2nd INTERNATIONAL WORKSHOP ON SHELLFISH AREA CLASSIFICATION AND MANAGEMENT – APPLICATIONS OF SANITARY SURVEYS

A. PHILOSOPHICAL CONSIDERATIONS - U.S. AND EU SYSTEMS

U.S. and EU systems each provide a framework of controls for the safe production of bivalve molluscan shellfish. Whilst the two systems differ in a number of aspects, the overarching aim of both is to protect shellfish consuming public from fecally borne and autochthonous pathogens - in this they are largely successful.

Comparability and equivalency initiatives between the FDA and EU have been underway for some time and are considered likely to reach a conclusion shortly. The tentative result of discussions to date has been the recognition that EU Class A and US Approved area shellfish are very similar with respect to risk whereas shellfish from EU Class B and Restricted areas appear to differ by degrees, in part dependent on the quality of the Class B area. Technical and microbiological basis of these, and other similarities (and differences) were further explored by delegates at this workshop[1].

Sections below summarize workshop findings.

1. Sanitary Surveys

- Sanitary surveys can be considered to be akin to risk assessments

- ❖ Reports- Components and outputs of NSSP and EU survey reports are similar; however, outcomes (uses) are different –*NSSP surveys inform decisions on **area classification and management** (**including monitoring**), whereas EU surveys enable the establishment of sampling plans for ongoing monitoring*.

- ❖ Initial survey and periodicity of review – EU legislation requires that all new (from 2006) and reclassified areas require a sanitary survey. EU guidance further recommends Member States put systems in place to establish sanitary surveys for all areas by 2015, with updates if significant changes occur or within 6 years. NSSP shellfish area classification requires detailed sanitary surveys to be completed for all shellfish areas, with annual updates, triennial updates, complete reassessments every 12 years, and a watershed approach.

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[1] Biotoxin management strategies were considered beyond the scope of the workshop and were excluded from these considerations

❖ NSSP pollution source assessments quantify or estimate contamination loads and impacts from sources on shellfish areas.

2. <u>Classification and harvesting</u>

❖ NSSP classifications aim to reflect the enduring and predictable sanitary quality of shellfish growing areas, with consideration of contiguous waters and based upon the outcomes of the sanitary surveys and periodic review. Verification is by regular water sampling and testing for faecal coliforms – *classification refers to a body of water, not shellfish species.*

❖ In the EU classified areas consist of discrete, delineated portions of an estuary or shoreline from which shellfish are harvested, regular monitoring data informs the classification (with monitoring points selected on the basis of the outcomes of the sanitary survey) – *classification refers generally to a shellfish species, not body of water*.

❖ The NSSP requires establishment of prohibited areas around sewage sources and forbids any direct fecal discharges into areas classified as Approved. EU legislation does not explicitly require the establishment of buffer zones, or minimum distances from pollution sources. Guidance in this respect is however provided in the EU Guide to Good Practice.

❖ Harvesting under the NSSP is managed, when prescribed under a shellfish area management plan. This is achieved by officially closing and re-opening areas according to predefined criteria (such as rainfall), and is controlled by law enforcement officials. EU legislation does not prescribe management plans. However, the EU system does require that areas are closed 'where the results of sampling show that the health standards for molluscs are exceeded, or where there may otherwise be a risk to human health.

3. <u>Flesh versus Water</u>

❖ The EU requires collection and testing for *Escherichia coli* from at least 8 shellfish flesh samples per year, results are reviewed annually (taking into account the last three years of monitoring data), classification is awarded on the basis of the assessment. Water testing may be carried out as part of the sanitary survey but

is not collected routinely as part of the monitoring programme. Methods are prescribed and required to meet ISO/IEC 17025 quality standards. *Flesh not water. E. coli not fecal coliforms.*

❖ The NSSP requires water sample locations be established to assess impacts from pollution sources and verify shellfish area water quality, with designated locations in the shellfish area sampled and tested for fecal coliforms at least 5 or 6 times per year, and results of the most recent 15 or 30 samples are reviewed annually. *Water not flesh. Fecal coliforms not E. coli.*

❖ Under the NSSP water sample locations may be established anywhere and up to any maximum number to characterize sanitary quality of shellfish harvest areas. Under the EU system flesh sample locations (sampling points) are established, according to the sanitary survey, to characterize the sanitary quality of shellfish harvested.

4. **Management of harvesting**

❖ NSSP Approved and EU Class A areas are designated for the production of shellfish for direct marketing and raw consumption – no further post harvest processing is required.

❖ NSSP Restricted and Class B areas are designated to produce shellfish for post-harvest purification processing by depuration or relay before marketing for raw consumption. Restricted area harvesting permitted with special permit and supervised by Authority only.

