FAO Reference Centre for Bivalve Sanitation workshop on the development of bivalve production in Africa

8th – 10th July 2025, Nairobi, Kenya

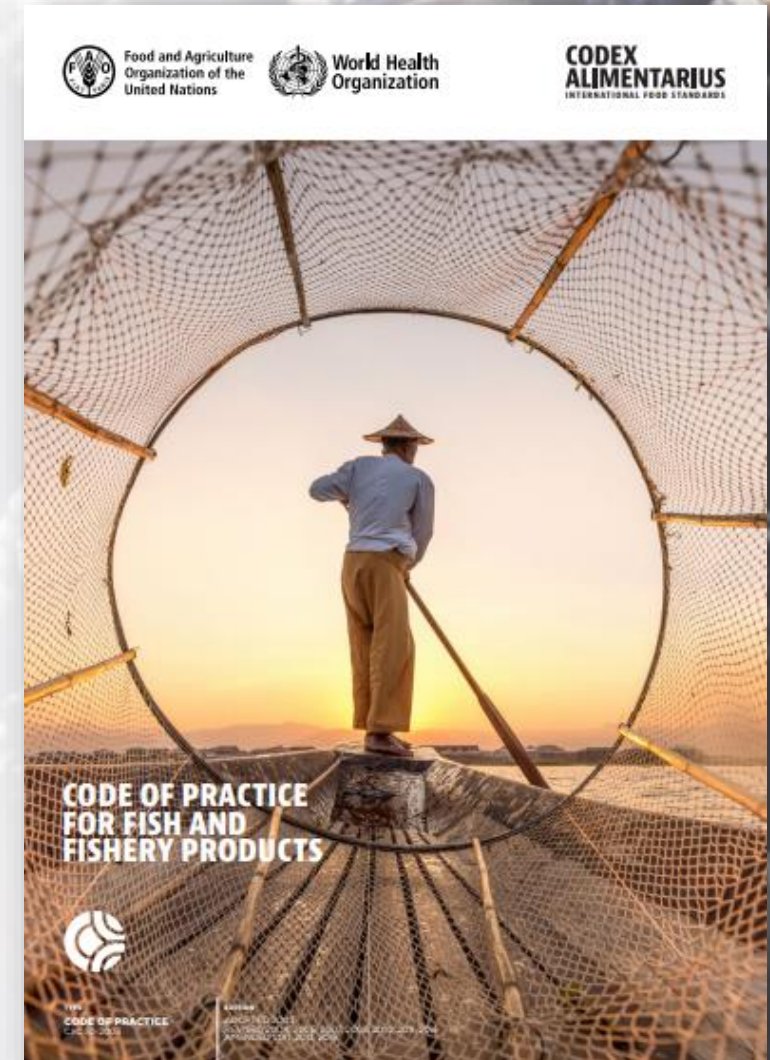## Preliminary monitoring including data assessment

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Definition of monitoring?

- **Codex code of practice** refers to monitoring water, bivalves or sediments
- **Monitoring** : **routine way** that we can collect **evidence** for **presence/absence** of **hazards**
- **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*

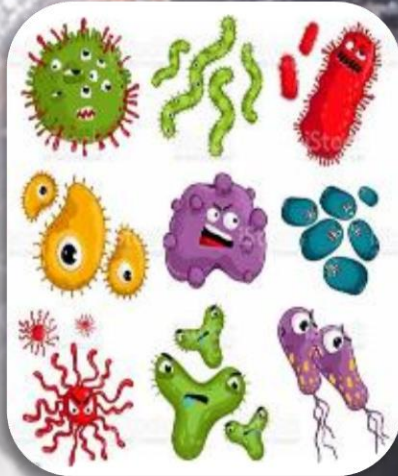# Primary and ongoing monitoring, how should we do this….?

