Classification and Monitoring

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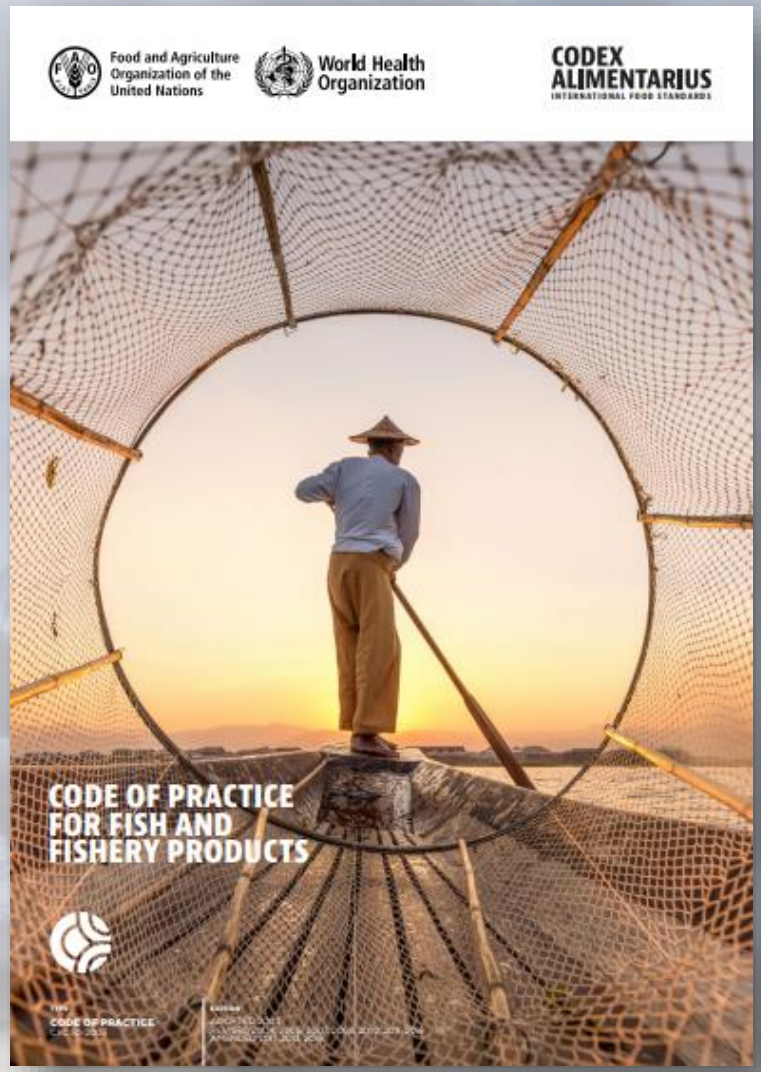
What do we mean by monitoring?

- The **Codex code of practice** refers to monitoring water/bivalves or sediments
- **Monitoring** is the **routine way** that we can collect **evidence** for the **presence/absence** of **hazards** in a production area
- It **cannot replace** risk profiling or the growing area assessment because:

  - *The hazard may not always be there*
  - *Even if there, concentration may vary with season, weather or time of day*
  - *The hazard may only be present in high amounts after unexpected events*



Primary and ongoing monitoring, how should we do this….?

From **the growing area risk profile** and **growing area assessment** we understand the **hazards**

We have a sampling plan……

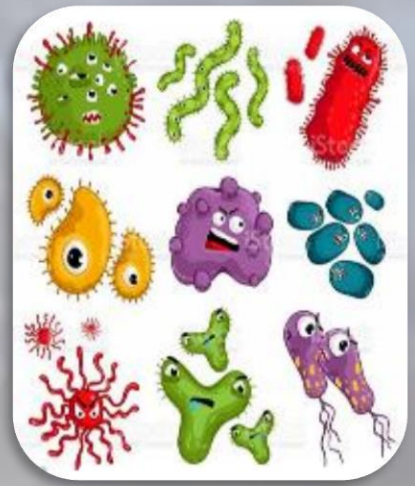
- Growing area identified
- Sampling site identified
- Matrix and species
- Location of sampling points, tolerances
- Frequency and depth
- Determinands
- Sampling body and authorization

Sampling plan tells us:

where to sample

matrix to sample

what to **test** for



Primary monitoring helps us to **establish a classification** and determine necessary controls

May identify need to **modify the sampling plans** for ongoing monitoring

Ongoing monitoring gathers data to **establish and confirm classifications**

Monitor indicators or pathogens for classification….?

