Bivalve Shellfish Hygiene Verification

A Seafish / REHIS course

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Here to give the UK seafood sector **the support it needs to thrive.**

Part One ~ An introduction to bivalve shellfish purification

- A two-day training programme for enforcement officers and third-party auditors
- Overview of Official Control Verification (OCV)
- Overview of bivalve purification operations
- The OCV study - Epidemiology of live bivalve molluscs
- The OCV study - The food science and technology of purification

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Part Two ~ Bivalve shellfish purification verification

- Recap of OCV
- The food science and technology of purification continued
- Verifying purification scenarios
- The limits of purification
- **Assessment: course examination and active engagement**

What is Seafish?

- A Non-Departmental Public Body (NDPB):
  - Founded in 1981 by an Act of Parliament
  - Sponsored by Department for Environment, Food & Rural Affairs (DEFRA)
- Funded by a levy on the first sale of seafood landed in the UK
- The only pan-industry body in the UK offering services to all parts of the seafood industry
- Seafish aims to support a thriving & sustainable seafood industry
- Their website address is **www.seafish.org**

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What is REHIS?

- The Royal Environmental Health Institute of Scotland:
  - a long-established awarding body
  - recognised nationally and internationally.
  - A wide range of qualifications in food hygiene and health & safety
  - UK Competent Authority
  - Their website address is https://www.rehis.com/

- REHIS/Seafish joint awards:
  - Developed by Seafish and accredited by REHIS
  - Seafood specific:
    - Food Authenticity and Integrity Verification
    - Food Hygiene
    - HACCP
    - Health and Safety
    - Various bivalve training courses

Part One

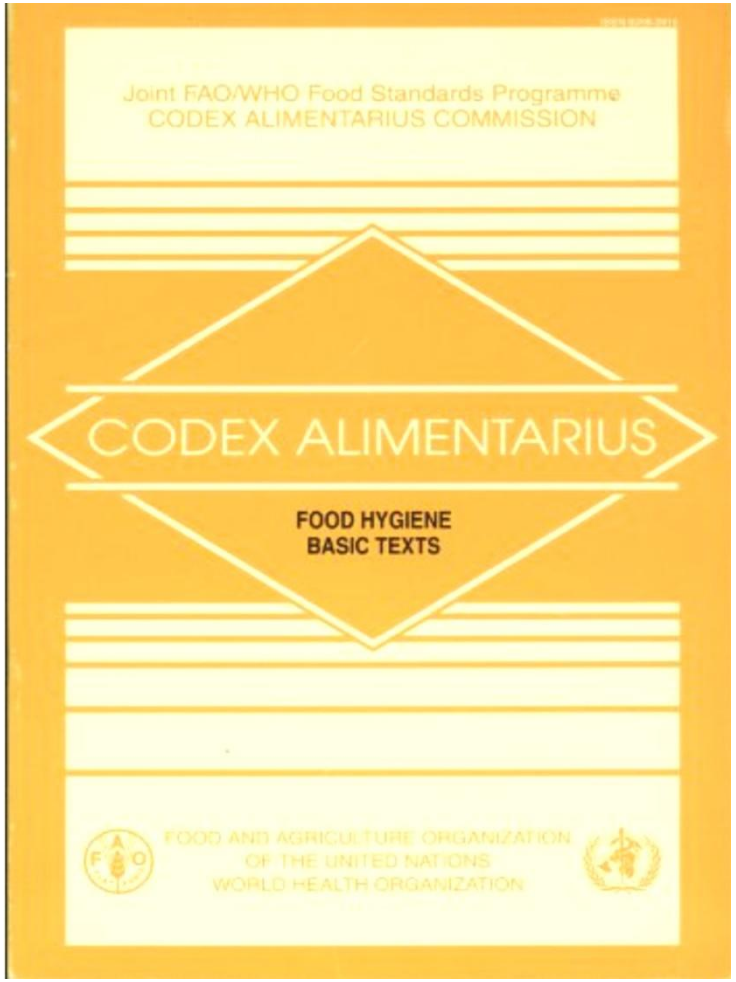
Introduction to OCV principles

The HACCP study

- Stages 1-5 (The preparatory steps):

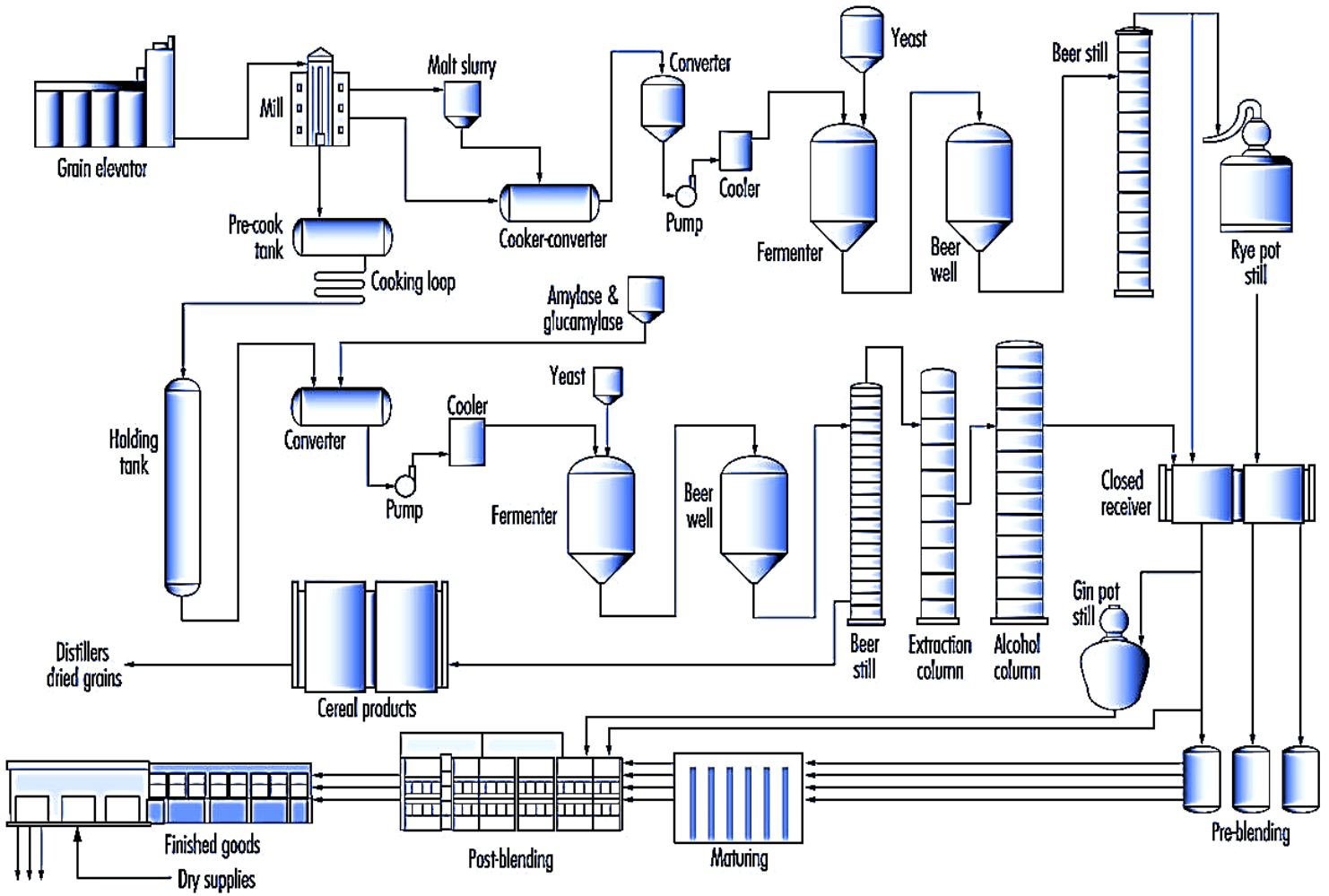
    1. Assemble multidisciplinary HACCP team
    2. Describe the product
    3. Define intended use
    4. Draw process flow diagram(s)
    5. Verify process flow diagrams

