

Depuration: An administrative overview

La purification, du point de vue administratif

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Abstract

At the 1964 National Shellfish Sanitation Workshop, Mr. Eugene Jensen presented a thought-provoking paper outlining the rationale for the depuration of shellfish. Mr. Jensen noted that "we are committed to the principal that shellfish must be as safe to eat as other ordinary food" and that "the problems of assuring the sanitary quality of coastal areas will increase rather than diminish. This is not the same as saying that pollution will increase" (Jensen, 1964). It is recognised that additional use of the waters and shore areas will have adverse impacts on the water quality and shellfish resource quantity and quality. If we are to maintain a program which will permit the consumer to eat shellfish in any form they choose, we must develop the means to provide, in Mr. Jensen's words, "a reasonable level of security to the consumer" (Jensen, 1964). This requires establishing procedures to assure that the public health is protected, particularly by setting limitations on the type and quantity of contaminant to be depurated.

This discussion is about public health protection - that is what the U.S. Food and Drug Administration (FDA) does, and that is what the Interstate Shellfish Sanitation Conference (ISSC) does.

The ISSC is an association of state public health and shellfish officials, FDA, the Environmental Protection Agency (EPA) and the National Marine Fisheries Service (NMFS). There is a general assembly, three task forces (administration, growing areas, plant sanitation) and about 15 committees. The committees review issues submitted and present recommendations to the appropriate task force. Committee members consist of representatives from academia, industry, state regulators, FDA, and NMFS. Committee reports are sent to the task force where they are reviewed, debated, and voted upon (states and industry vote). Then they go before the general assembly where only states vote. FDA reviews the decisions later to insure that changes are consistent with federal regulations. Once concurrence has been obtained, the changes become part of the program and binding on all participants.

This paper discusses the requirements for the depuration control authority and the plant operator. The procedures for designing the plant, writing the scheduled depuration process, verifying the process effectiveness, and the ongoing operation of the depuration plant have been extracted from the *NSSP Manual* in a tabular form. The applicable sections of the *Manual* have been referenced for each requirement.

Résumé

En 1964, lors du séminaire National Shellfish Sanitation Workshop, Eugene Jensen avait présenté une communication exposant une argumentation en faveur de la purification des coquillages. Monsieur Jensen observait que « nous sommes attachés au principe que les coquillages doivent présenter la même sécurité au consommateur que les autres aliments », et que « les problèmes concernant le contrôle de la qualité sanitaire des zones littorales iront en croissant plutôt qu'en diminuant. Ce qui ne revient pas à dire que la pollution augmentera »

(Jensen, 1964). Il est admis que l'exploitation accrue des eaux et des zones côtières aura des impacts défavorables sur la qualité des eaux ainsi que sur la qualité et la quantité des ressources en coquillage. Si nous voulons maintenir un programme qui permette au consommateur de manger des coquillages sous quelque forme que ce soit, il nous faudra mettre en œuvre des moyens pour assurer, selon les termes de M. Jensen, « un niveau raisonnable de sécurité pour le consommateur » (Jensen, 1964). Ceci nécessite la mise en place de procédures garantissant la protection de la santé publique, et notamment en fixant des limites sur le type et la quantité de contaminants à purifier.

Ce débat concerne la protection de la santé publique — et c'est précisément la mission de la US Food and Drug Administration (FDA) ainsi que celle de la Interstate Shellfish Sanitation Conference (ISSC).

L'ISSC est une association regroupant des responsables de la santé publique et de la conchyliculture : FDA, EPA (Environmental Protection Agency) et NMFS (National Marine Fisheries Service). Elle comporte une assemblée générale, trois commissions de travail (administration, zones conchylicoles, hygiène des installations) et environ 15 comités. Les comités étudient les questions qui leur sont soumises et présentent leurs recommandations aux commissions de travail.

