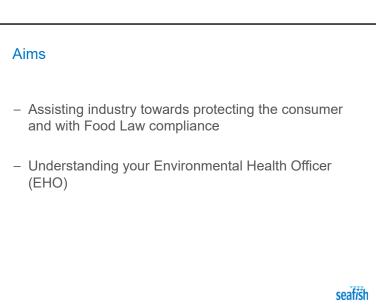


Objectives

- To provide industry with a greater understanding of what is possible, practicable and reasonable in operating a commercial purification and despatch centre in the UK
- To allow industry to be able to discuss with EHOs about their current operating protocols so that Official Controls imposed are effective and result in requirements that are not too onerous or too lenient, but appropriate, balanced, proportionate and consistent



2

Outcomes

 Greater individual understanding of the hazards involved in bivalve shellfish purification and the management controls needed to produce safer shellfish

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- Seafish / REHIS qualification

Scope

- All of the scenarios are real and have been observed
- They do not represent mainstream or normal practice
- They have been selected to illustrate key learning points

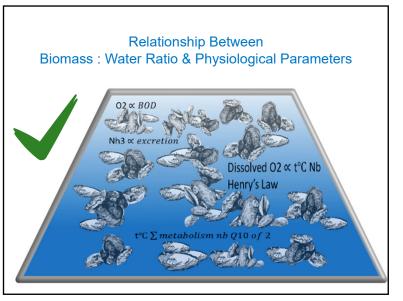
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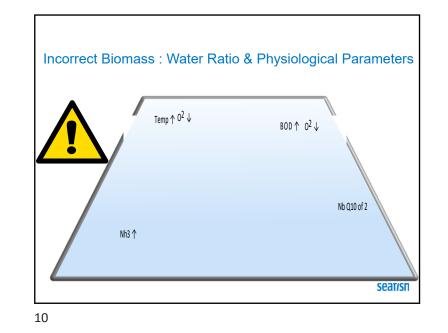


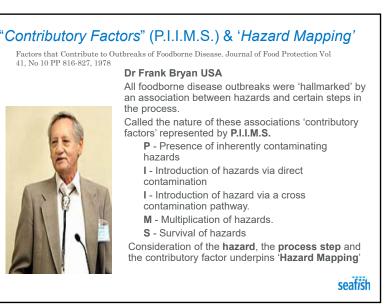


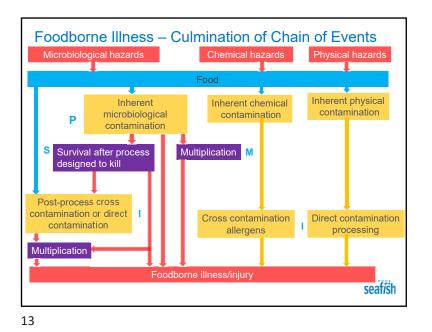
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	Time (h)	Escherichia coli (MPN/100 g)*	Escherichia coli (log MPN/100 g ± SD)*	Percentage (%)†
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	0	7.1 × 10 ⁵	5.8±0.2	100
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	4	3.8×10^4	4.6 ± 0.1	5.3
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	6		4.6 ± 0.2	6.1
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	10	2.0×10^4	4.3 ± 0.2	2.9
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	16	4.0×10^{3}	3.6 ± 0.1	0.6
0 2.4×10 ³ 3.4±0.1 0.3	20	9.2×10^{3}	3.9±0.3	1.3
	24	3.0×10^{3}	3.5±0.2	0.4
2 54×10 ³ 37+03 08	30	2.4×10^{3}	3.4 ± 0.1	0.3
2 3.4×10 5.7×0.5 0.6	42	5.4 × 10 ³	3.7 ± 0.3	0.8



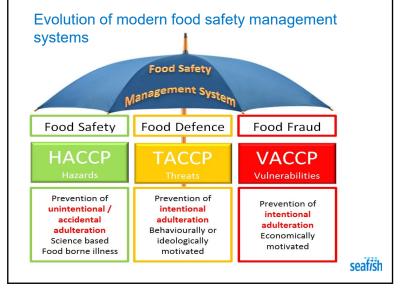








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Using contaminated water in purification operations – legal & scientific considerations

- GMPG Step 13 Purification Structural Hygiene
- Science
 - Existing purification systems are validated to treat water supplies contaminated with low levels of microbiological contamination, but not with highly contaminated water.
 - The engineering capability exists to treat even the foulest of seawater to bring it within specification. The only true limitation is the cost.