- Stage 6 - Identify and analyse **hazards** and define control measures
- Stage 7 - Identify CCPs
- Stages 8-10 - Implement monitoring, critical limits and corrective actions
- Stage 11 - Verification – validation and verification
- Stage 12 - Establish documentation systems

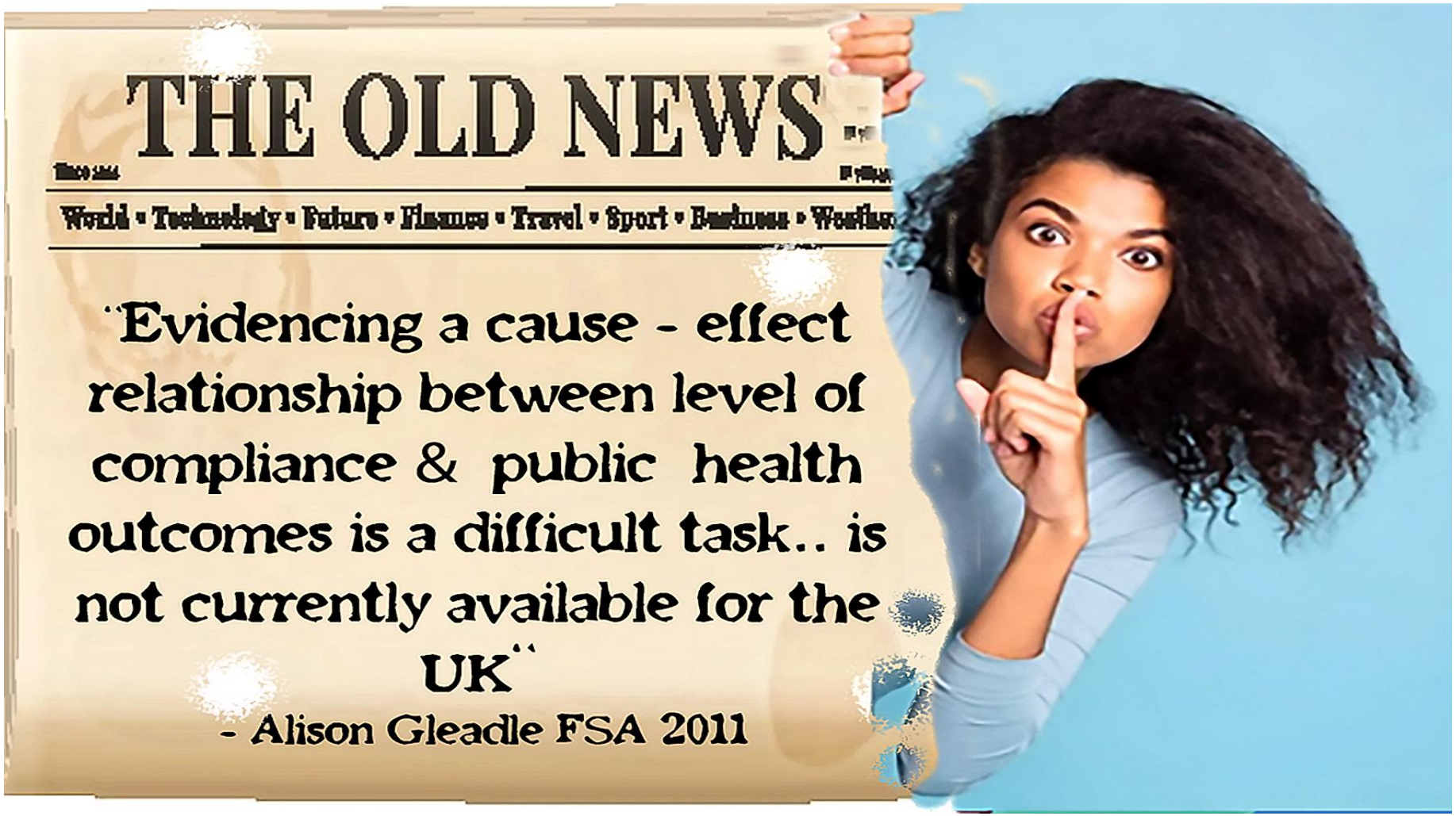


Codex – general principles of food hygiene CXC 1-1969 Rev. 2020

The Complexity Challenge



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THE OLD NEWS
"Evidencing a cause - effect relationship between level of compliance & public health outcomes is a difficult task.. is not currently available for the UK"
- Alison Gleadle FSA 2011