Les membres des comités comprennent des représentants des secteurs universitaires et industriels, des législateurs des états, des responsables de la FDA et du NMFS. Les comptes-rendus des comités sont envoyés aux commissions où ils sont examinés, discutés et votés (vote des représentants de l'État et de l'industrie). Ils sont ensuite soumis à l'approbation de l'assemblée générale où seuls les représentants de l'État ont le droit de vote. La FDA étudie ensuite les décisions adoptées pour s'assurer que les modifications sont cohérentes avec la réglementation fédérale. Une fois établie leur conformité, les modifications deviennent partie intégrante du programme et prennent un caractère obligatoire pour tous les participants.

Le document traite des obligations pour les autorités chargées du contrôle de la purification et des gestionnaires de centres de purification. Les procédures pour la conception de la station, l'élaboration du cahier des charges, la vérification de l'efficacité du traitement, et la mise en œuvre opérationnelle de la station sont extraites du manuel technique NSSP sous forme de tableaux. Les références aux sections du manuel sont données pour chaque prescription.

Background

Processes that are technologically feasible or economically desirable, from the viewpoint of the harvesters or the resource manager, may not provide the requisite public health protection for the consumer. Shellfish are eaten whole, raw and alive; they have the ability to concentrate bacteria in their bodies up to 100 times the ambient level and cannot distinguish between pathogenic (harmful) and non-pathogenic bacteria. All bacteria are ingested readily.

Water quality

Consistent with the precepts expressed by Jensen at the 1964 Workshop, the National Shellfish Sanitation Program (NSSP) provides a very conservative approach to the classification of the harvest area ; and to the handling, processing and distribution of shellfish. This is best illustrated by a comparison of U.S. water quality standards for various uses, as shown in the table below.

Intended water use

Drinking water

Direct market shellfish harvest area

Depuration shellfish harvest area

Swimming beach water quality

Median bacterial indicator values

< 1 total coliform/100 ml

≤ 14 fecal coliform/100 ml

≤ 88 fecal coliform/100 ml

≤ 200 fecal coliform/100 ml

Depending upon which level of water quality we are concerned with, when the maximum allowable level is exceeded, we say the water is polluted. The meaning of the word polluted is not precise. It is used to refer to the situation where the standard under discussion is exceeded. For example, water with a median of say, twenty (20) fecal coliform per 100 ml is considered polluted because it is not acceptable as an area for the harvest of shellfish for direct market sale (i.e., without depuration or relaying). However, it is very acceptable water for the harvest of shellfish for depuration, or for water contact ! The confusion caused by this imprecision is compounded by the connotation of the word polluted when contrasted with the visual evidence of clear water - not colored, not greasy, and without noxious floating and suspended materials. It is important that we remember that the water quality in shellfish harvesting areas must be carefully appraised through a sanitary survey to insure proper classification. Shellfish, which are eaten whole, raw, and alive, concentrate bacteria and viruses from the waters. The term sanitary survey used in the NSSP is the classic sanity engineering survey conducted to determine the suitability of a potential water supply. It involves a survey of each property which could affect the water quality, all natural sources of pollution (animals, birds), water flow parameters (quantity, velocity), and any waste treatment or disposal systems which could impact the water quality. A series of water quality samples are collected which form a profile of conditions in the harvest area (different tide stages and weather conditions). Intensive sampling is conducted to develop data for the area. All of this information is analysed and evaluated to determine the proper classification of the area, and the information is presented in a comprehensive report. Sampling and shoreline surveys continue periodically to monitor the water quality in the harvest area and to detect adverse changes. (For more detailed information on growing area survey and classification, see the NSSP *Manual*, Part I.).

Depuration requirements

The ISSC has adopted stringent guidelines for the process known as controlled purification, or depuration, because the untreated shellfish are, by definition, adulterated (unsuitable for consumption) and may pose a health hazard to the consumer. The process of instituting and operating a depuration program requires a high level of commitment from the regulatory agency and the depurator. The regulatory agency must demonstrate to the FDA that it has the ability to provide and maintain the required oversight through monitoring, inspection, sampling, and evaluation of the information generated. The depurator must provide plans and specifications; a scheduled process; a plant evaluation study; and maintain the operational standards of sanitation, process control, process evaluation, supervision, and record keeping. The responsibilities of each party and the specific references for each of the requirements are listed in the table "Administrative Requirements for Depuration". The requirements may be found in the NSSP *Manual*, Part II (NSSP, 1990b).