- Understand hazards from **G**rowing **A**rea **R**isk **P**rofile and **G**rowing **A**rea **A**ssessment

- We have a sampling plan

Sampling plan tells us:

where to sample

matrix to sample

what to test for

Bivalve Mollusc Production Areas in England and Wales: Sampling Plan

Production Area: The Fleet
Local Authority: Weymouth PHA

Classification

Classification zone	RMP	RMP name	NGR	Latitude & Longitude (WGS84)	Species	Growing method	Harvesting technique	Sampling method	Tolerance	Frequency
Fleet Oyster Farm (Pacific oysters)	B25AI	Fleet Oysters	SY 6647 7627	50° 35.112 N 2° 28.499 W	Pacific oyster	Trestle	Hand	Hand	10m	Monthly

For classification results please click on the following link (select the species to display the RMP results)
https://www.cefas.co.uk/data-and-publications/shellfish-classification-and-microbiological-monitoring/england-and-wales/shellfish-monitoring-results/

Biotoxin monitoring

Classification zone	RMP	RMP name	NGR	Latitude & Longitude (WGS84)	Species	Frequency of flesh sampling	Frequency of water sampling
Fleet Oyster Farm	B25AI	Fleet Oysters	SY 6647 7627	50° 35.112 N 2° 28.499 W	Pacific oyster	Four weekly	1st April to 30th Sept – Fortnightly 1st Oct to 31st Mar – Four weekly

For biotoxin results from the current year please click on the following link:
https://www.cefas.co.uk/data-and-publications/habs/

Updated by	Date
S Hart	3/12/2020

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

Ongoing monitoring gathers data to **establish and confirm classifications**
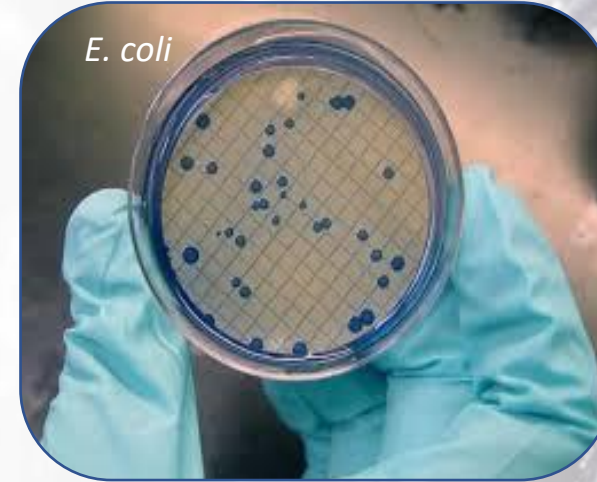
Monitor indicators or pathogens for classification?

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

E. coli

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

- **Pathogen monitoring** measures direct risk
- Multiple pathogens may require multiple tests
- Can be expensive/difficult

Male specific coliphage

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 pathogen

- Usually only test bivalve flesh directly

- Specific testing of parts possible where only those parts of the bivalve are eaten

- Influenced by what intended market consumers eat

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 water or bivalve shellfish 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 categorises risk

- Allows for common risk management procedures
- And, common processing requirements

Estimate of current/future risk based upon past performance

Growing area risk profile

↓

Growing area assessment

↓

Results from primary monitoring

→ Initial classification

↓

Results from ongoing monitoring

→ Established classification

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

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

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 (Category I)	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 (Category II)	90% ≤4600, all results ≤46,000 *E.coli*/100g flesh
Protected relaying (> 2 months)			Class C (Category III)	All samples ≤46,000 *E.coli*/100g flesh