Decision depends on:

Existing Regulations, intended market

Sampling and/or laboratory capability

- **Faecal indicators** Provide an indication of risk from a range of pathogens
- More indicator = more risk
- Rely on time series and lots of data

If a wide range of animal or human sewage-derived pathogens are expected

- **Pathogen monitoring** measures direct risk
- Multiple pathogens may require multiple tests
- Tests generally more expensive/difficult

If only enteric viruses are expected and may not be controlled by faecal bacteria e.g. intermittent sewage spills

Monitoring pathogens for classification…

- If the risk profile and growing area assessment indicates specific pathogens could be present (or present in unacceptable concentrations)
- Usually only applied to bivalve flesh
- Specific testing of parts possible where only those parts of the bivalve are eaten
- Influenced by consumption patterns

Monitor water or bivalve shellfish for classification….?

Decision depends on:

Existing Regulations, intended market

Costs of sampling, practicality of sampling

Water and bivalve sampling should be:

- at fixed and identified points
- representative of the area
- either random or worse case
- frequent enough to reflect changing conditions

Need to consider health and safety of samplers

Monitor bivalve shellfish or water for classification….?

Could be each species or an ‘indicator’ species (representative of more than one species)

Reflect the prevailing concentrations in the water

Should be at least 12-15 animals per sample

Collect by ‘normal’ method of harvest so may need a boat

But can be collected at low tide if necessary

Water sampling usually requires a boat

Results often very variable with time (hours/days/months) and across an area

So may need more monitoring points and take more samples

Generally restricted to *E. coli*/faecal coliforms

Classification - components

Classification is a way of **categorising risk**

- It allows for **common risk management** procedures
- And, **common processing requirements**

It enables an **estimate** of **near** to **mid-term risk** based upon **past** performance