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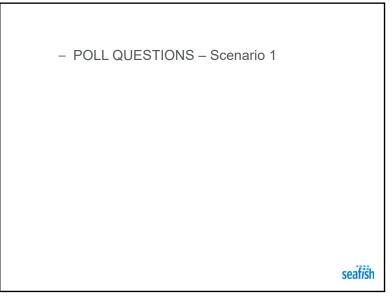
Using contaminated water in purification operations – reasonable?

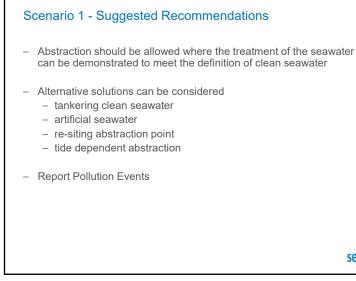
- Consider
 - Type and degree of contamination
 - Availability of effective technical solution
 - Competence of a business to implement solution
 - Availability of **alternatives** to treatment (what are these?)
- What works for your business?

Using contaminated water in purification operations – possible and practicable

- Water treatment can render any water safe – at a cost.
- Single pass systems are sensitive to abstracted water quality.
- Recirculation systems have reduced water requirements.









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Obstructed seawater feed & flow – legal & scientific considerations

- Legislation 852/2004, Chap. II, article 5
- GMPG Step 18 Purification Centre HACCP Systems
- Science
 - Reduced flow rate and oxygen levels of water
 - Potential additional contamination

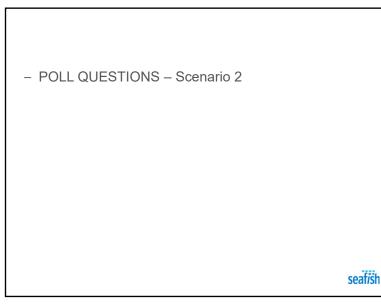
Obstructed seawater feed & flow – possible and practicable

- Caged inlet points
- In-line catch baskets
- Back flush
- with hypochlorite to deter long term fouling of pipes by mussel settlement
- Acute blockage by crabs and seabirds (isolated examples witnessed)
- System may still be operating within approved parameters, but not as efficiently as it can



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Obstructed seawater feed & flow in purification systems – reasonable?

- Discussion
- Consider
 - Flow rates
 - Dissolved oxygen levels above minimum required (5mg/litre)
 Records
 - Records
 - Verification measurements (what does your DO or flow meter say?)
 - Impact on UV efficiency
 - Remedial action required
- Why did it happen?
- Recommendations

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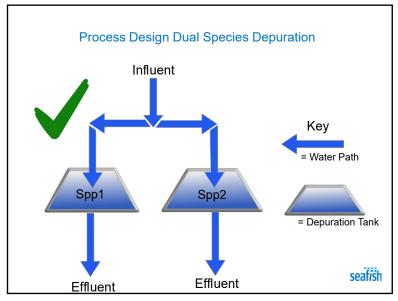
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	Considering Depuration Control Measures in Terms of tributory Factor of Introduction of Hazards by Cross Contamination.
Scenario 3:	Placing two bivalve species within the same system.
Scenario 4:	Holding crustaceans and bivalve shellfish in adjacent systems or together in the same water system
Scenario 5:	Placing purified bivalves back into active purification tanks.
Scenario 6:	Dead bivalves and mud balls in tanks.
Scenario 7:	Cross contamination during post purification handling.
Scenario 8:	Algal matt growth in purification systems and water holding tanks.
Scenario 9:	Washing purified batches with contaminated seawater.
Scenario 10:	Re-immersion in display cabinets, post purification.
Scenario 11:	Temperature & time control.
seafis	Here to give the UK seafood sector the support it needs to thrive.

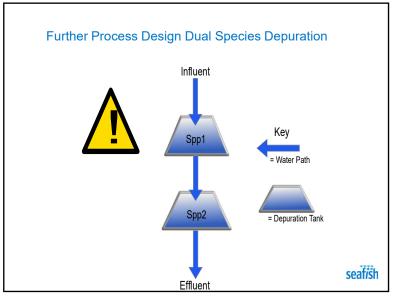
- Introduction by Cross Contamination

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SCENARIO 3: Placing two bivalve species within the same system





Two species within the same system – legal & scientific considerations

- Legislation 853 / 2004, Annex III, Section VII, Chap. IV a4 and a6
- GMPG Step 14 Purification Loading Tanks

Science

- Different bivalve species have different environmental and physiological needs
- Cross contamination is a risk