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

Conditional classifications

- For areas subject to **predictable** intermittent/periodic microbiological pollution
- Certain conditions trigger change in classification status (e.g. season, rainfall, river flow, performance of sewage treatment works etc.)
- Areas may be either closed **OR** classified at two different levels
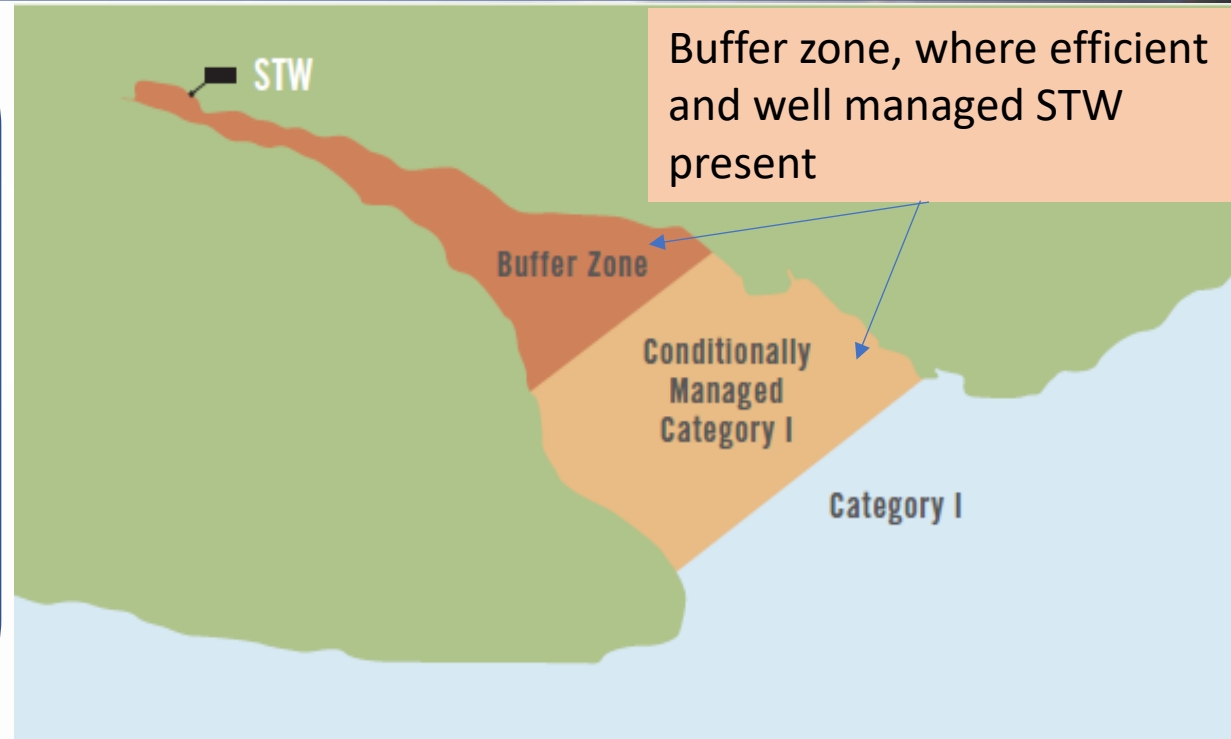
Classification – Buffer zones