The first step is to develop a scheduled depuration process (SDP), based on knowledge and experimental data, to substantiate that the process adequately reduces the microbiological load consistently. This is a key word - consistently. To assure consistent reduction of the bacteria, a sampling protocol and end-pro-

duct criteria have been adopted by the NSSP (Section I.8., NSSP, 1990b). The criteria define the number of samples and frequency of sampling of raw and depurated shellfish, the maximum bacterial levels for raw and finished product, and the median bacterial level of finished product samples. Operational standards for the depuration plant include a median and variability limit for a series of processed shellfish lots.

The SDP for each plant is developed separately in accordance with Part II, Section I of the NSSP *Manual of Operations* (NSSP, 1990b). There are many variables which must be addressed in considerable detail that are identified in the *Manual*. Some are : species, seasonal effects, water temperature, salinity, dissolved oxygen, turbidity, sources of shellfish and process water, treatment of process water, tank design and construction, tank hydraulics, container spacing, processing time, raw product quality, end-point criteria, process monitoring, and general plant sanitation. The maximum allowable 0-hour level of fecal coliforms is determined during comprehensive process verification studies which demonstrate that the scheduled process is adequate and that shellfish purification occurs in all parts of the tank. Shellfish must be treated for a minimum of 48 hours.

The usual sanitation requirements apply to materials, cleaning, plumbing, etc. There are strict requirements for temperature, salinity, dissolved oxygen, and bacteria in the process water.

Since shellfish cannot be harvested from areas exceeding the 0-hour maximum established for each plant, the effectiveness of the plant's process has an impact on the growing area classification. Some areas which are within the overall possible restricted area classification (that is, have a median fecal coliform level of less than 88/100 ml) may produce shellfish that exceed the 0-hour maximum allowable because of the cleansing efficiency of the plant. To operate economically, the plant must be assured of a long-term source of shellfish.

There must be a quality assurance program based on microbiological testing of each lot (including nearly all incoming lots) and, generally, duplicate samples of all finished product. These sample results must fall within the parameters for the 0-hour and finished product release criteria.

The question of marketing the shellfish during the process verification study was raised at the ISSC. Initially the NSSP did not allow the marketing of those shellfish. However, because of the hardship involved in relaying or destroying a valuable product, the ISSC now allows the shellfish to be released for consumption if the plant has provisional certification by the State Shellfish Control Agency (SSCA), establishes an accepted sampling plan, and the sample results conform to the end-product criteria.

The specific requirements for depuration are discussed in several subsections of the *Manual* (Section I), making it easy to overlook significant qualifiers and additional discussion in other sections. It is important that all parties to depuration recognise the extent and significance of the responsibilities of a depuration program. Two tables have been developed to try to put the requirements in perspective and to provide ready-reference to the appropriate section of the *Manual*. The section of the *Manual* referencing each requirement is in parenthesis follo-

wing the requirement. No claim is made that these are all-inclusive, but they should help put the task in perspective.

The first table, Administrative Requirements for Depuration, addresses the administrative requirements for the regulatory (oversight) agency, and for the applicant (perspective plant owner). The process begins with the state providing the FDA with documentation that they have the ability to monitor and administer a depuration program. The applicant submits preliminary design information and a SDP is developed. The design is finalised, the SDP tested by conducting a plant evaluation study, and the operating procedures refined. Certification is awarded, and ongoing monitoring and evaluation programs are implemented.