Steps to classification

Growing area risk profile

Growing area assessment

Results from primary monitoring

Initial classification

Results from ongoing monitoring

Established classification

Profile

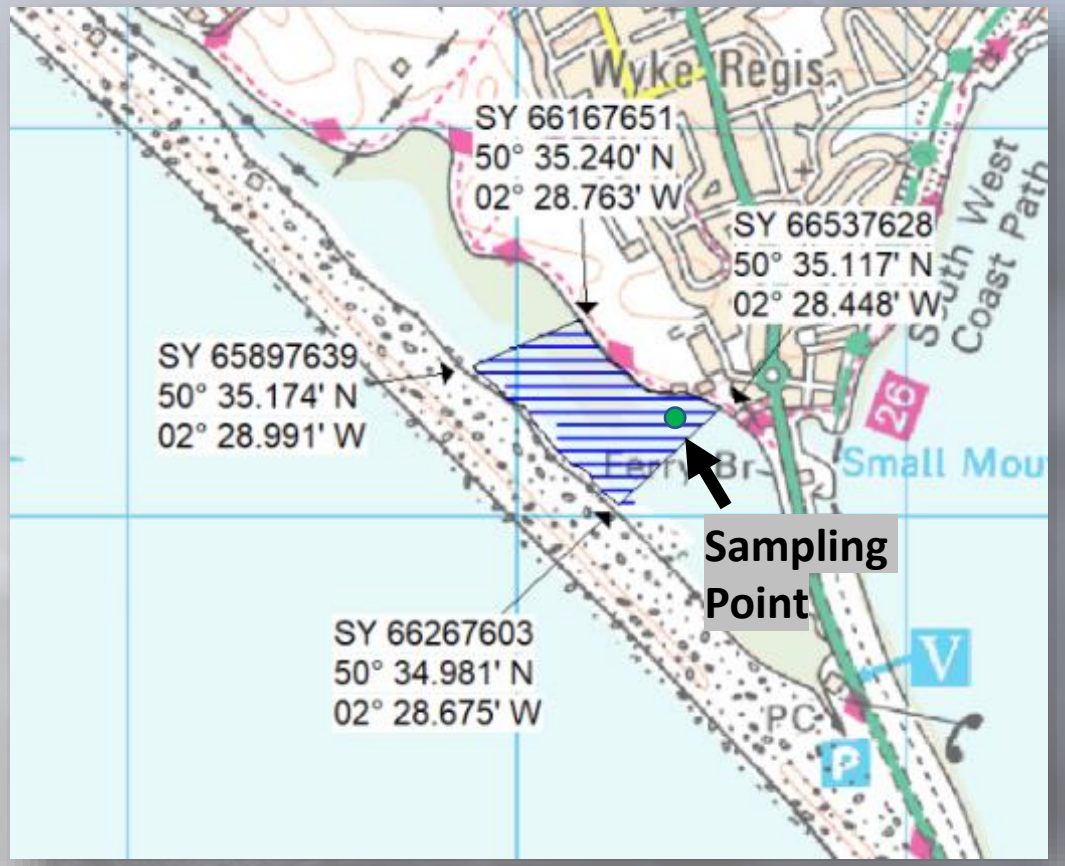
Assess

Review

Classify

Classification – definition of the area

- The classification boundaries of the area should be defined using geographical coordinates (ideally 10m accuracy)
- The area should be homogeneous in terms of contamination
- It should have at least one sampling point



Classification - types

Requirement may be stipulated by trading partners

If no such requirements exist – define the **public health objective** then decide if criteria need to be **developed** or if existing international criteria can be applied

No treatment before eating live, raw e.g. Codex standard n=5, c=1, m=230, M=700 *E. coli* MPN/100g

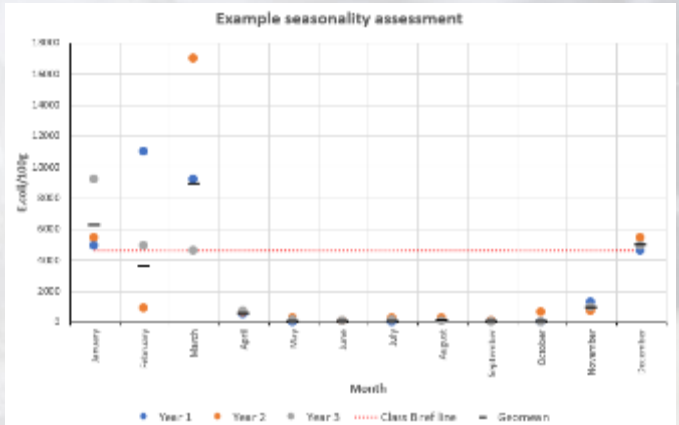
Treatment needed	US classification	Microbiological standard in water	EU classification	Microbiological standard in shellfish flesh
None	Approved	GM <14 FC cfu/100ml and 90%ile <43 FC cfu/100ml	Class A	80% ≤230, all results ≤700 *E.coli*/100g flesh
Purification or relaying	Restricted	GM <88 FC cfu/100ml and 90%ile <260 FC cfu/100ml	Class B	90% ≤4600, all results ≤46,000 *E.coli*/100g flesh
Protected relaying (> 2 months)			Class C	All samples ≤46,000 *E.coli*/100g flesh

Moderate treatment before eating live, raw e.g. US restricted areas or EU class B (depuration or relay)

Substantial treatment before consumption e.g. EU class C criterion (relay or heat treatment)

Conditional classifications

- For areas subject to intermittent/periodic microbiological pollution
- **Conditions must be predictable i.e. to allow management**
- Certain environmental conditions must be met (e.g. season, rainfall, salinity, river flow, performance of sewage treatment works etc.) in order to meet the classification type
- Areas may be closed when the conditions for the class level are not met **OR** classified at two different levels.
- When using indicators (e.g. faecal indicator bacteria) the timing of the open status or better classification level should consider clearance of the relevant hazards (e.g. Norovirus) to acceptable levels.