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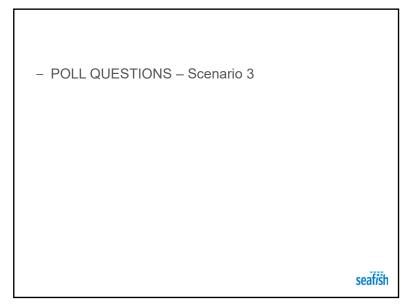


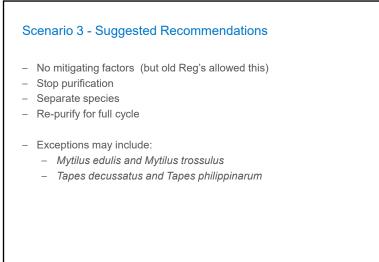
Two species within the same system - possible and practicable

- Can share water supply in _ single pass system if held in separate tanks as long as all discharge to waste
- Separate tanks in a single pass system do not count as the same system
- An operator may have multiple species and multiple batches in the same facility



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Holding crustaceans and bivalve shellfish together – legal & scientific considerations

- Legislation 853 / 2004, Annex III, Section VII, Chap. IV a4 and a6
- GMPG Step 14 Purification Loading Tanks



- Science
 - Crustaceans excrete Vibrio spp.
 - Represent a serious human health risk in Ready To Eat products
 - Spray could carry cross contamination into bivalve tanks and packing area aerosol transmission
 - The mechanism for cross contamination is not fully understood



SCENARIO 4: Holding crustaceans and bivalve shellfish in adjacent systems or together in the same water system



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- Temporary physical barriers may be effective at separating crustaceans and bivalve holding areas
- Water systems **MUST** be separate
- Cross contamination must be avoided
- Management capability?
- Risk assessment? e.g. proximity of tanks

Together in the same water system– possible, practicable and reasonable?

- No mitigating factors for LBM/Crustacea mixing
- Don't do it
- However, storing crustaceans in display or wet holding systems is permissible scalish





- POLL QUESTIONS - Scenario 4

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SCENARIO 5: Placing purified bivalves into active purification tanks



Holding crustaceans and bivalve shellfish in adjacent systems – Suggested Recommendations

- Separate by: Time / Space / Barriers
- Cleaning of screens and barriers as part of regular hygiene and cleaning practice
- Cross contamination must be avoided
 - Onus on the operator to demonstrate adequate safety

Together in the same water system - Recommendations

- Bivalves must not be used for human consumption and should:
 - Be disposed of, or
 - Be purified (consider potential length of Vibrio residence time), or

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- Be relayed
- Crustaceans can continue to market and sale

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Placing purified bivalves back – legal & scientific considerations

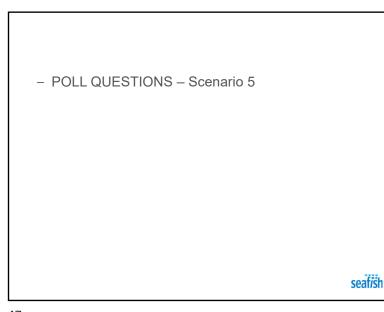
- Legislation 853 / 2004, Annex III, Section VII, Chap. IV a4
- GMPG Step 15 Purification Operation Checks
- Science
 - Contamination of purified batch
 - Re-suspension of detritus
 - Possible recontamination

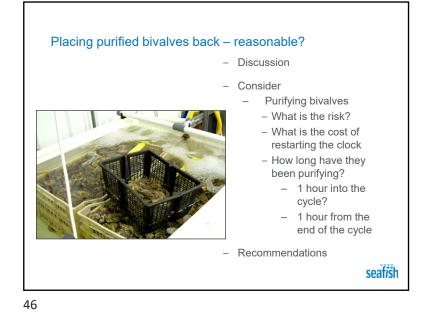
Placing purified bivalves back – possible and practicable

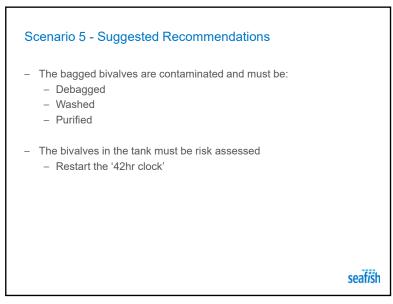


- Bivalves do not have to be suspended in seawater after purification
- Chilled storage is adequate
- Conditioning can be carried out using clean seawater in tanks set aside for that purpose

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SCENARIO 6: Dead bivalves and mud balls in tanks



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Dead bivalves and mud balls in tanks – possible and practicable