Recap - Dr Frank Bryan - CDC/WHO Codex

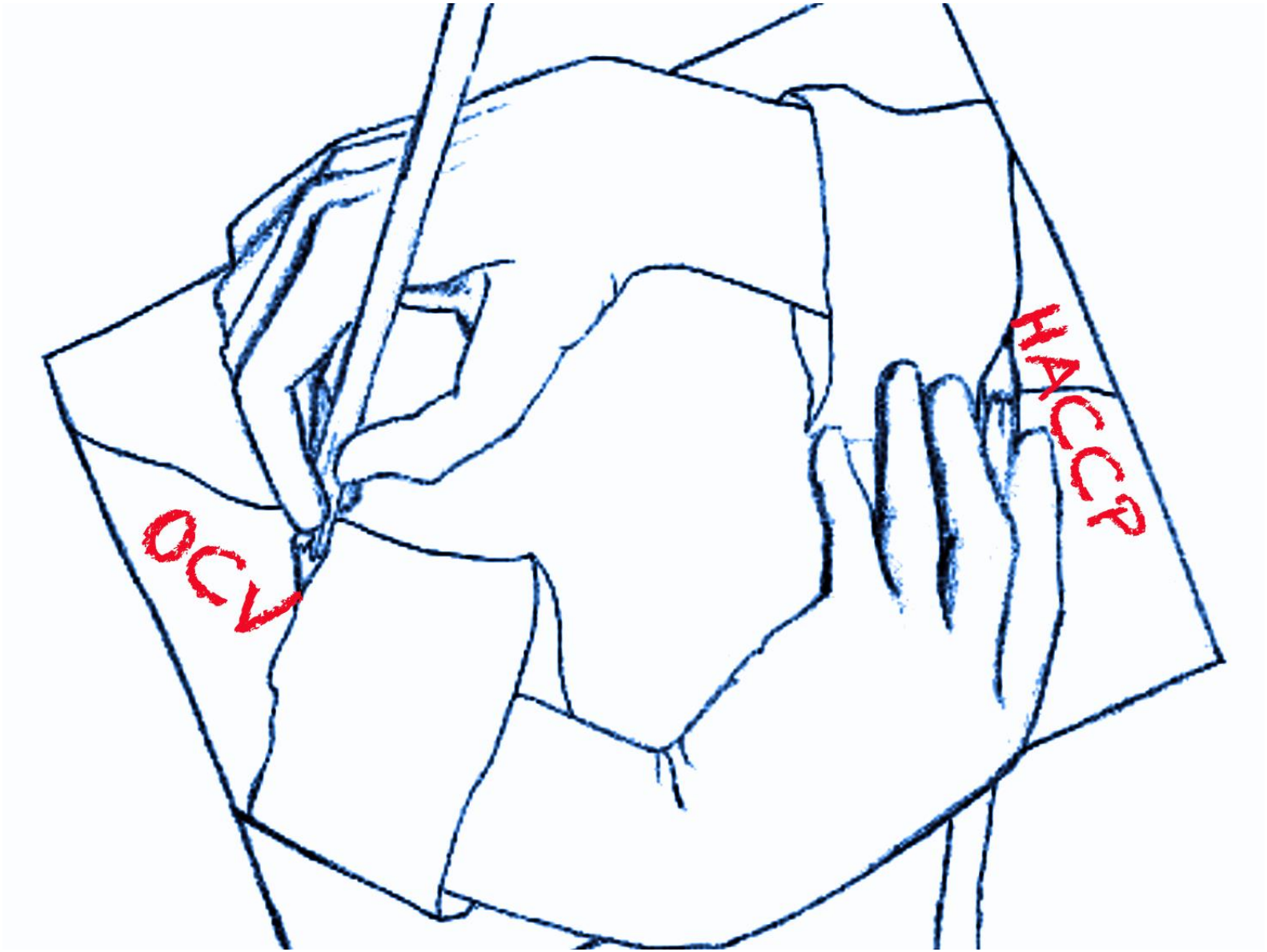
"HACCP approach is based on an understanding of the factors that contribute to outbreaks of foodborne disease and on applied research on the ecology, multiplication, and inactivation of foodborne pathogens. Even where data are not available, a hazard analysis can detect potential problems and identify the critical control points of an operation. Thus, food safety agencies can target their resources on the greatest public health risks in an establishment, rather than on general sanitation and superficial Improvements."

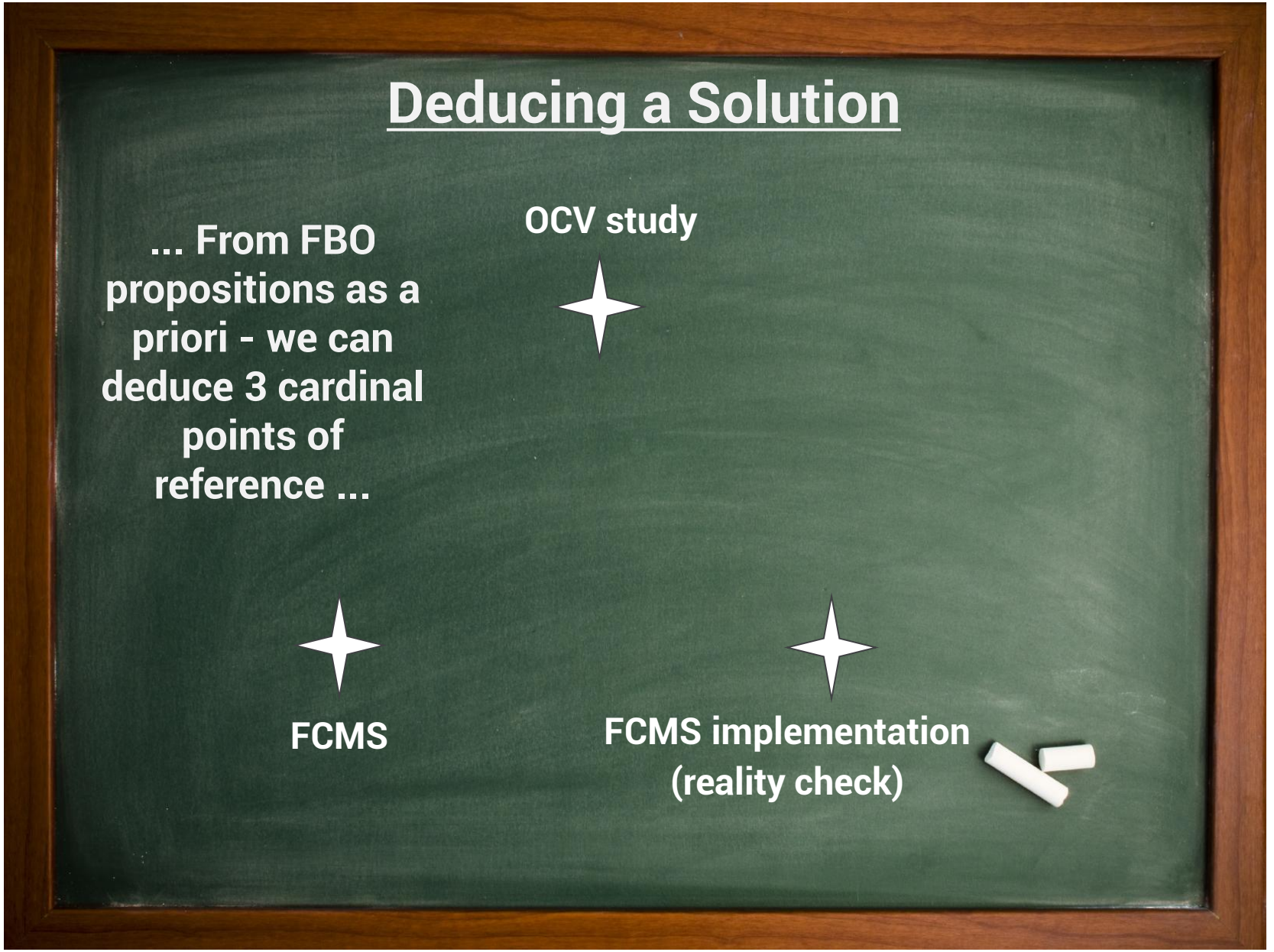
- BRYAN F, .L. (1978) Factors that contribute to outbreaks of foodborne disease. Journal of food protection, 41: 816-827.