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

Buffer zone, where efficient and well managed STW present

STW

Buffer Zone

Conditionally Managed Category I

Category I

Example data interpretation from EU

European Regulations: 2019/627 Classification categories

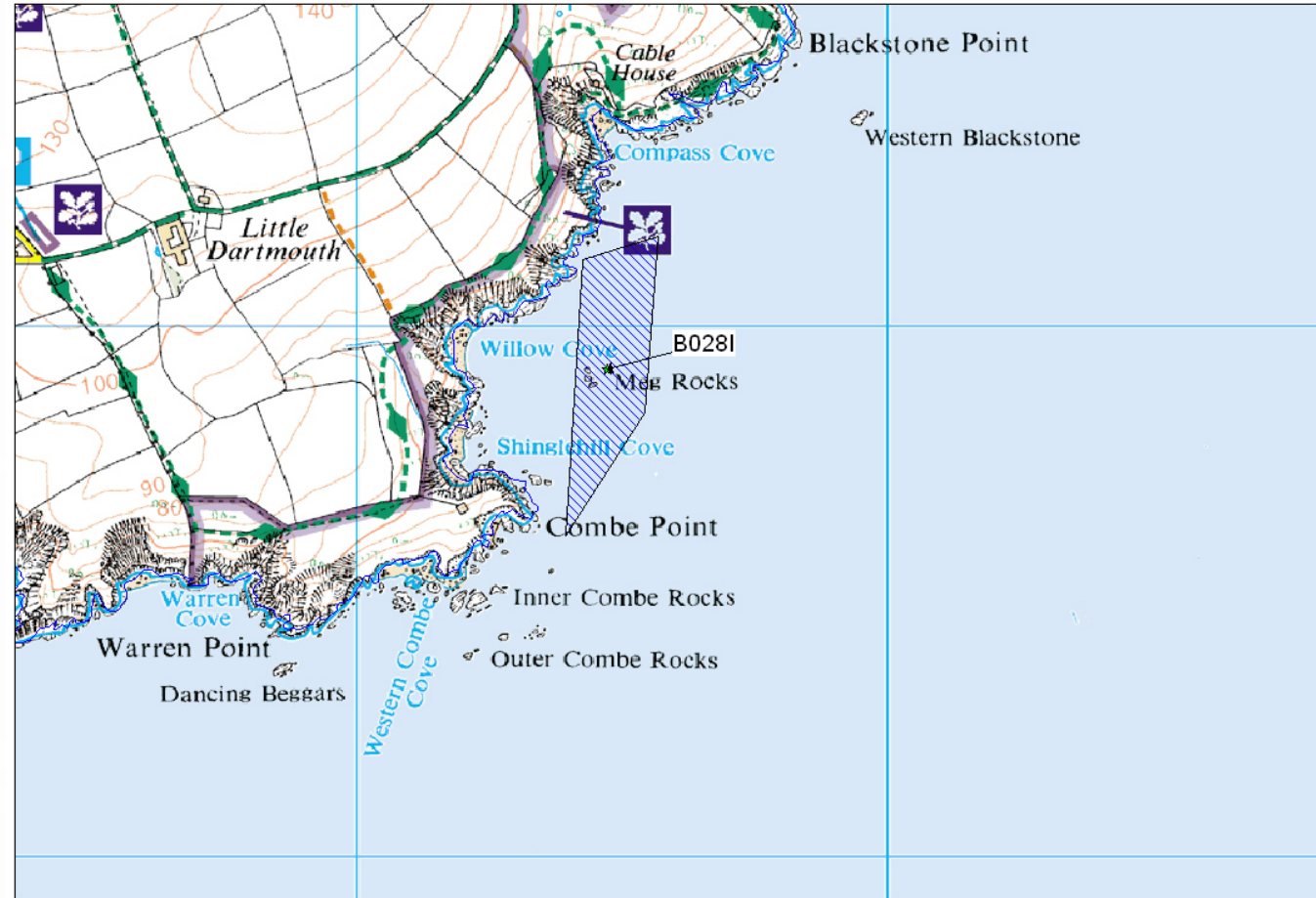| Classification (EU)	Microbiological standard
Class A (Category I)	80 % ≤230, all results ≤700 *E.coli*/100 g
Class B (Category II)	90 % ≤4 600, all results ≤46 000 *E.coli*/100 g
Class C (Category III)	All results ≤46 000 *E.coli*/100 g

Three stages of classification:

Preliminary (12 results over 6 months)

