limits must be met to ensure that a CCP is under control.

Critical limits are set for factors such as temperature, time, chlorine concentration. These parameters, if maintained within boundaries, will confirm that a given hazard is under control at a given CCP.

The critical limits should meet requirements of government regulations and/or company standards and/or be supported by other scientific data. It is essential that the person(s) responsible for establishing critical limits have knowledge of the process and of the legal and commercial standards required for the products.

As an example, the HACCP plan (Table 11.1) defines the critical limits for the measures designed to control the identified hazards at each identified CCP.

9. Establish a monitoring system for each CCP
Monitoring is defined as the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control. The monitoring procedures will determine if the control measures are being implemented and ensure that critical limits are not exceeded. The monitoring procedures must be able to detect loss of control at the CCP.

The purposes of monitoring include the following:

- To measure the performance level of the system's operation at the CCP (trend analysis)
- To determine when the performance level of the system results in a loss of control at the CCP, e.g. when there is deviation from a critical limit
- To establish records that reflect the performance level of the system's operation at the CCP to comply with the HACCP plan

The monitoring procedures should give information on:

What will be monitored (What?)

Monitoring may mean measuring a characteristic of the depuration process or of the product to determine compliance with a critical limit. Monitoring may also mean observing whether a control measure at a CCP is being implemented. Examples include verification of the duration and intensity of a UV treatment.

How critical limits and control measures will be monitored (How?)

Deviation from a critical limit should be detected in as short a time as possible to allow corrective action to limit the amount of adversely affected product. Microbiological testing is rarely effective for monitoring CCPs for this reason. Instead, physical and chemical measurements (e.g. pH, time, temperature, oyster physical appearance) are preferred, as they can be done rapidly and can often be related to the microbiological control of the process. This correlation between rapid measurements and microbiological control needs to be regularly validated.

Equipment used for monitoring procedures should undergo periodic calibration or standardization as necessary to ensure accuracy.

Operators should be trained in proper use of the monitoring equipment and should be provided with a clear description of how the monitoring should be carried out.

Frequency of monitoring (When?)

Where possible, continuous monitoring is preferred; it is possible for many types of physical or chemical methods. Examples of continuous monitoring would include the automatic measurement of free chlorine levels in water.

Where non-continuous monitoring is the chosen system, the frequency of monitoring should be determined from historical knowledge of the process and product. When problems are detected the frequency of monitoring may need to be increased until the cause of the problem is corrected.

Who will monitor (Who?)

Careful consideration should be given to assigning responsibility for monitoring. Once assigned, the individual responsible for monitoring a CCP must:

- Be adequately trained in the CCP monitoring techniques
- Fully understand the importance of CCP monitoring techniques
- Have ready access (be close) to the monitoring activity
- Accurately report each monitoring activity
- Have the authority to take appropriate action as defined in the HACCP plan
- Immediately report critical limit deviation

Examples would include the indication of the Purchase Manager as the responsible for the monitoring procedures at the CCP receiving harvested oysters.

Where to monitor (Where?)

Monitoring takes place at each CCP where a given control measure is applied to control a given hazard.

The HACCP plan (Table 11.1) summarizes the monitoring procedures recommended for the operations described in Figure 11.2.

10. Establish corrective actions

Since the main reason for implementing HACCP is to prevent problems from occurring, corrective actions should be taken when the results of monitoring at the CCP indicate a loss of control. Loss of control can cause a deviation from a critical limit for a CCP. All deviations must be controlled by taking predetermined actions to control the non-compliant product and to correct the cause of non-compliance.

Product control includes proper identification, control and disposition of the affected product. The control and disposition of the affected product and the corrective actions taken must be recorded and filed.

The establishment should have effective procedures in place to identify, isolate (separate), mark clearly and control all products depurated during the deviation period.

Corrective action procedures are necessary to determine the cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure that the action taken is effective. Reassessment of the hazard analysis or modification of the HACCP plan may be necessary to eliminate further recurrence.

Examples would include the rejection of oysters not certified as coming from an unauthorized harvesting area or from a non licensed harvester or dealer.

Records should be available to demonstrate the control of products affected by the deviation and the corrective action taken. Adequate records permit verification that the producer has deviations under control and has taken corrective action.

The HACCP plan (Table 11.1) summarizes corrective actions recommended for the operation described in Figure 11.2

For example, the following verification procedure can be recommended for the depuration operation described in Figure 11.2.

Wherever needed but at least weekly, the HACCP team assesses internally all the results of the controls, monitoring and corrective actions and draws conclusions for the subsequent production weeks.