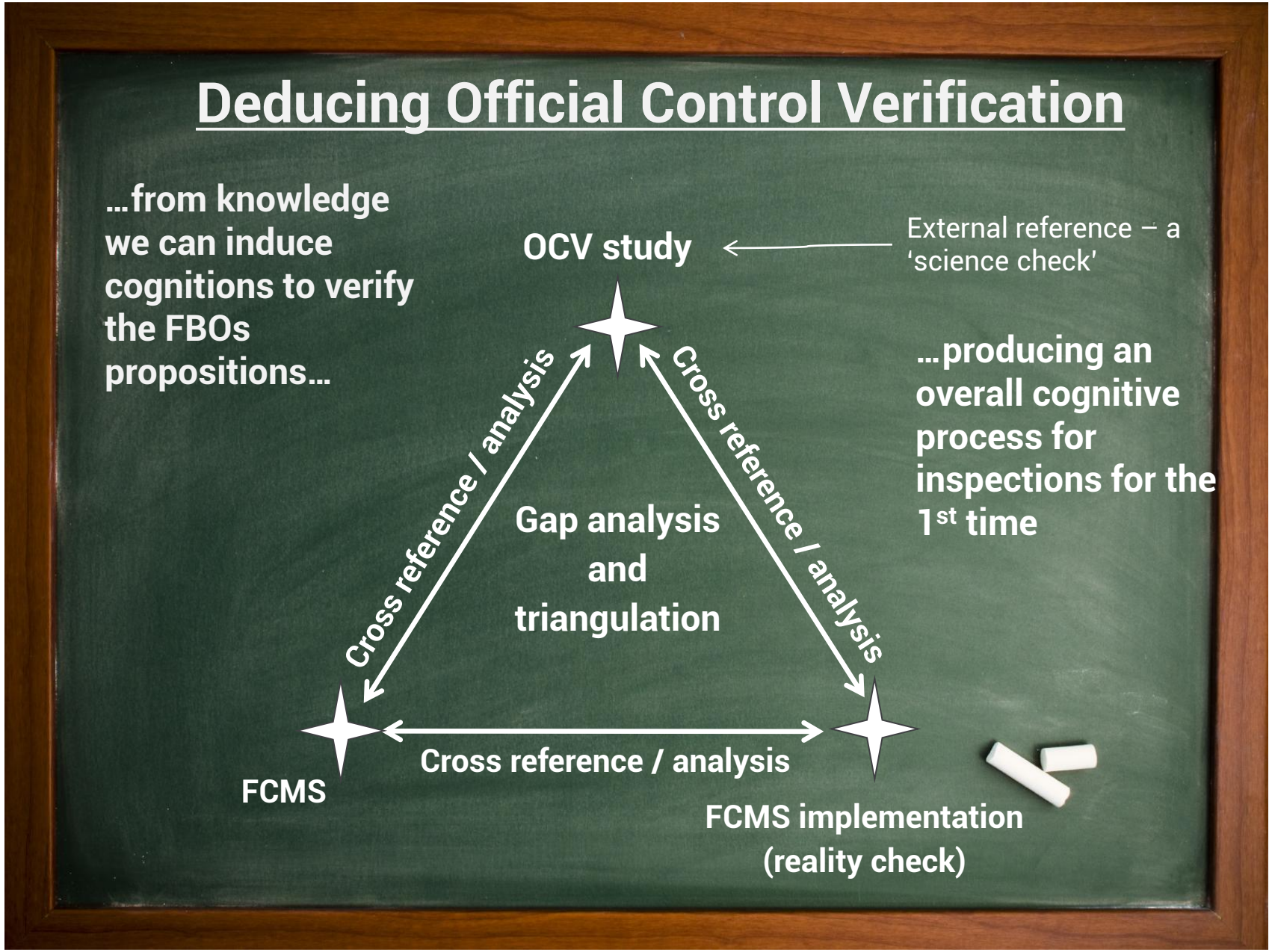


"Dr. Bryan was 20 years ahead of the rest of us in terms of where his vision was for food safety and getting into the causes of outbreaks."
- SR. ENVIRONMENTAL HEALTH OFFICER CDC

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OCV
HACCP


Deducing a Solution
... From FBO propositions as a priori - we can deduce 3 cardinal points of reference ...
OCV study
FCMS
FCMS implementation (reality check)


Deducing Official Control Verification
…from knowledge we can induce cognitions to verify the FBOs propositions…
OCV study
External reference – a 'science check'
…producing an overall cognitive process for inspections for the 1st time
Cross reference / analysis
Cross reference / analysis
Gap analysis and triangulation
Cross reference / analysis
FCMS
FCMS implementation (reality check)

Break down the FBO's proposition into individual triangulations - reverse engineering

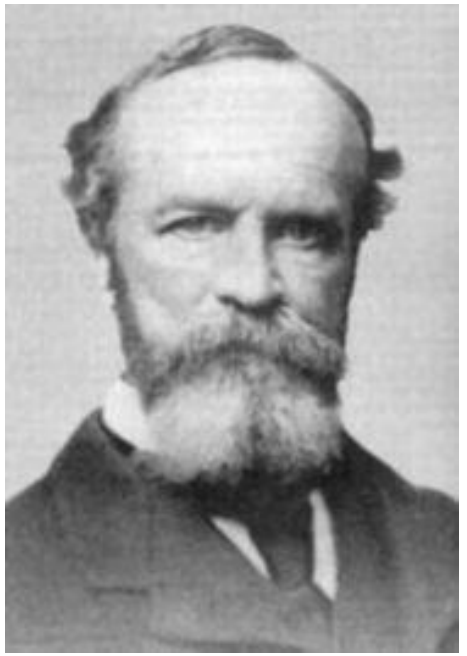






"***Objective evidence and certitude are doubtless very fine ideals to play with, but where on this moonlit and dream-visited planet are they found?"***

- William James 1842 –1910 (considered to be one of the greatest philosophers of the pragmatic school)



"Information that can be proved true, based upon facts obtained through observation, measurement test or other means"

- First defined BS EN 8402/1995
- Referred Regulation (EC) 178/2004 - but not defined

Attributes of objective evidence

✓Scientific — Can the data be evaluated by independent observers to reach the same conclusions?

✓Scientific — Are the data documented in a manner to allow re-creation of the data or the events described?

✓Scientific — Does the documented evidence provide sufficient data to prove what happened, when, by whom, how, and why?

✓Legal — Was the documentation completed concurrent with the tasks?

✓Legal — Is the documentation attributable?



Denise Dion
USA FDA Office of Regulatory Affairs
Primary Editor of the FDA Investigations Operations manual

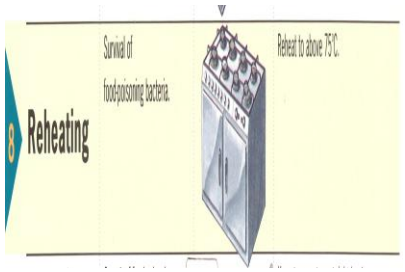




Example from catering

>82^{O}C measured @ slowest point of heating using calibrated disinfected thermometer

Observed Eva Contadori measure >82^{O}C @ center paella/Bain Marie @ times xxxx & xxxx Date xx xxx xxxx
Rachel Everdene



Re-heat

Reality

No record available
Date xx xxx xxxx
Rachel Everdene

"Aye gonnae have to stay at higher than 82^{O}C @ the deepest bit or we are gubbed by the law but!"
Danny McChancer @ times xxxx Date xxxxx