Initial full (sampling over 1 year)
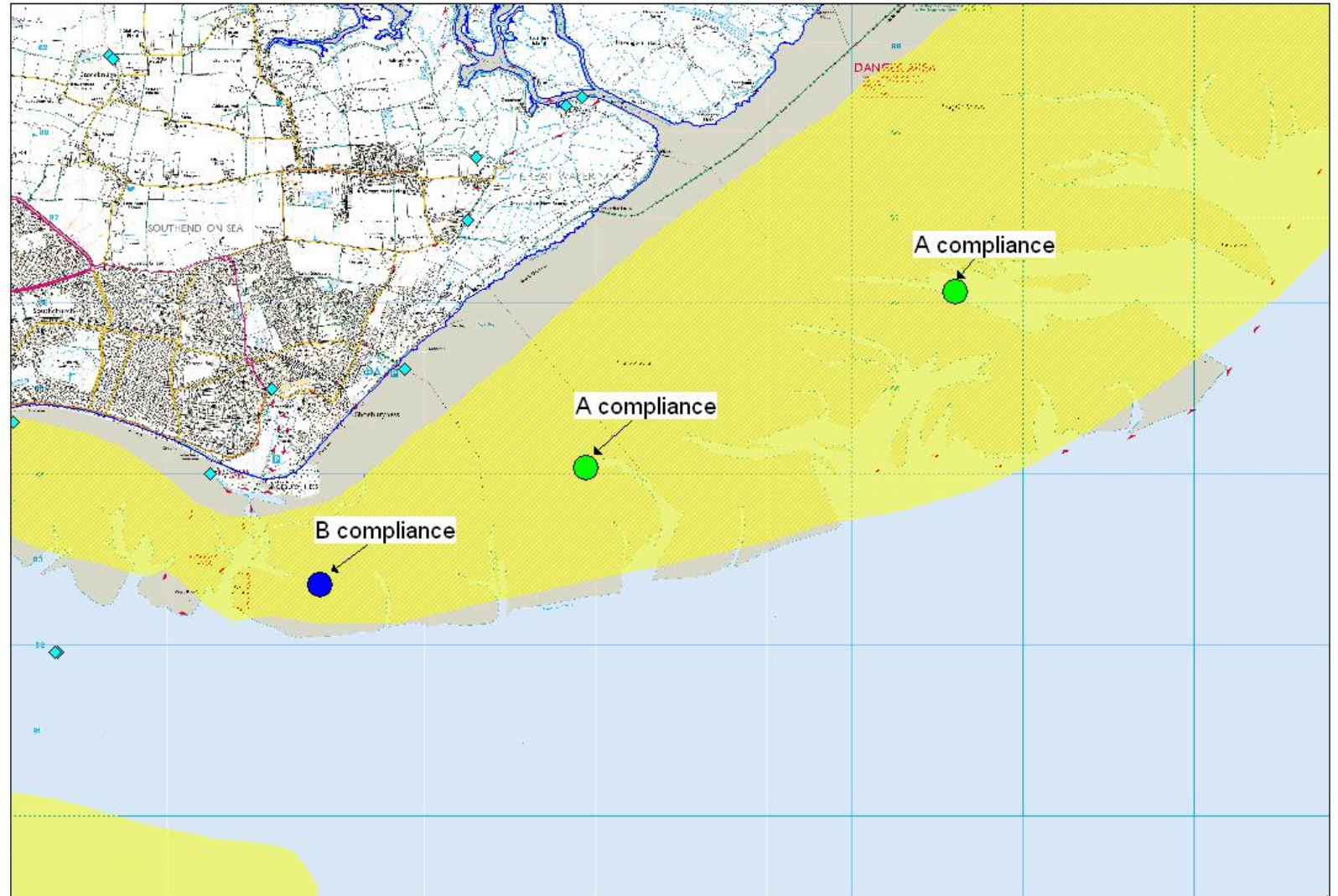
Established (sampling over 3 years)

Interpretation of data in a zone with a single sampling point

- For EU: The dataset should be assessed against requirements of EU Regulation 2019/627:
  - Class A – 230 *E.coli*/100g (80% of samples) – no result to exceed 700 *E.coli*/100g
  - Class B – 4600 *E.coli*/100g (90% of samples)
  - Class C – 46000 *E.coli*/100g