- Dead bivalve shellfish may not open
- Mud balls may not be apparent
- Automated grading prior to purification may not identify duds
- Hand grading will find duds but is very labour intensive
- Animals should not die during normal purification
- Regular visual inspections of tanks help to spot problems
- Decaying bivalves do smell



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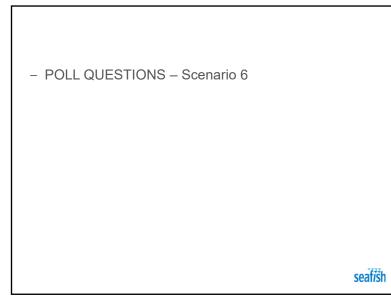
Dead bivalves and mud balls in tanks – legal & scientific considerations

- Legislation 852/2004, Chap. II Article 5
- GMPG Step 14 Purification Loading Tanks
- Science
 - Dead bivalves contaminate batch
 - Mud balls contaminate batch

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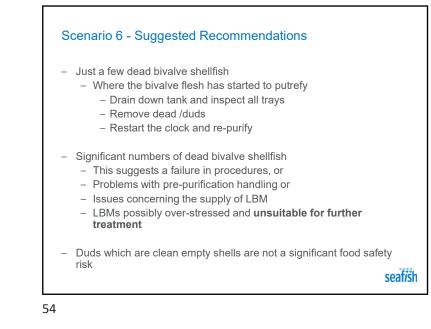
52

Dead bivalves and mud balls in tanks – reasonable? Discussion Consider How many dead or duds? What species? Size and type of operation Staff resources available Use of mechanical grading Seasonality Harvesting methods Post harvest / and pre-purification handling and storage Impact on shelf life / mortality of LBM Recommendations



SCENARIO 7: Cross contamination during postpurification handling





Cross contamination – legal & scientific considerations

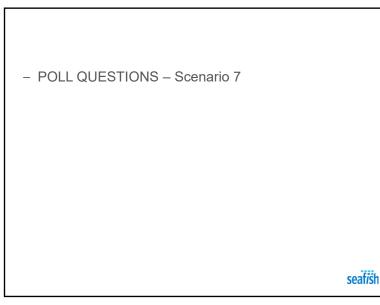
- Legislation 852/2004, Chap. II Article 5
- GMPG Step 19 Purification Centre HACCP Systems and FSA Cross Contamination Guidance
- Science
 - Cross contamination between un-depurated and depurated batches

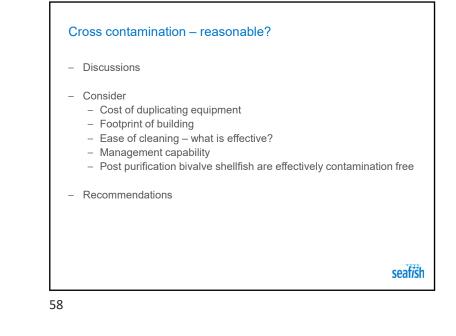
Cross contamination – possible and practicable

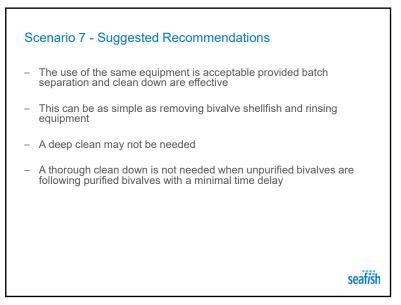
- Many operators only have one set of debyssing, grading and cleaning equipment in the Centre through which both preand post-depuration mussels must pass
- Effective cleaning of equipment between batches will remove sources of cross contamination
- How is cleaning properly validated?



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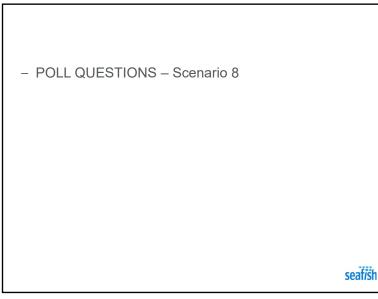




SCENARIO 8: Algal mat growth in purification systems and water holding tanks



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Algal mat growth - legal & scientific considerations

- Legislation 852/2004, Annex I, Part A II 4 (a-b) and 853/2004, Annex III, Section VII, Chap. II B I (c)
- GMPG Step 16 Purification Centre HACCP Systems
- Science
 - Potential for these algal species to be toxic
 - Potential to crash oxygen level during dark period
 - Algal mats can provide a reservoir of contaminated material

Possible and practicable

- Purification systems should be cleaned down between purification cycles
- Purification and conditioning operations should use clean seawater

Reasonable?