Reframing the metric - an epidemiological metric

- **Dr Betty Hobbs & Dr Diane Roberts - UK**



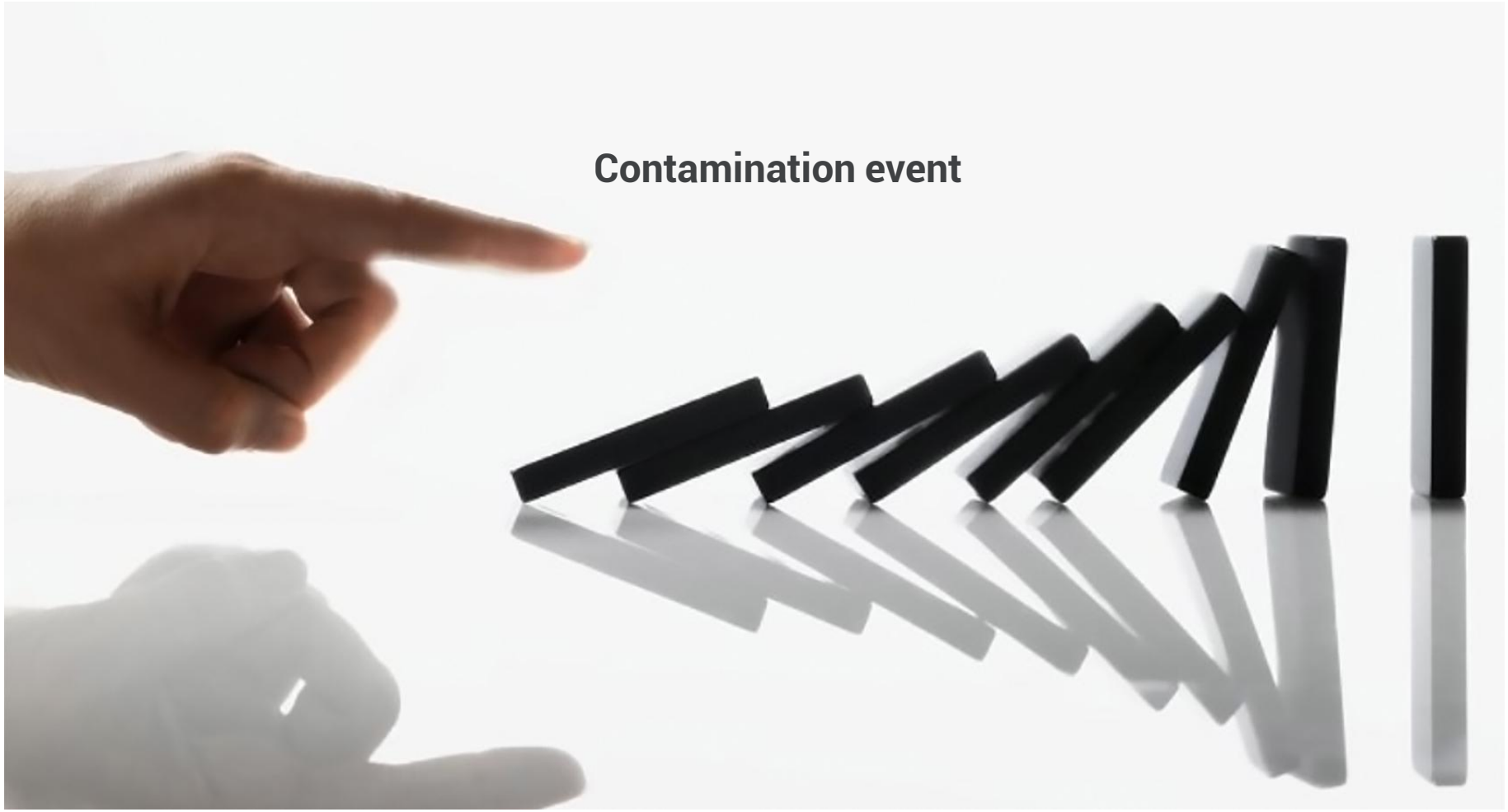
Factors contributing to outbreaks of food poisoning in England and Wales 1970-1979 J.Hyg. Camb (1982) 89, 491-498

- **Dr Frank Bryan USA – '*Contributory factors*' ('*EPI Factors*' = P.I.I.M.S)**



Factors that contribute to outbreaks of foodborne disease. Journal of Food Protection Vol 41, No 10 PP 816-827, 1978