On a longer term, annually, the HACCP team can:

- Evaluate the monitoring and corrective actions data to assess performance and analyses the reason for any loss of control or for complaints from clients and/or control authorities.
- The results of this analysis will be used to update the HACCP manual, identify any internal need for further training and improved practices and performance, maintenance, modify frequency (increase or decrease) of specific monitoring, revise list of approved suppliers.
- An audit by the advisor to assess the performance of each control, monitoring or corrective procedure. He/She will audit the different records, including records for monitoring, calibration and maintenance, training, complaints and reports from clients and control authorities. He will prepare a report that will be submitted to management and discussed during a meeting with management and the HACCP team. The audit exercise will be also used as an opportunity to introduce new procedures, monitoring techniques or critical limits to take into consideration new developments, including new regulatory requirements.

11. Establish verification procedures

Verification is the application of methods, procedures and tests, including random sampling and analysis and other evaluations, in addition to monitoring to determine compliance with the HACCP plan. The objective of verification procedures is to determine if the HACCP system is working effectively.

Careful preparation and implementation of the HACCP plan does not guarantee the plan's effectiveness. Verification procedures are necessary to assess the effectiveness of the plan and to confirm that the HACCP system adheres to the plan.

Verification should be undertaken by an appropriately qualified individual or individuals who are capable of detecting deficiencies in the plan or its implementation.

Verification activities should be documented in the HACCP plan. Records should be made of the results of all verification activities. Records should include methods, dates, individuals and/or organizations responsible, results or findings and actions taken.

12. Establish documentation and record keeping

Records are essential for reviewing the adequacy of the HACCP plan and the adherence of the HACCP system to the HACCP plan. A record shows the process history, the monitoring, the eventual deviation and subsequent corrective actions that occurred at the identified CCP. It may be in any form, e.g. processing chart, written record, computerized record. It is imperative to maintain complete, current, properly filed and accurate records. Failure to document the control of a CCP would be a critical departure from the HACCP plan.

Several types of records should be considered among those relevant in a HACCP program:

- Support documentation for developing the HACCP plan
- Records generated by the HACCP system: Monitoring records of all CCPs
- Deviation and corrective action records, Verification/validation records
- Documentation on methods and procedures used
- Records of employee training programs

Tables 11.2 to 11.4 provide examples of forms to record monitoring different elements of HACCP application in a depuration plant. Other formats can be used to suit specific needs of a given depuration plant as long as they allow capturing the required information.

11.3 TRACEABILITY

Traceability is "*the ability to trace the history, application or location of that which is under consideration*" (ISO 9000:2000). When considering a product, traceability relates to the origin of materials and parts, the processing history and the distribution and location of the product after delivery.

In the case of food safety, the *Codex Alimentarius* (CAC, 2005) defines "*traceability/ product tracing as the ability to follow the movement of a food through specified stages of production, processing and distribution*".

This definition has been further refined into a regulation by the EU to signify "*the ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated in a food or feed, through all stages of production, processing and distribution*" (EU, 2002).

Traceability can use either paper or electronic systems, although most are a mixture of the two. Paper traceability systems are widespread and have been used for a long time throughout the food supply chain. Electronic traceability uses either the bar code systems or the more recent radio frequency identification (RFID) systems. Bar code systems have been in use since the 1970s and are well established in the food industry. RFID technology uses tags that send identification codes electronically to a receiver when passing through a reading area.

Traceability can be divided into *internal* and *external* traceability. *Internal* traceability is traceability of the product and the information related to it, within the company, whereas *external* traceability is product information either received or provided to other members of the food supply chain.

The following information is the minimum required for incoming live shellfish traceability in a depuration plant:

- Name, address and permit number of the harvester
- Date of harvest
- Harvest area and sanitary status (e.g. A, B or C in the EU)
- Shellfish species
- Quantity
- Lot or batch number

In addition, the depurated shellfish may need to trace the following (Figure 11.4):

- Name, address and registration/certification number of depuration plant
- Shellfish specie and quantity

- Depuration date, cycle number or lot number
- Address of place of destination

The traceability records should be kept for a minimum of 90 days (if consumed raw or live) to 1 year for frozen shellfish or longer for canned products.