- Consider
 - How long has this been going on?
 - Does this suggest a systemic management failure?
 - How can we know the seawater is clean?

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Scenario 8 - Suggested Recommendations

- Seawater may be contaminated
- As biotoxin contamination is a possibility the potentially affected batch should be:
 - Relayed, or
 - Disposed of, or
 - Released for sale **following** re-purification and EPT = positive release
- As this suggests a failure in management controls, a review of all procedures and practices may be warranted

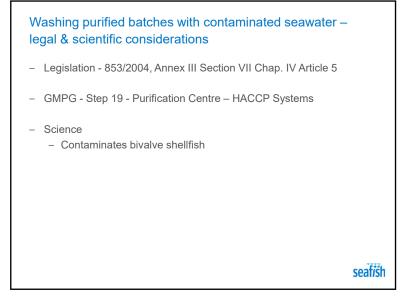
SCENARIO 9: Washing purified batches with contaminated seawater



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Washing purified batches with contaminated water – reasonable?

- Discussion
- Consider
 - Why might this have happened / what went wrong?
 - Who was responsible?
 - How should it be avoided?
- Recommendations



– POLL QUESTIONS – Scenario 9

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SCENARIO 10: Re-immersion in display cabinets, post purification



Scenario 9 - Suggested Recommendations

- No mitigating circumstance contaminated water must never be used in this way
 - Halt dispatch
 - All suspect bivalves should be re-purified
 - Check records to see if this error has occurred previously
 - Consider product recall
 - Permanent Management Procedures should be modified to avoid re-occurrence
- This is a significant system failure and will require a new risk assessment

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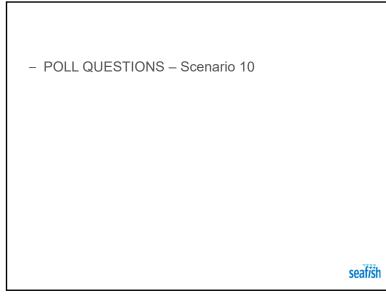
Re-immersion in display cabinets, post purification – legal & scientific considerations

- Legislation 853 / 2004, Annex III, Section VII, Chap. VIII 2
- GMPG Step 20 Wrapping and Packing
- Science
 - Poor controls can lead to stressed and cross-contaminated bivalves

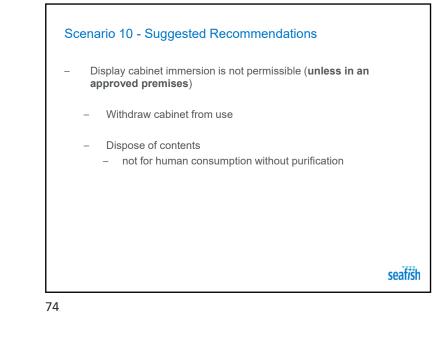
Possible and practicable and reasonable?

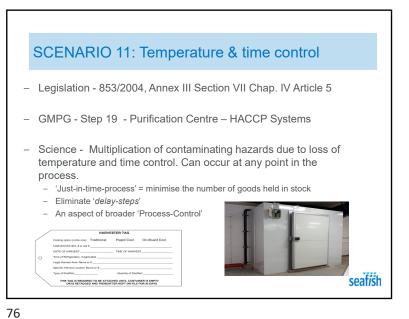
- Animals will survive in cabinets
- Design of cabinets is inadequate to provide confidence that the LBM will remain safe for consumption
- Not allowable in Legislation

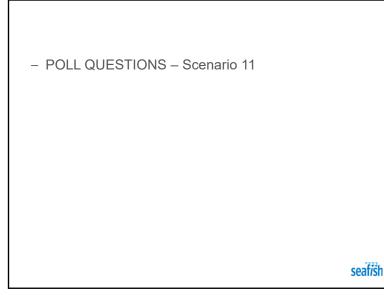














Scenario 11 - Suggested Recommendations

- This a critical aspect of Process Control Either in OPPs (GMPs) or CCPs
- Includes both temperature and time aspects
- Shelf life and end User Instructions cover multiplication Control Measures
 - Live Product/Discard dead shellfish
 - Store chilled
 - Dispose of contents
- Options for bivalves that have fallen out of temperature and time controls?
 - Re-depurate
 - Discard
 - Root Cause Analysis Potentially broader failure of process control

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SCENARIO 12: Incorrect biomass to water ratio