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Contamination event

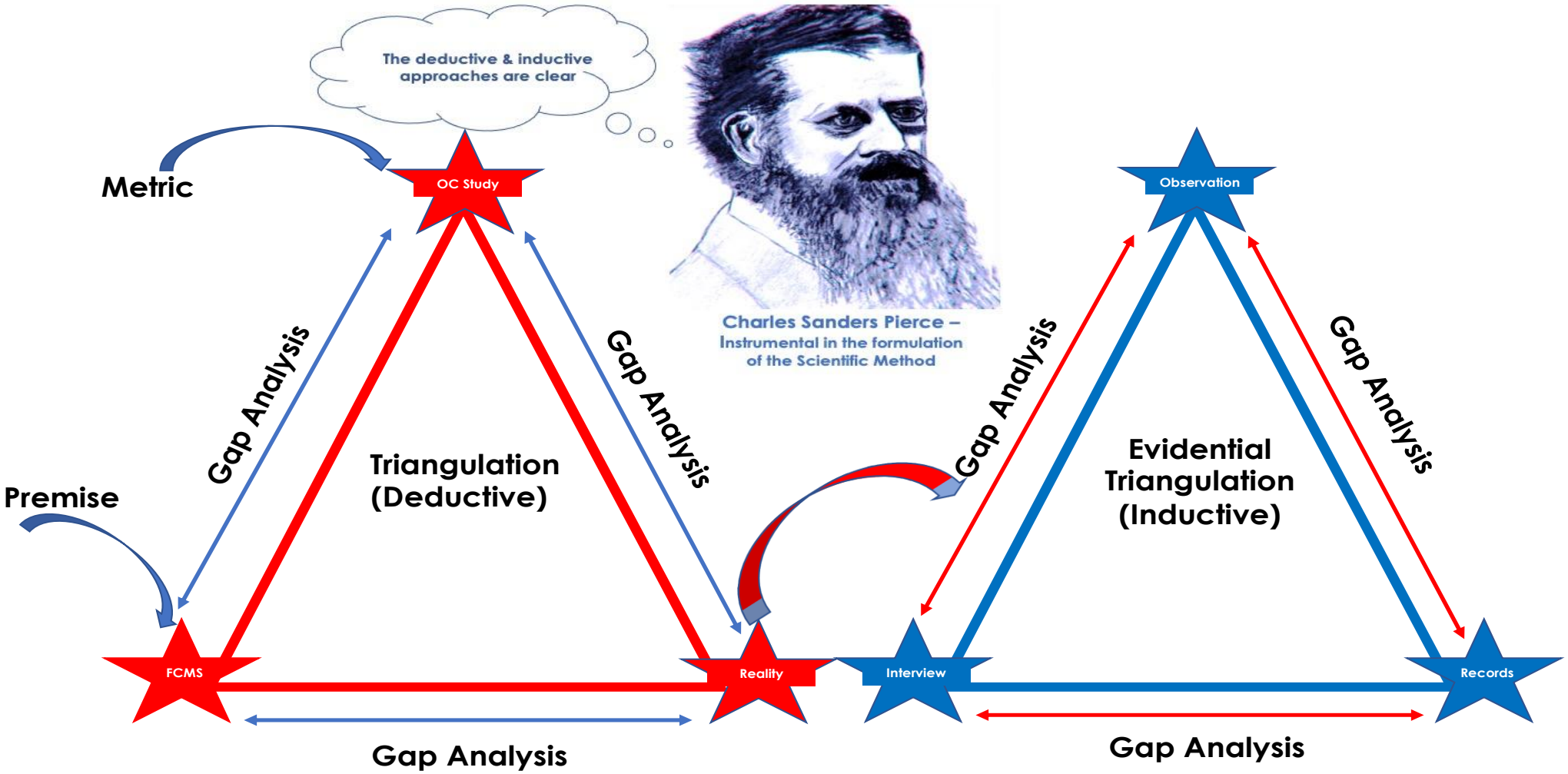

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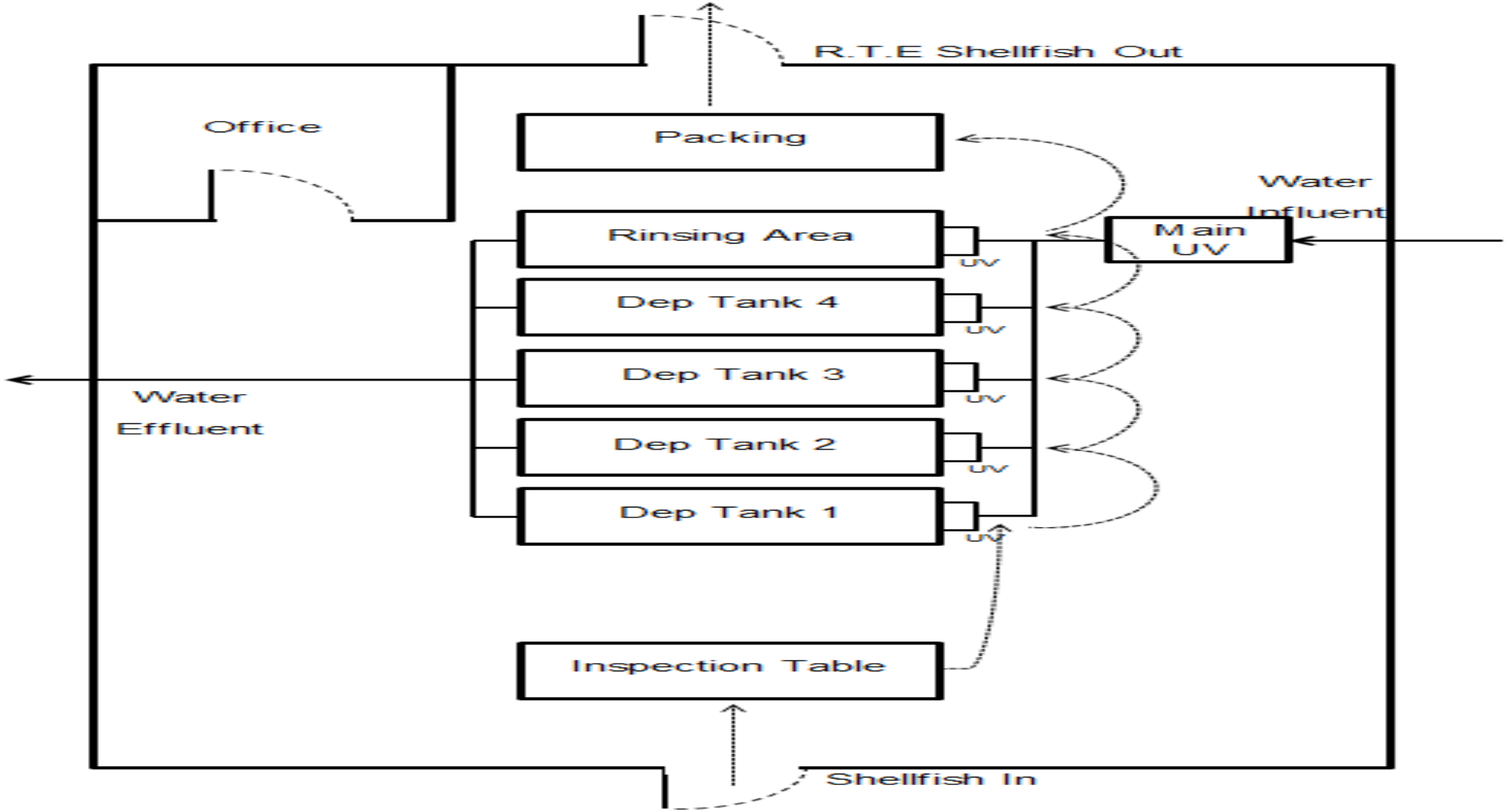




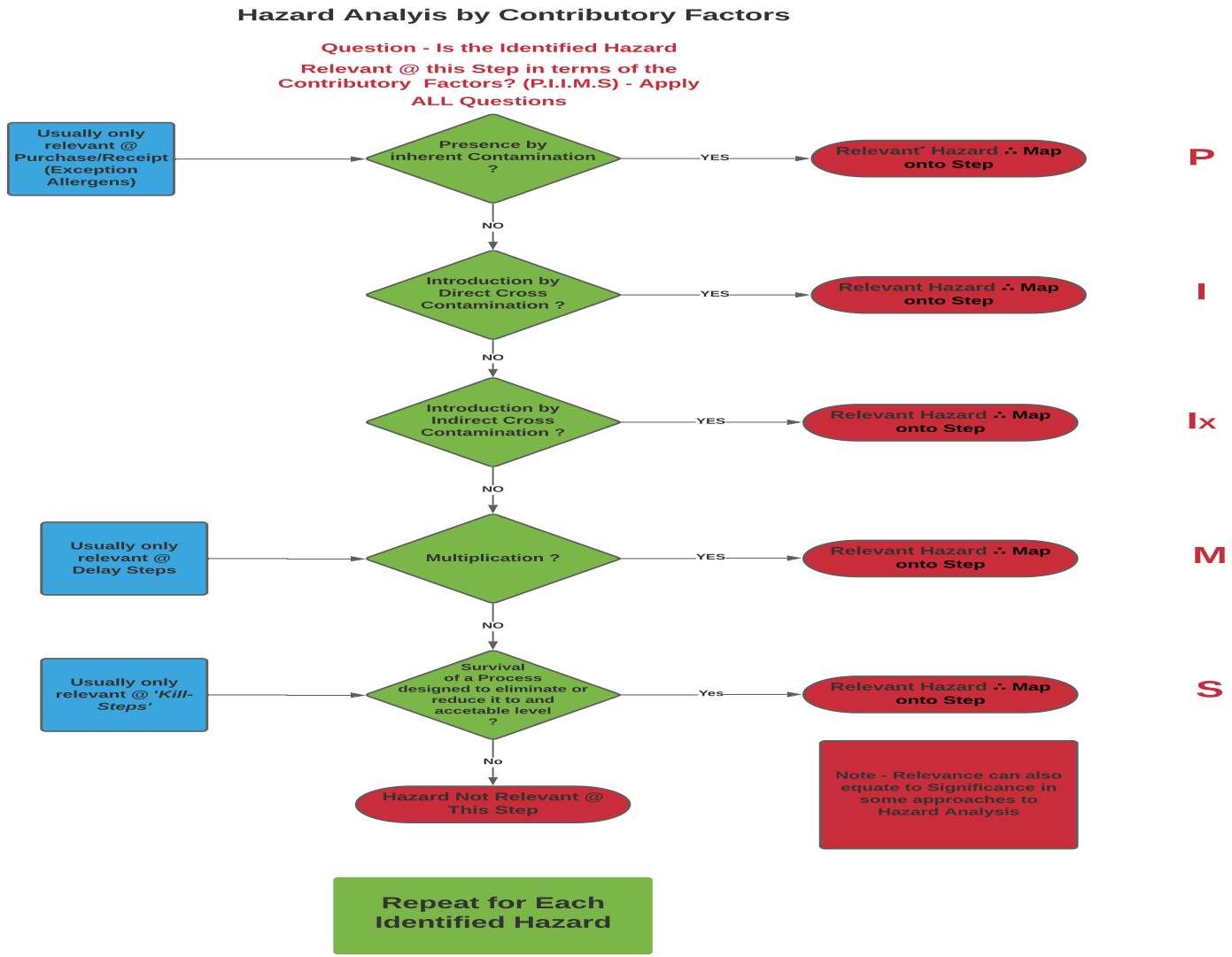
Relationship to science



The Official Control FCMSS study - tracking the process flows and the water flows



Hazard analysis by contributory factors algorithm



Stage 6 - A structured approach

There must be a logical relationship between identified hazard and the control measure

List

- **"List all potential hazards" (i.e. what are the hazards?)**

Hazard analysis 1

- Significance? – **what/which** are the significant hazards? (i.e. "likely occurrence" & "severity"?)

Hazard analysis 2

- Map hazards to process steps by considering "*contributory factors*" – associate hazards to steps as relevant - presence/introduction/multiplication/survival of hazards? (i.e. **where/when** hazards are occurring?)

Hazard analysis 3

- Cause/source(s) and vectors(s)? (**why** the hazards occur and why they occur at particular steps?)

Control measures

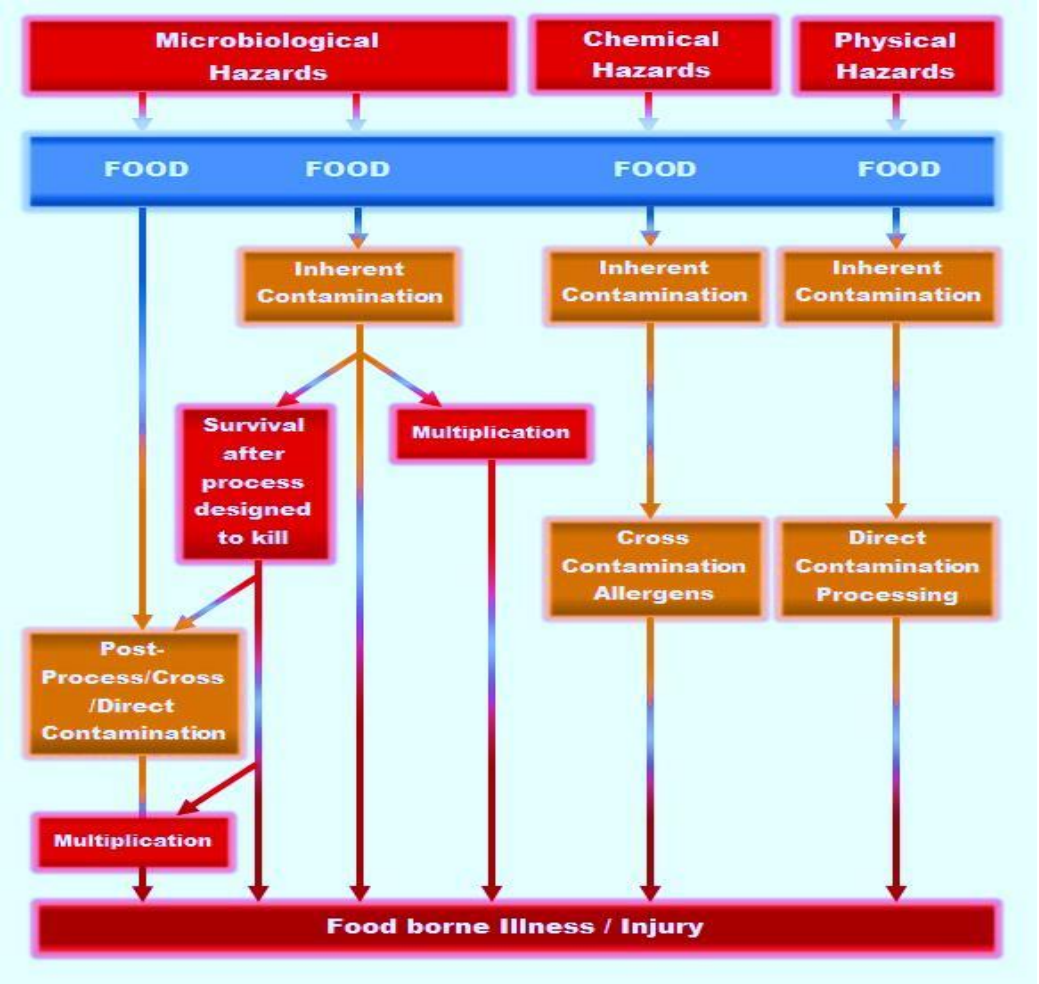
- Control measures? (**what** control measures can be applied?)

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Contributory factors and hazard mapping

- Contributory factors can be classified according to whether an outbreak was the result of:
  - Contamination
  - Microbial survival
  - Microbial growth
    - WHO 1992

- "Contributing factors those factors that, directly or indirectly, influence the level of a risk factor":
  - CDC – Undated ref
- "Contributory factors are conditions that enable or amplify an outbreak":
  - Brown et al National Centre for Environmental Health Atlanta