The second table, Scheduled Depuration Process Requirements, outlines the information required for the SDP, including the minimum requirements for variables that are specified. The others must be addressed and the limits defined. The end result of this effort is a document which provides an evaluation of the expected interrelationships of the variables for the specific depuration process. The evaluation study verifies that the expected effects are achieved, and provides some direction for process optimisation. Any substantive changes in the process or parameters must, of course, be shown to consistently produce shellfish meeting the end-product criteria before the process can be revised on an ongoing basis.

Summary

Although depuration is a recognised process that allows mildly (or potentially) contaminated products to be cleansed under controlled conditions, the practice requires strict supervision and controls. Both the states and industry share responsibility for producing safe products certified under approved practices and quality assurance programs... Depuration is a costly, management-intensive program that involves a (continuing) industry and state partnership (beginning) prior to (the plant) becoming operational. The *NSSP Manuals of Operation* specify criteria which must be rigidly followed" (Dressel and Snyder, 1991).

The basic requirements for depuration are complex and require demonstration of process effectiveness and reliability. These are complex, time-consuming, and expensive procedures that must be taken very seriously for the program and the process to provide protection to the consumer and the industry.

Administrative requirements for depuration (Part II, Section I) Program administration - State

- State applies to FDA for evaluation of new program element (Part I, A.2.a.)
- State demonstrates :
 - Adequate laws (I.1.a.)
 - Adequate resources (I.1.a. ; I.4.c.)
 - Adequate equipment (I.1.a.)

- Interstate transport for depuration MOU (I.1.j.)
- Interagency MOU (I.1.k.)
- Records retained in central file (I.1.i.)
- Depuration control plan (I.1.c.)

Pre-approval

Plan review and approval prior to construction (I.1.b.) - State
Scheduled Depuration Process (SDP) developed (I.2.a.) - Applicant

Pre-certification

Plan design (applicant), evaluation & approval (I.1.e.) - State
SCPP reviewed and approved (I.2.a.) - Requires plant evaluation study
(I.2.a. ; I.6.f.) - State/Applicant
Plant construction evaluation and approval (I.1.e.) - State
Process operation (SOP) evaluation and approval (I.1.e. ; I.6.) - State

Certification

Per Section A.2. (I.1.f.) - State
Subsequent inspections (I.1.g.) - State
Evaluation of processing data and records (I.1.h. ; I.2.b.iii.) - State
Harvester licensing/permitting (I.1.d.) - State
Supervision (I.10.a.) - Applicant

Operations - Plant

Evaluation of processing data and records (I.2.b.iii.)
SOP onsite (I.2.c. ; I.10.e.)
Plant sanitation, maintenance, and sanitary practices at required levels (I.4.d. ;
I.5.a. ; I.6. ; I.7. ; I.9.)
Records retention (I.4.e. ; I.8.h. ; I.10.d.)
Adequate supervision and process control (I.10.a. ; I.10.b.)
Tagging (I.4.f. ; I.9.d.)

Scheduled Depuration Process (SDP) requirements (Part II, Section I)

1. Developed for each plant based on experimental data (I.2.a.)
2. Plant evaluation study to demonstrate the effectiveness of the SDP (I.2.a.)
3. Developed by someone knowledgeable (review of credentials) (I.2.b.i.)
4. Account for critical process variables :
 - Species to be depurated (I.2.b.ii.)
 - Seasonal effects (I.2.b.ii.)
 - Water temperature (I.5.d.iv.) :
 - ≥ 2° C for soft shell clams
 - ≥ 10° C for oysters, hard clams
 - ≤ 20° C for hard shell clams, soft shell clams
 - ≤ 25° C for oysters