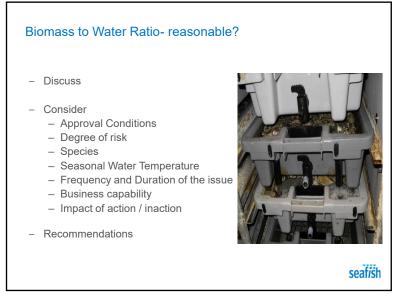


Incorrect biomass to water ratio - legal & scientific considerations

- Legislation 853/2004, Annex iii, Section VII, Chap. a3. Chap. III.2 (ac)
- GMPG Step 14 Purification Loading Tanks
- Science
 - Oxygen depletion and degraded environmental conditions result in reduced shelf life and increased mortality
 - Species and purification system dependent

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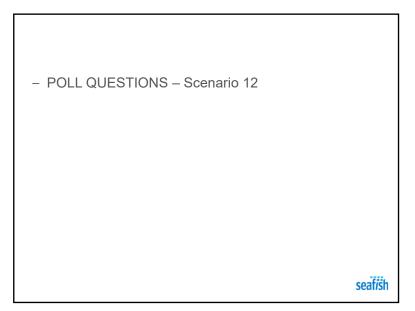


Biomass to Water Ratio- possible and practicable?



- Centres should monitor water quality
 - Oxygen levels
 - Animal activity
 - General water quality
- Higher Biomass/water ratios can be accommodated in some systems and for some species by:
- Higher flow rates of well oxygenated water
- Reducing the mass of animals in the system and restart the process

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Scenario 12 - Suggested Recommendations

- Overstocking of tanks should not take place as a standard practice
- May be allowed as a temporary solution to a short-term problem
 - Not an excessive increase.
 - Compensatory actions are taken.
- Increase frequency of monitoring
- End product testing of the affected batch



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Bivalves not submerged – legal & scientific considerations

- Legislation 852/2004, Chap. Il Article 5
- GMPG Step 15 Purification Operation Checks
- Science Bivalves cannot depurate when not immersed

Possible and practicable

- Some bivalves will 'climb' out of the water even under optimal conditions. Shortly after initial immersion bivalve shellfish will expand as they open their shells.
- For large masses of bivalve shellfish it is not easy to estimate the expansion of the total volume i.e. Bulk bin systems are susceptible to this

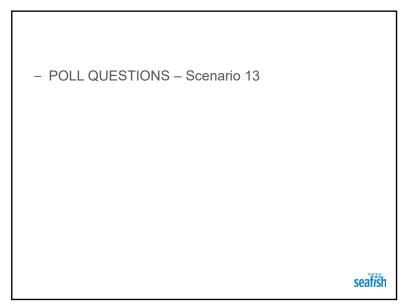
Reasonable?

- Why is it happening?
- What should be the appropriate operator action?
- Impact of action / inaction



SCENARIO 13: Bivalves not submerged during purification operation





Scenario 13 - Suggested Recommendations

- Reduced Headspace
 - Ongoing monitoring and specific end product testing may be necessary
 - Where there is evidence that 'adjustments' to environmental parameters is sufficient to accommodate reduced headspace this may be allowable as a **temporary** solution to a **short-term** problem
- Overfilled systems with non-immersed bivalves should be:
 - Emptied
 - Cleaned down
 - Correctly stocked
 - Purification cycle restarted
- However, where there are just a few bivalves that have climbed up the side of the tank and out of the water, these can be picked off, and set to one side, allowing the greater bulk of (immersed) bivalves to continue purification

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Animals bagged - legal & scientific considerations

- Legislation 852/2004, Chap. Il Article 5
- GMPG Step 18 Purification Centre HACCP Systems
- Science Animals unable to open and respire = cannot effectively depurate.

Possible and practicable

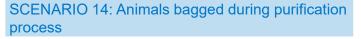
- Not possible to effectively purify bagged bivalves
- Operators do condition bagged bivalves
- Operators may mistakenly attempt to purify bagged bivalve shellfish

Reasonable?