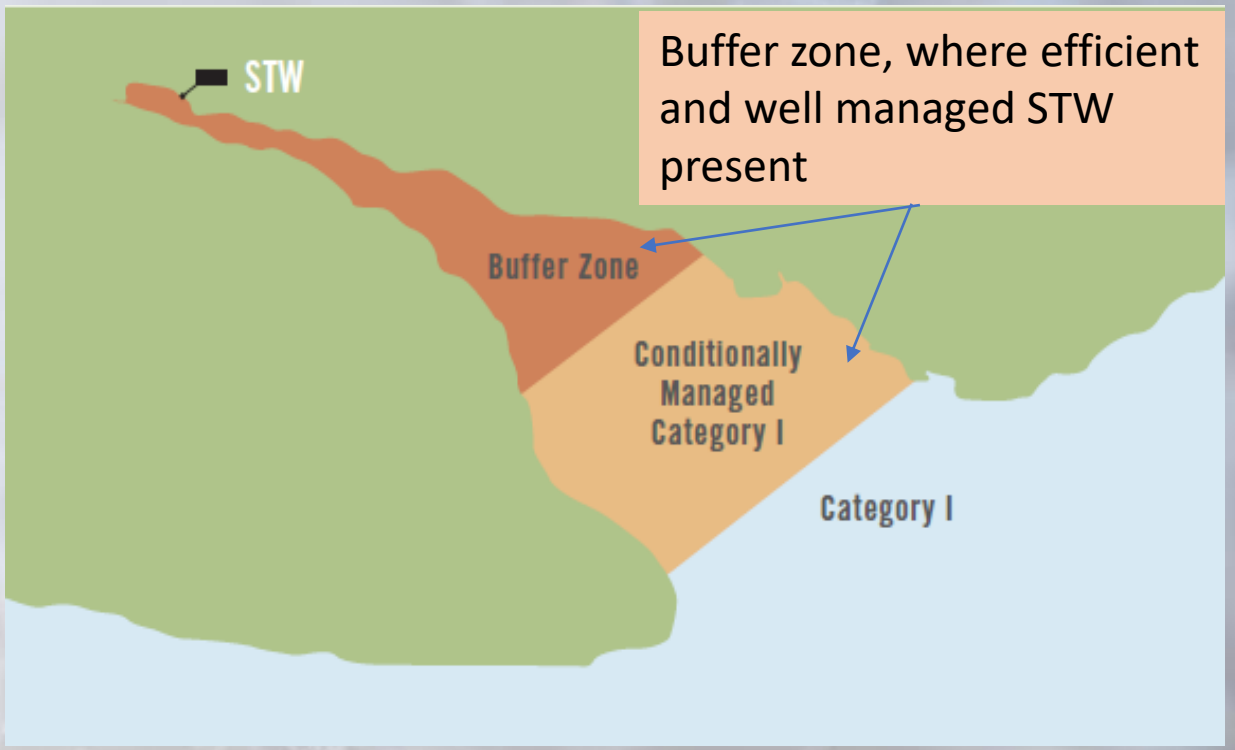
Classification – Buffer zones

Buffer zones around sources of contamination are **recommended**
Buffer zones are **stipulated by some national legislation**/programmes e.g. US National Shellfish Sanitation Program (NSSP)

Buffer zones = prohibited areas around a point source or hazard (marinas or other boating activities)

Size of the area can be established by:

- Dilution calculations
- Salinity studies
- Drogue studies
- Dye tracing studies
- Using tracers
- Hydrodynamic modelling



Summary - Classification and Monitoring

- **Codex** requires **monitoring**
- Monitoring provides **evidence** for the presence of **hazards**
- Monitoring **data** establishes **classifications**
- Classification standardises **risk management** and **processing**
- **Protects consumers from risk**
- Enables shellfish industry to **plan**
- **Facilitates trade**