Live Bivalve Mollusc
End Product Testing (EPT)

It is the responsibility of the person or Food Business Operator (FBO) placing a food product on the market to ensure it is fit for consumption.

Frequency of testing and what constitutes a batch should be based on risks such as:

- The status of the harvesting waters as regards known or suspected algal toxin blooms.
- Sewage discharges, and trends or the presence of *Escherichia coli* and norovirus (NoV).
- Changes in the depuration or handling process, etc.

Only the FBO can make the decision as to what constitutes a batch or the appropriate frequency of testing.

The reason is that the FBO knows the history of the product better than anyone else.

A FBO can either use:

- A system of testing and positive release, which will involve holding the animals in a way that will ensure they cannot be contaminated whilst waiting for the lab results.
- Or a system of process validation where testing over a period of time is used to give confidence on the safety of the process and the product produced.

Careful and appropriate risk assessment, based on the principles of HACCP should be carried out by the FBO. This and other information will be used by the FBO to establish procedures and policies that lead to good manufacturing practices being followed. This will include an appropriate sampling plan.

It is anticipated that FBO's that can demonstrate by historical sampling that their process is valid (process validation) and that the business has effective HACCP-based procedures in place will require less end product testing.

FBOs should be mindful of *EC Regulation 2073/2005 on the microbiological criteria for foodstuffs* and its guidance on sampling. The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

This states amongst other things that, '…The new legislation on microbiological criteria for foodstuffs does not impose a general requirement for increased end product microbiological testing or positive release…'.

From 1 January 2017 the classification of category 'A' harvesting areas will be enacted.

For samples of live bivalve molluscs taken for enforcement purposes:

- No sample should exceed 700 E. coli per 100g of flesh and intravalvular liquid at any time.
- At least 80% of samples taken must not exceed 230 E. coli per 100g of flesh and intravalvular liquid.
- This suggests that at least 5 samples will be required.

If a FBO adopts the approach of process validation with the potential for reduced end product testing, there may still be occasions when more intense end product testing is required to verify the safety of product batches.

Regulators sampling results can also be used in monitoring trends. Collaboration with other harvesters in your area on sharing results may give a better picture of the overall potential microbiological or biotoxin loading to be expected.

Below are the legal minimum standards required for bivalve molluscs.

Product standard for live bivalve shellfish:

1. Less than 230 colony forming units of E. coli in 100g of flesh and intra-valvular liquid.
   a) From 1 January 2017, samples of live bivalve molluscs from Class A waters must not exceed, in 80% of samples collected during the review period, 230 E. coli per 100g of flesh and intravalvular liquid. The remaining 20% of samples must not exceed 700 E. coli per 100g of flesh and intravalvular liquid.
2. Must not contain Salmonella bacteria in 25g of flesh.
3. Be alive, fresh and in good condition.
4. Normal amounts of intra-valvular liquid at sale and adequate response to percussive tap.
5. Must taste fresh, no off-flavours and be free of detritus.
6. Must not contain marine biotoxins in excess of those stated below.

Bivalve shellfish biotoxin limits

Limits for toxins after which bivalves cannot be sold for human consumption:

- PSP (Paralytic Shellfish Poison): 800 micrograms per kilogram.
- ASP (Amnesic Shellfish Poison): 20 milligrams of domoic acid per kilogram.

For Lipophilic toxins tested by LCMS:

- For okadaic acid, dinophysistoxins and pectenotoxins together: 160 micrograms okadaic acid equivalents per kilogram.
- Yessotoxins: 3.75 milligram equivalent per kilogram.
- Azaspiracids: 160 micrograms of azaspiracid equivalents per kilogram.

DSP (for species not tested by LC-MS): DSP toxins must not be present.

Sources of information and further guidance

Seafish Bivalve webpage

Seafood Training Academy Library Guide on Bivalves

Also these documents:

www.food.gov.uk/sites/default/files/multimedia/pdfs/ecregguidmicrobiolcriteria.pdf

www.foodstandards.gov.scot/sites/default/files/volume2_14f.pdf

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2285&from=EN

www.food.gov.uk/business-industry/guidancenotes/hygguid/microbiolreg

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