- Why is it happening?
- What should be the appropriate operator action?
 - Are there any mitigating factors?
 - Conditioning vs. purification what is the difference?
- Impact of action / inaction

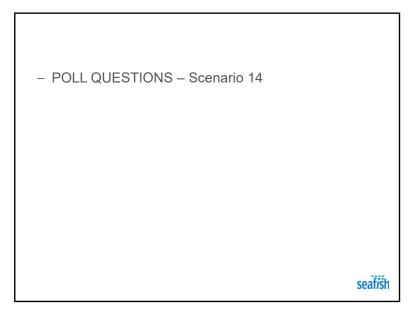


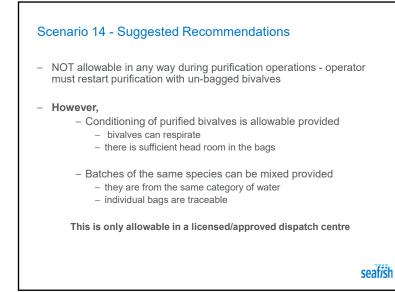
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Poorly maintained UV system – legal & scientific considerations

- Legislation 852/2004, Chap. Il Article 5
- GMPG Step 18 Purification Centre HACCP Systems
- Science
 - Fouled quartz tube reduces UV transmission
 - Can result in an unsafe system and an invalid process

SCENARIO 15: Poorly maintained UV system - quartz tubes fouled



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Poorly maintained UV system - possible and practicable?

- Fouling takes time
- Site specific factors
- Seasonality
- Environmental conditions
- Can be predictable
- Planned maintenance
- High intensity systems usually have a wiper and UV sensor



Poorly maintained UV system - quartz tubes fouled – reasonable?

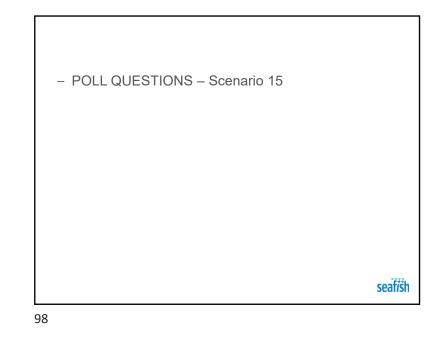
- Discussion
- Consider
 - How long does it take to clean the tube?
 - Low intensity min's
 - High intensity hrs
 - Risk assessment
 - Cleaning schedule
 - Records
 - Is there a system in place to manage this?

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- Is there a failure in the system?
- Recommendations

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Scenario 15 - Suggested Recommendations Cleaning frequency – after every cycle is most likely unreasonable Frequency should be based upon evidenced need If on examination a UV tube is found to be fouled, then a reasonable response would be to have the tube cleaned and the 'clock restarted' You must have, and must use a system to manage UV tube planned maintenance for: Inspection Cleaning Replacement

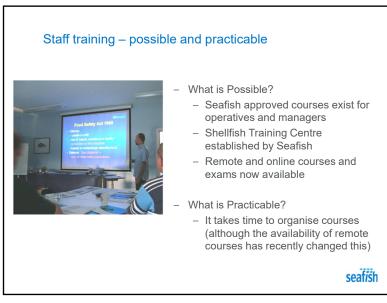


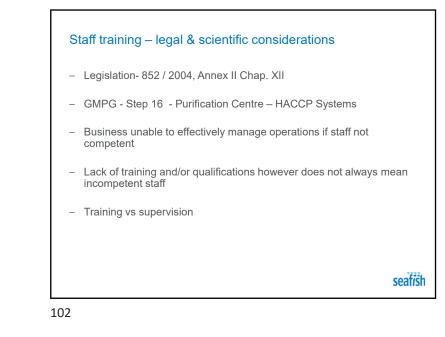
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SCENARIO 16: Purification Centre staff not adequately trained



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Staff training – reasonable?

- Discuss
- Consider
 - What are the risks
 - Size of business
 - Availability of specialist training
 Business capability to offer inhouse training
 - Business capability to provide adequate supervision
 - Evidence of competence, or lack of competence
 - Impact of action / inaction
- Recommendations

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- POLL QUESTIONS - Scenario 16

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SCENARIO 17: Food Fraud/Crime

Legislation

- Food Safety Act 1990 (UK) as amended by Regulation 178/2002/EC; contains rules to ensure that food placed on the market is safe to eat; consumer is not mislead as to the quality or description of the food
- 852/2004, 853/2004, 2017/625 and 2019/624 all apply, along with other non food legislation.
- Food Fraud definition:

Any **deliberate** act by a business or individual to deceive others in regards to the integrity of food to gain undue <u>advantage</u>.