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Figure 11.4: Depurated and packed bivalve products clearly labelled for traceability

Table 11.1: HACCP plan for shellfish depuration*

Critical Control Point(s)	Hazard(s)	Control measure(s)	Critical limit(s)	Monitoring procedure(s)				Corrective action(s)	Record keeping	Verification of records
				What	How	Who	When			
CCP-1 Receiving shellfish	Presence of pathogenic bacteria and viruses in shellfish	Only shellfish from approved harvesting area and delivered by licensed harvester are accepted	Shellfish from unauthorized area or non licensed harvester should not be accepted	License of harvester	Visual verification	Safety supervisor	Each delivery	Identify the affected product and, if feasible, increase the depuration duration. If not, remove product from distribution	Table 11.2	Daily under normal circumstances and at every delivery when a deviation occurs
				Tag accompanying container or transaction record	Visual verification	Safety supervisor	Each delivery	Investigate why the heavily contaminated shellfish was accepted into the plant and deal with the problem		
	Presence of biotoxins in shellfish	Only shellfish from approved harvesting area and delivered by licensed harvester are accepted for depuration	Shellfish from unauthorized area or non licensed harvester should not be accepted	Licence of harvester	Visual verification	Safety supervisor	Each delivery	Identify the product suspect of containing biotoxins and remove it from distribution	Table 11.2	Daily under normal circumstances and at every delivery when a deviation occurs
				Tag accompanying container or bulk shipment transaction record	Visual verification	Safety supervisor	Each delivery	Investigate why the contaminated shellfish was accepted in the plant and deal with the problem		
	Presence of unsafe levels of *Vibrio parahaemolyticus*	Concentrations in harvesting area below statutory or recommended safe limits	Only shellfish from areas deemed to conform to limits are accepted for depuration	Source area of shellfish confirmed as conforming to limits	Visual verification of tag or transaction record	Safety supervisor	Each delivery	Do not accept any shipment with a risk of *Vibrio parahaemolyticus*	Table 11.2	Daily under normal circumstances and at every delivery when a deviation occurs
		Refrigerated shellfish transport	5°C ≤ T ≤ 10 °C Transport duration ≤ 6 hours	Shellfish temperature and transport duration	Temperature measurement and visual verification	Safety supervisor	Each delivery	Do not accept any shipment with a risk of *Vibrio parahaemolyticus*	Table 11.2	Daily under normal circumstances and at every delivery when a deviation occurs
CCP-2 Depuration	Survival of pathogenic bacteria in shellfish	Ensure that water disinfection is operating to design specifications	Depuration design specifications (see chapter 6.2 and manufacturer's specifications)	UV intensity (≥ 10 mW/cm^2/sec)	See chapter 6.2 and manufacturer's specifications	Depuration supervisor	Weekly or as needed	- Identify the affected product and re-depurate. If not possible remove product from distribution - Investigate the cause to bring water disinfection back to operate to design specifications	Table 11.3	Weekly under normal circumstances and at every cycle when a deviation occurs
		Duration	≥ 44 hours	Duration	Timing	Depuration supervisor	Every depuration cycle	- Identify the affected product and re-depurate. If not possible remove product from distribution. - Investigate cause of deviation and deal with it	Table 11.3	Weekly under normal circumstances and at every cycle when a deviation occurs
CCP-3 Storage	Multiplication of surviving bacteria	Refrigerated storage	5°C ≤ T ≤ 10° C	Temperature	Thermometer reading	Safety supervisor	Daily	- Identify the affected product and assess duration of storage at T>10°C. If needed and feasible, re-depurate. If not possible remove from distribution - Investigate cause of deviation and deal with it	Table 11.4	Weekly under normal circumstances and at every cycle when a deviation occurs

* The HACCP plan is provided for illustrative purposes only. Depuration plants operators should adapt it to their specific situation and needs to ensure that the actual hazards and the needed control measures are identified.

Name and address of the company: _____

Name and signature of the manager: _____ Date: _____

Name and signature of the safety supervisor: _____ Date: _____

Table 11.2: Control of shellfish at receiving

Receiving date	Specie and quantity (kg)	Harvest date	Harvest area and area type	Name and licence number of harvester	Duration of transport	Temperature of shellfish at receiving

Name and signature of delivery person: _____ Date: _____

Name and signature of safety supervisor: _____ Date: _____

Table 11.3: Control of shellfish at depuration

Lot number	Date and time in	Date and time out	Quantity	Depuration cycle

Name and signature of depuration supervisor: _____ Date: _____

Name and signature of safety supervisor: _____ Date: _____

Table 11.4: Storage of depurated shellfish

Date in	Lot number	Specie and quantity (kg)	Temperature	Date out

Name and signature of the production manager: _____ Date: _____

Name and signature of safety supervisor: _____ Date: _____

Table 11.5: Recording corrective actions

Date:	Lot:	Critical Control Point:
Description of the control loss (deviation):		
Description of the corrective measure:		
Date and time when control was restored:		
Description of the new situation:		
Name and signature of the production supervisor:		Date:
Name and signature of the safety supervisor:		Date: