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The current bivalve mollusc harvesting area classification system in England and Wales explained (under EC Regulation 854/2004)

The aim of monthly monitoring and the classification

- The purpose of monthly E. coli monitoring is to establish the classification level for the area (only)
- Classifications need to be based on a time series of results to take account of the variability of shellfish E. coli data in the environment due to weather, seasonal effects etc.
- In areas subject to intermittent contamination, E. coli levels in shellfish can vary from high levels (1000's) down to much lower levels (100's, or even 10's) in the space of only a few hours.
- Therefore, you are very likely to miss contamination events in between monthly sampling occasions.
- Monthly monitoring is <u>not</u> intended to protect public health on a reactive basis as it is nowhere near frequent enough.
- If relying on monitoring for a 'reactive system' then a much higher frequency of sampling (ideally daily) would be needed.

The chance of detecting truly rare events with monthly monitoring – 'it's just a spike'?

- If detecting high results in 1 out of 10 samples on average over, for example, 3 years then the assumption is that for approximately 10% of the time throughout the year (i.e. equivalent to 37 days), contamination events will be occurring and, very likely, when sampling is not taking place.
- Detecting truly exceptional/spike/rare events with only monthly monitoring is very unlikely.
- If a contamination event was to only happen once in a year then, with monthly monitoring, the chance of detecting it would be (crudely) 1 in 30. In reality, the odds against detection may be even higher than this as E. coli is cleared from shellfish in a matter of hours (i.e. doesn't take a whole day). For example, if a contamination event took place in the early hours of the morning and sampling took place in the late afternoon then the shellfish E. coli content may have reduced back down to background levels (although any viruses introduced by the event may still be there) and the event effectively not detected.

Downgrades can sometimes occur weeks/months after the last high result - why?

- Downgrades may sometimes occur a while after the last high monthly result and this may be followed by a number of low results. A downgrade may still be necessary, however, if the 1 and 3 year datasets are showing poor compliance. Even though more recent data is compliant it doesn't necessarily mean that contamination events have not occurred they may just have been missed due to the timing of sampling.
- Historic data generally gives a very good indication of future performance although weather patterns (e.g. wet vs dry years) can distort things which is why 3 or years' worth of data is assessed to take this variability into account.



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- Delays in downgrade action are essentially for the industry's benefit to allow time for investigations to take place with the aim, hopefully, of avoiding unnecessary downgrades. Investigation outcomes may provide justification to allow high results to be waived.
- Sometimes downgrades are delayed if the compliance is marginal in such situations obtaining more monthly monitoring data can help clarify what the right level of classification should be.

What does E. coli tell us?

- E. coli is a faecal indicator bacterium. The idea of a faecal indicator is that it is present in greater numbers than the disease causing organisms, the pathogens, thus providing an early indication of risk. Bivalve shellfish can concentrate levels of E. coli in the water by up to 100 times. From this point of view E. coli is very good where there is faecal contamination (animal or human) there will always be E. coli.
- Unfortunately, the reverse situation is not always true i.e. when E. coli is absent in shellfish, due to depuration or natural cleansing in the environment, it does not always mean that there will not be pathogenic micro-organisms such as norovirus still present. Norovirus can take much longer to clear (possibly weeks or even a month or two when water temperatures are low).

Reliance on end product testing

 Relying on end product testing for E. coli does not guarantee a safe product. For example, many outbreaks are caused by depurated shellfish meeting the end product standard as they still contain norovirus. Harvesting area monitoring gives the best indication of the faecal pollution levels to which the shellfish have been exposed. This determines the appropriate level of classification which in turn dictates the treatment necessary to produce a safe product.* End product testing in this context merely serves to confirm (as far as possible given the limitations mentioned above) that the treatment process has worked effectively and that the product complies with the requirements of the legislation.

*It is recognised that depuration is currently unable to guarantee a safe product if norovirus is present in significant levels.

In summary, the current system is protective of public health to a reasonable degree if it is applied correctly. Of course, it has its limitations and could be improved but not without significantly more expense. It is a precautionary system, using E. coli as an indicator of faecal contamination – we don't know whether this is human or animal (current test cannot differentiate) but both can contain pathogens for humans and consequently both represent a human health risk.

Cefas Weymouth Laboratory.

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