For example:

- Adulteration, substitution, tampering, simulation, counterfeiting and misrepresentation
- GMPG Appendix 4 and 5 Record keeping general; registration doc.
- Science
 - The monitoring and control of provenance, loading and environmental parameters is essential to effective management of purification
 - Provenance and category of harvest seawater

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Scenario 16 - Suggested Recommendations

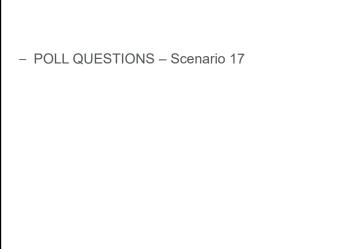
- Operators should be given a reasonable time period within which to receive training from an approved trainer
- Note: do not confuse lack of training qualifications with lack of competence. Any requirement for formal training of experienced staff must be based on evidence of lack of competence.
- Competent managers are able to deliver informal instruction to staff, particularly new entrants
- Stronger case exists for requiring managers to have formal qualifications
- Ensure all inhouse training is documented and dated
- Staff may require additional
 - Training
 - Instruction
 - Supervision
- What else?



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False records – possible and practicable Monitoring equipment available, reasonable cost and reliable Training is available to ensure staff trained and competent Management must be effective Clear guidance exists of what is to be measured Seafish guidance Training courses Examples of evidence for traceability Registration document; GPS records; photos False records – reasonable?

- Consider
 - Operator error?
 - Management failings?
 - Malicious intent?
 - Breaking the law for financial gain?
- Risk to public health?



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Scenario 17 - Suggested Recommendations - Effective documented traceability is key to ensuring provenance of LBMs. - Ensure that staff have the correct calibrated equipment and training in order to ensure that they have the ability to keep accurate records. - Know your suppliers and, if necessary, inspect/audit their operations. They shouldn't have anything to hide. - Expect customers such as retail multiples to audit your processes and documentation. Food fraud resilience self-assessment tool _ - Develop a counter-fraud strategy that considers the risk of food fraud. - Establishing an anti-fraud culture within a business is vital. A negative or ambivalent culture can become problematic as bad practice may go unchallenged, or taking short cuts may be normalized (Source: FSA). seafish 110

Challenge Test Your Business – EHO for a day!

- Sometimes it can be hard to spot issues and identify both good and bad practise when you are 'too close to the coalface'
- Could you step back and put on another hat for the day? Imagine you are an EHO and this is the first inspection of your purification centre.
 - How would you approach this?
 - Where would you start?
 - What are the main things that you are trying to establish?

Steps to forming an accurate first impression - step 1

- 1. Walk the Line Water & Shellfish
 - Water intake to waste discharge (source; storage; treatment; reuse; disposal)
 - Raw material reception to product dispatch (handling; washing; chilled storage; records; traceability; avoid recontamination)
 - Challenge your staff ask your staff questions about the systems



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Steps to forming an accurate first impression - step 3

- 3. Audit the records and paperwork this will be a priority for any EHO inspection
- Bivalves in +42hrs = Bivalves out. Therefore, check the intake/dispatch
- Tank records (UV on/off; temp.; flow rates; cleaning; water re-use)





Steps to forming an accurate first impression - step 2

- 2. Don't inspect the kitchen?
 - Or the walls
 - Or the doors

These areas are important, <u>but</u> they aren't where you should focus in order to identify the main food safety issues with LBM purification. NB: Not all Control Points are Critical!



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Where should your priority for scrutiny therefore be? \longrightarrow What affects the operation of the purification tanks and the shellfish within them?

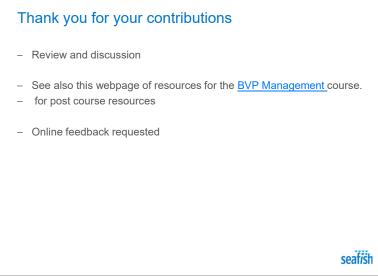
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Steps to forming an accurate first impression - step 3

- 3. Audit the records and paperwork contd.
- When was the current HACCP plan and underlying policies last reviewed? Have there been any changes/modifications since the last review?
- EPT (type; frequency)
- Other records?







Techniques and approaches to also consider

EPT

- More needed?
- Frequency of testing based on risk-based analysis

Technology Adopted

- Are you using existing technology to maximum affect? (optimisation; cleaning; maintenance; calibration)
- Is there other technology that you could use to enhance your systems? (ozone; protein skimmers; venturis; chillers)

Training

- Are your staff trained and/or supervised? Training up to date? Need refreshing?
- Are they motivated and do they understand why what they do matters?

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Seafish Update... Training opportunities for Industry include BVP Operations course for your colleagues HACCP for Bivalve Purification Elementary and Intermediate Food Hygiene training available online Food Authenticity and Integrity Verification Vocational Qualifications/Apprenticeships Contact Seafish for more information onshore@seafish.co.uk