❖ EU Class C areas are designated to produce shellfish for purification by relay before marketing for raw consumption.

❖ "Unclassified" areas are managed under the NSSP as prohibited. Harvesting from "Prohibited" areas is not permitted under the EU system.

❖ Emergency closures are introduced for WWTP failures, flooding, major storms, spills, or other adverse events under both systems.

❖ Most US States tend to manage harvest of all shellfish versus a species-by-species approach. With some exceptions EU Member States separately classify, monitor and manage on species-by-species basis.

5. **End-Product Compliance**

Testing is not required by the NSSP for Approved area and long-term relayed shellfish. EU shellfish testing and method is stipulated in HACCP plan requirements and regulatory end product compliance with an *E. coli* criterion.

6. <u>Pathogen Monitoring</u>

- Testing for pathogens is not required by NSSP for shellfish, unless implicated by reported illness or as stipulated for State management plan or hazard control plan. Pathogen testing is not required by EU legislation although is foreshadowed in legislative text when methods (for viruses and *Vibrio parahaemolyticus*) are sufficiently developed.

7. <u>Training and supervision</u>

- NSSP standardized training provided to State shellfish program officials by FDA annually or as needed. EU training and supervision of official control laboratories is the responsibility of the EU and National Reference laboratories. EU reference methods are prescribed and are required to accredited to ISO IEC 17025.

8. <u>Audits</u>

- The FDA conducts annual audits in all NSSP States and biennial audits in NSSP-participating countries. In the EU the Member State Competent Authority is required to audit a food business operators HACCP plan. The EU's Food and Veterinary Office carries out audit of shellfish systems every 3 – 5 years on a risk assessment basis.

9. <u>Law Enforcement</u>

- Law enforcement officers are routinely required to enforce harvest restrictions and control shellfish harvest in the U.S. Competent Authorities are tasked with enforcement across the EU.

B. VISIONS OF A UNIFIED SHELLFISH SAFETY SYSTEM

No two molluscan shellfish growing areas are exactly alike; each has a unique set of characteristics. The microbiological hazards potentially transmitted by shellfish and the

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consequent risks to consumers can vary significantly by world region, country, state and season. Additionally, raw shellfish present a higher risk relative to most other food that are consumed after cooking. It is not feasible to test for every potential or actual hazard associated with shellfish routinely thus controls based upon proxy indicators of risk have evolved since the 1900's. Preventing illnesses and intoxications among shellfish consumers is the prime objective of any shellfish safety programme irrespective of the approach; when applied effectively these can help to assure a relatively safe product.

Following presentation of technical aspects of both programmes and discussion the workshop identified that:

- For compliance with the EU system, the NSSP and U.S. States would need to enhance the legal basis of the NSSP, conduct *E. coli* flesh testing, ensure analytical labs were certified and employ equivalent, validated methods of analysis.

- For compliance with the NSSP system, the EU Member States need to establish minimum [management] requirements, consider shellfish area classifications in light of the sanitary quality in waters including contiguous areas and conduct comprehensive, regular audits.

- At present, it was considered feasible to conduct equivalency assessments at specific pre-qualified sites using an area-by-area approach.

The workshop further considered building a prospective "best practice" components of a shellfish safety programme. A best practice approach included:

- Classification of shellfish areas based on sanitary quality – *considered the most effective approach for preventing fecal-borne hazards being transmitted by shellfish.*

- Sanitary surveys – *characterizing a shellfish area is considered to be fundamental in safe shellfish production.*

- A documented risk assessment – *possible approach for every shellfish area, feasible and could be relied upon to prevent unsafe shellfish.*

Major components of a "**documented risk assessment**" might include:

   a. A Sanitary Survey Report that includes:

(1) Watershed survey results;

(2) Shoreline survey results;

(3) Pollution source assessments;

(4) Hydrographic factors;

(5) Bacteriological survey results, and future viral and biotoxin results;

(6) Impacts from meteorological and environmental factors;

(7) Analyses of all information and data available;

(8) Pollution source assessments and mitigations;

(9) Identification of areas unsuitable for shellfish harvesting;

(10) Identification and delineation of shellfish area, boundaries, and designated classification

b. **A Comprehensive Management Strategy that includes:**

(1) Targeted monitoring plans;

(2) Established critical limits (criteria) for designated classifications;

(3) Identification of suitable post-harvest processing control options;

(4) Closure and length of closure criteria;

(5) Definable reopening criteria;

(6) Harvester, processor and boater education programmes;

(7) Regulator training and certification programme;

(8) Control of harvest plan;

(9) *Vibrio* control plan;

(10) Unified definitive closure criteria and length of closure criteria needed;

(11) Emergency situation advanced planning.