- Salinity (I.5.d.iii.) :
± 20% of harvest area
- Dissolved oxygen (I.5.d.i.) :
≥ 50% of saturation
- Turbidity (I.5.e.) :
Does not interfere with disinfection nor physiological activity.
- Source of shellfish :
Harvest areas meet restricted or approved area criteria (I.4.a. ; I.4.b.).
Shellfish meet 0-hour product specifications established in process verification study (I.2.b.iii. ; I.4.a.).
- Source of process water :
Must meet parameters for safety and normal physiological activity (I.5.d.)
Must be amenable to treatment (I.5.e.).
- Process water treatment :
Treatment system (I.5.e.)
Adequate quantity and quality of water (I.5.e.)
No detectable coliform levels in tank influent (I.5.d.ii.)
pH between 7.0 and 8.4 (I.5.d.v.)
Treated water does not interfere with depuration, normal physiological activity, or process water disinfection (I.5.e.)
Treated and untreated process water sampled daily for critical parameters (temperature, salinity, D.O., turbidity, coliform bacteria) (I.8.e.)
- Tank and plumbing design and construction :
Non-toxic, corrosion-resistant materials (I.5.a.)
Easily cleanable (I.5.a.)
Self-draining (I.5.a.)
Clearance between containers ; clearance between containers and tank walls/bottom (I.5.b. ; I.6.f.)
Shellfish container construction (D.13.a.-b ; D.13.e.-f.)
- Hydraulics :
Uniform flow, minimum turbulence (I.5.b. ; I.6.f.)
Flow measurement devices (I.5.b.)
Minimum flow rate of 1 gallon per minute per bushel (I.6.g.)
Minimum volume (I.6.g.) :
 8 cubic feet per bushel of hard clams or oysters
 5 cubic feet per bushel of soft shell clams
Maximum depth of shellfish (I.6.h.) :
 3 inches for hard clams and oysters
 8 inches for soft shell clams
- Processing time (I.6.i.) :
Minimum of 48 hours
- Raw product microbiological quality (I.2.b.iii.) :
Estimated for SDP and determined in the process verification study so process consistently meets the end-point criteria

- End-point criteria (I.8.g.) for various sampling intensities
- Process monitoring :
 - Routine sampling program (I.8.a.)
 - Continuing evaluation of plant performance (I.8.c.)
 - Special requirements for more intensive sampling (I.8.d.)
 - Daily untreated and treated process water samples (I.5.d. ; I.8.e.)
 - Samples properly analysed (I.8.f.)
 - End-product standards are met consistently (I.2.b.iii. ; I.8.g.)
- General plant sanitation encompasses all of the construction, maintenance, and sanitary practices cited in the following sections :
 - 1.3. Location, design, construction (D.1.b. ; D.1.e. ; D.2.a.-c. ; D.2.e.-g ; D.3. through D.10.)
 - 1.4.d. Handling (B.1.a.-e. ; B.1.g-i. ; B.3. ; B.4.a.-b. ; B.5.b. ; E.2.b. [D.1.a.-c. ; D.1.e.f. ; D.1.h. ; D.2.a.-f. ; D.3.-D.7 ; D.8.a.-b. ; D.8.d.-e. ; D.9-D.11. ; D.14.] ; E.2.c. [D.23.] ; E.2.d.-e. [D.14.a. ; D.23.]
 - 1.5.a. Tanks and plumbing maintained in good repair (D.9. ; D.13.a. ; D.13.f.)
 - 1.6. Operating procedures (wash, cull, storage, lot integrity) (Sections B-F ; ZI CFR 110)
 - 1.7. Maintenance and cleaning (D.11. ; D.14. ; D.15.b. ; D.15.c.)
 - 1.9. Wash, cull, package, lot integrity, storage at $\leq 10^{\circ}$ C
- 5. Plant evaluation (process verification) study (I.2.b.iii.) :
 - Determine maximum allowable 0-hour fecal coliform level so that end-product criteria are met consistently (I.2.b.iii.)
 - Conducted over sufficient time to encompass environmental extremes in harvest area and depuration facility (I.2.b.iii.)
 - Maximum allowable level of turbidity (I.5.e.)
- 6. Records and record keeping :
 - Harvest records (I.4.e.)
 - Tagging (I.4.f. ; I.9.d.)
 - Treatment records (I.10.c.)
 - Retention (I.8.h. ; I.10.d.)

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