  - 3 year dataset used for established classifications

Interpretation of data in a zone with several sampling points

- Multiple points may be needed to reflect multiple sources of contamination

- If data is different between points then point showing the <u>highest</u> results for that species (or indicator species) should determine classification - unless a split classification is viable
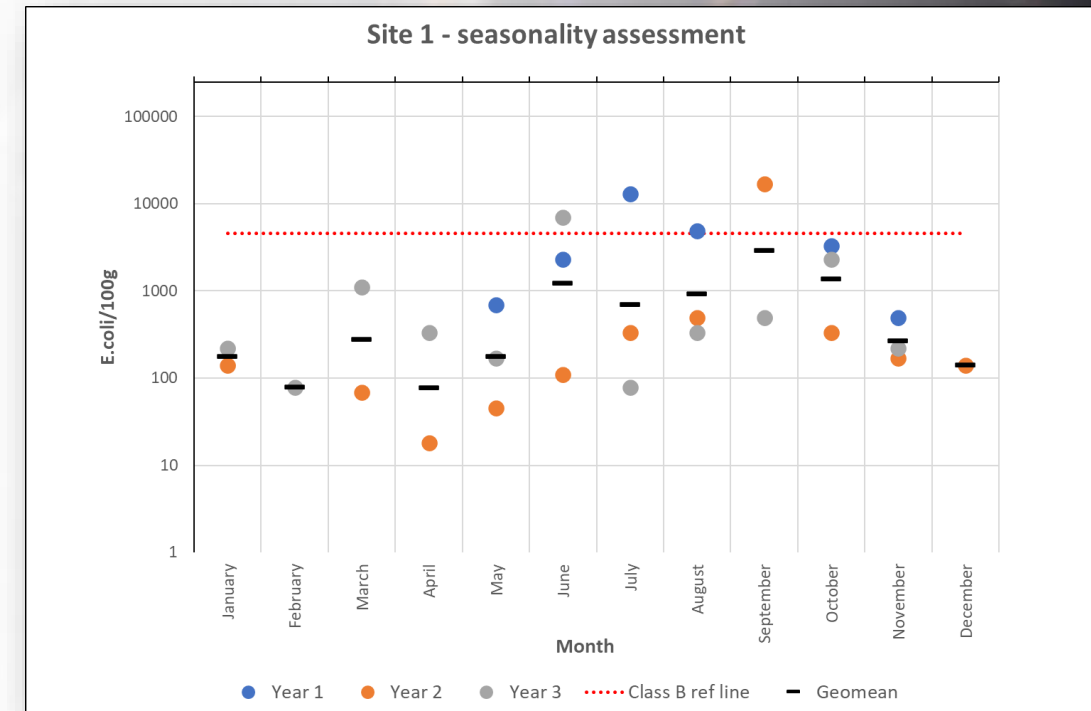
Anomalous results – EU criteria

- Results due to the following may be excluded ('waived') from the classification dataset:

  1. Failure to comply with sampling protocol (e.g. temperature/time requirements)

  2. Failure of sewerage network, sewage treatment systems, animal slurry store (since rectified and unlikely to recur)

  3. Rainfall event with >5 year return period

Important to establish a causal association (not just a chance association) before waiving result
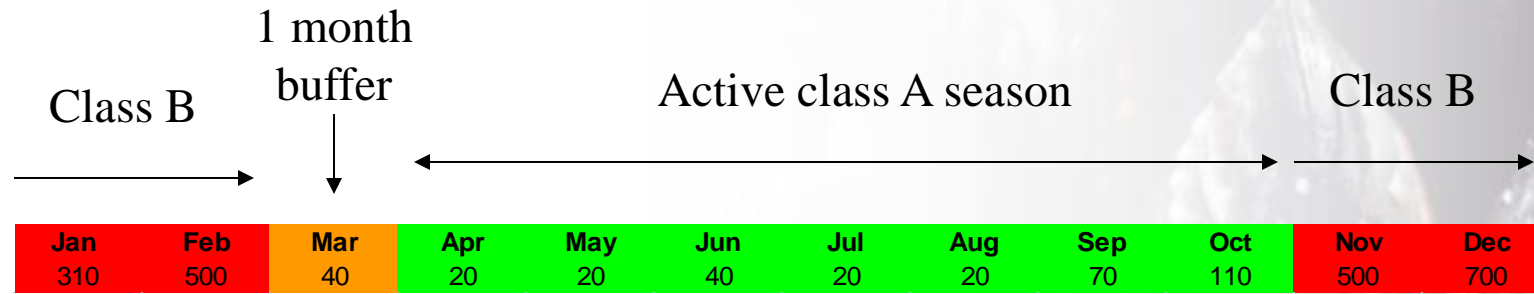
Seasonal classifications – EU criteria

- At least 3 years' worth of data showing a clear seasonal trend necessary for seasonal classification

- *'Buffer'* periods (for 'clean up'):
  - 1 month from class C to B or B to A
  - *Buffer* periods must also conform to the improved classification category

- Buffer periods allow time for shellfish to clean up prior to start of harvesting season at the improved classification level

Seasonal classifications

Class B	1 month buffer	Active class A season							Class B	

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
310	500	40	20	20	40	20	20	70	110	500	700

Summary - Classification and Monitoring

- Monitoring provides **evidence** for the presence of **hazards**
- Monitoring **data** establishes **classifications**
- Classification standardises **risk management** and **processing**
- **Protects consumers from risk**
- **Facilitates trade**

Thank you

Any questions?