- **Labeling** is a vital component of maintaining safe shellfish production.

The workshop considered that:

a. Unified, unambiguous product labeling was essential.

b. Trace-back to harvest location was essential.

- **Pathogens**

Noroviruses[2] are considered a universal, persistent hazard - approaches to prevent them are required, these included:

a. Unified testing system – reference methods, internationally recognized quality assurance programmes.

b. Established critical regulatory limits.

c. Identification of sources of human sewage, which may transmit viral pathogens.

d. Requirements that shellfish areas are located sufficiently far from polluting sources (dilutions of sources or distances).

- **Post harvest processing**

a. Defined and verified criteria for depuration;

b. Defined and verified criteria for relay;

c. Defined and verified criteria for other post harvest processing strategies.

- **Compliance** – the workshop recognized that compliance with requirements was essential.

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[2] Other fecal borne pathogens should also be considered e.g. hepatitis A virus, *Giardia*, *Salmonella* spp.

a. Routine, comprehensive system audits by Competent Authority;

b. Occasional targeted or comprehensive audits by outside competent authority.

- **Epidemiological surveillance and communication systems** - should be active, not passive, in order to readily and clearly identify illness or intoxication cases and outbreaks caused by shellfish.

- **Consumer advisories** should be available

a. Standardized language;

b. Unified messages;

c. Wholesale and retail levels.

Comments noted but not fully discussed due to lack of time are as footnotes[3,4,5,6,7,8,9,10,11]

C. RESEARCH AND DATA GAPS

1. Significance of environmental impacts - influence of seasonal, temperature, and related environmental factors.

2. Adequacy of management strategies:
   a. Verification of appropriate trigger levels, lengths of closures, and re-opening criteria under different conditions.
   b. Adequacy of post-harvest treatment processes (depuration and relaying) to control viruses in shellfish from Class B and Restricted areas.

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[3] Sanitary surveys are a critical, fundamental cornerstone for identifying risks

[4] Shellfish from pristine areas are readily managed safely

[5] Routine monitoring for specific naturally-occurring hazards that historically have never occurred in a region is unnecessary

[6] Even for secondary sewage treatment sources, a standard for a protective buffer zone is needed

[7] The variety of wastewater treatment operations necessitates developing options for managing shellfish resources that are variable and fit for purpose

[8] Verify the appropriate trigger levels, lengths of closures, and re-opening criteria for rainfall events with non-point sources versus those with activated sewage point sources

[9] Routine monitoring for intermittent pathogens conveyed by fecal contamination is not essential or cost-beneficial.

[10] After closure and remediation, re-opening criteria should be verified by water and meat testing.

[11] *E. coli* may offer a more accurate assessment of fecal inputs than generic fecal colifoms.

c. Definition of the acceptable level of dilution from source to shellfish resource considering site specific variations. Consideration of differential survival differences for bacteria, bacteriophage and enteric viruses.

3. Adequacy of post-harvest treatment processes (depuration and relaying) to control viruses in shellfish from Class B and Restricted areas.

4. Research efforts on noroviruses are recommended.
    a. Periodic retail shellfish surveys.
    b. Enhanced epidemiological surveillance and reporting.
    c. Illness outbreak investigations on root causes and remedies.
    d. Pollution source and impact studies.
        i. Wastewater treatment plant and collection systems.
        ii. Individual subsurface disposal (septic) systems.
        iii. Marine sanitation devices and vessel discharges.
    e. Infectious dose calculations.

5. Development of a global process for characterizing and managing shellfish areas, and mandatory actions to take; decision trees etc.

D. WORKSHOP RECOMMENDATIONS

1. It was agreed a consensus approach on best practice should be reached with a assessment tool box providing fit for purpose strategies according to *inter alia* the characteristics of the area, species, pathogen risks, etc.

2. Further to the above, FAO/WHO should be approached to support an international expert working group to draft a "best practice" guide based upon the preexisting framework used in the Codex Ailmentarius: Code of Practice for fish and fisheries products – section 7- live and raw bivalve molluscs[12]

3. The outcomes from the proposed working group should have the objectives of:

    a. Providing a flexible framework for:
        i. the technical application of current shellfish sanitation programs
        ii. the development of new programs by countries that do not currently have such health controls

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[12] http://www.fao.org/docrep/011/a1553e/a1553e00.htm

b. Enabling the broader application of shellfish sanitation programmes in order to:
   i. Protect a larger proportion of the world's population from shellfish-associated infections
   ii. Assist a wider range of countries to trade safe shellfish

4. Technical consensus on recommended guidance should ultimately lead to a review of policy requirements to allow its application to established programs.