FCMS



Process control



Validation



Steps 1- 6



CCPs / Critical limits / monitoring / corrective actions



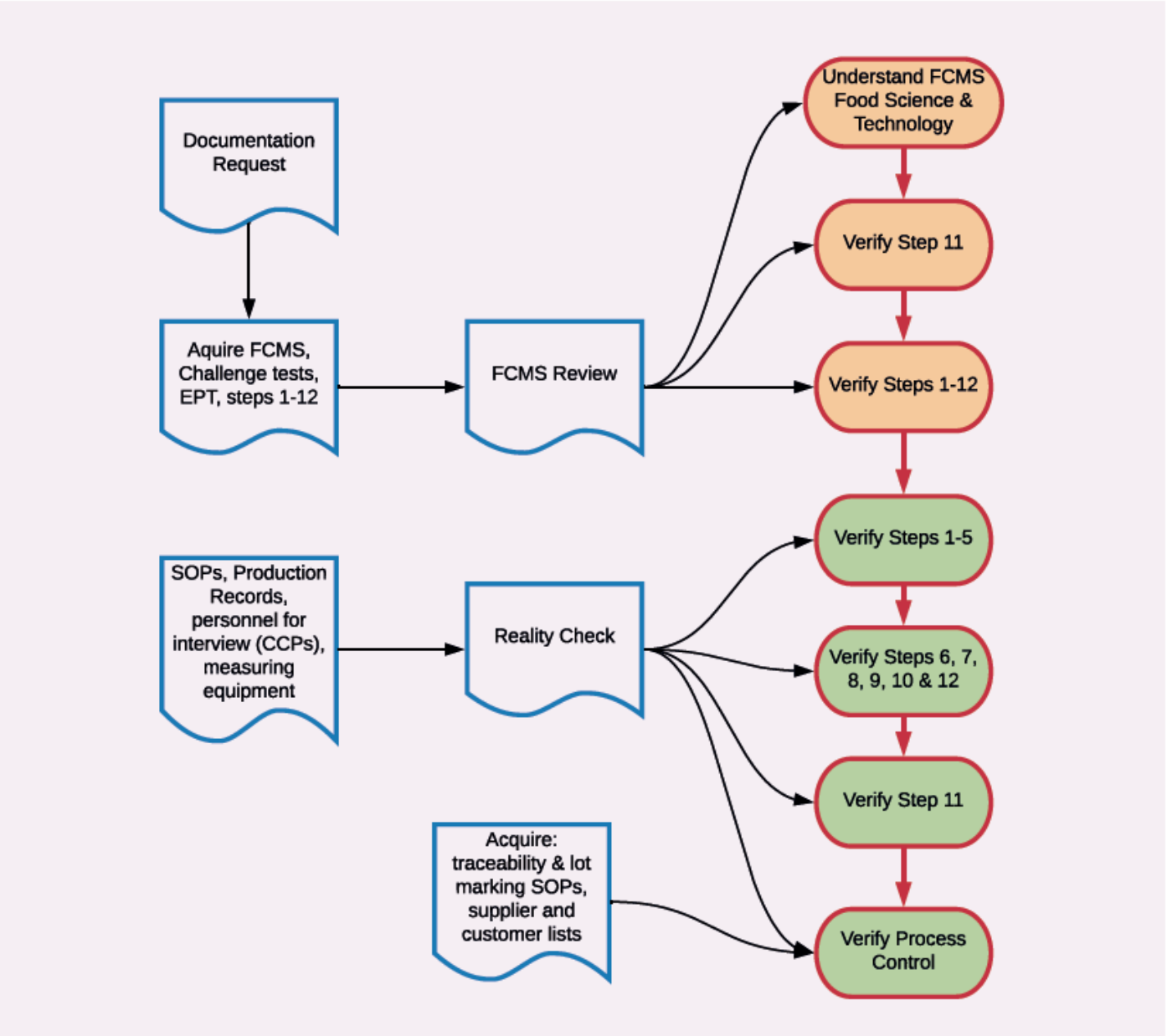
OPPs

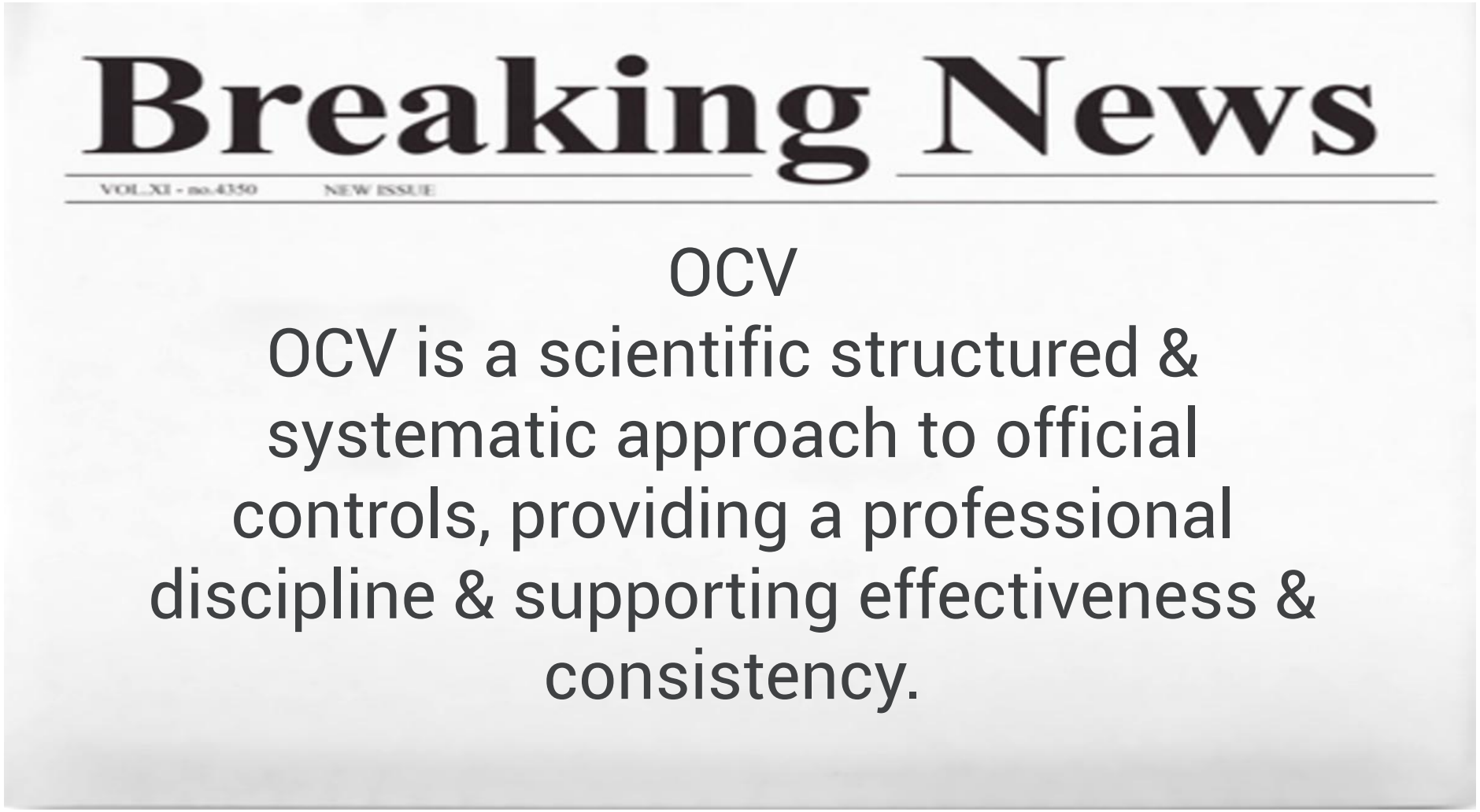


PRPs



Food information


Documentation Request
Aquire FCMS, Challenge tests, EPT, steps 1-12
FCMS Review
Understand FCMS Food Science & Technology
Verify Step 11
Verify Steps 1-12
SOPs, Production Records, personnel for interview (CCPs), measuring equipment
Reality Check
Verify Steps 1-5
Verify Steps 6, 7, 8, 9, 10 & 12
Verify Step 11
Acquire: traceability & lot marking SOPs, supplier and customer lists
Verify Process Control


Breaking News
VOL_XI - no.4350 NEW ISSUE
OCV
OCV is a scientific structured & systematic approach to official controls, providing a professional discipline & supporting effectiveness & consistency.

OCV Study – Introduction – epidemiological aspects

Introduction

- What is bivalve shellfish purification?
- What species are purified?
- When do we need to use it?
- What does purification involve?

What is depuration/purification?

- The use of a ***controlled***, aquatic environment to reduce low-level contamination by ***bacteria*** and viruses in live bivalve shellfish (to a safe, acceptable level for human consumption).

- A ***natural*** biological process to ***purge pollutants*** from bivalve shellfish, managed at a plant.

- **NB:** Relaying bivalve shellfish is a process used exclusively for the natural purification of live bivalve shellfish, the areas used are classified areas of sea, estuaries or lagoons with clearly marked boundaries indicated by buoys, posts or any other fixed means

  – ***only the time period and location are actively managed!***

  - No relaying area in Scotland

Bivalve shellfish - Species

- Pacific oyster (*Crassostrea gigas*)
- Native oyster (*Ostrea edulis*)
- Mussels (*Mytilus sp.*)
- Razor clams (*Ensis sp.*)
- Cockles (*Cardium edule*)







Overview: bivalve purification operations

Aim - To provide the information you need to:



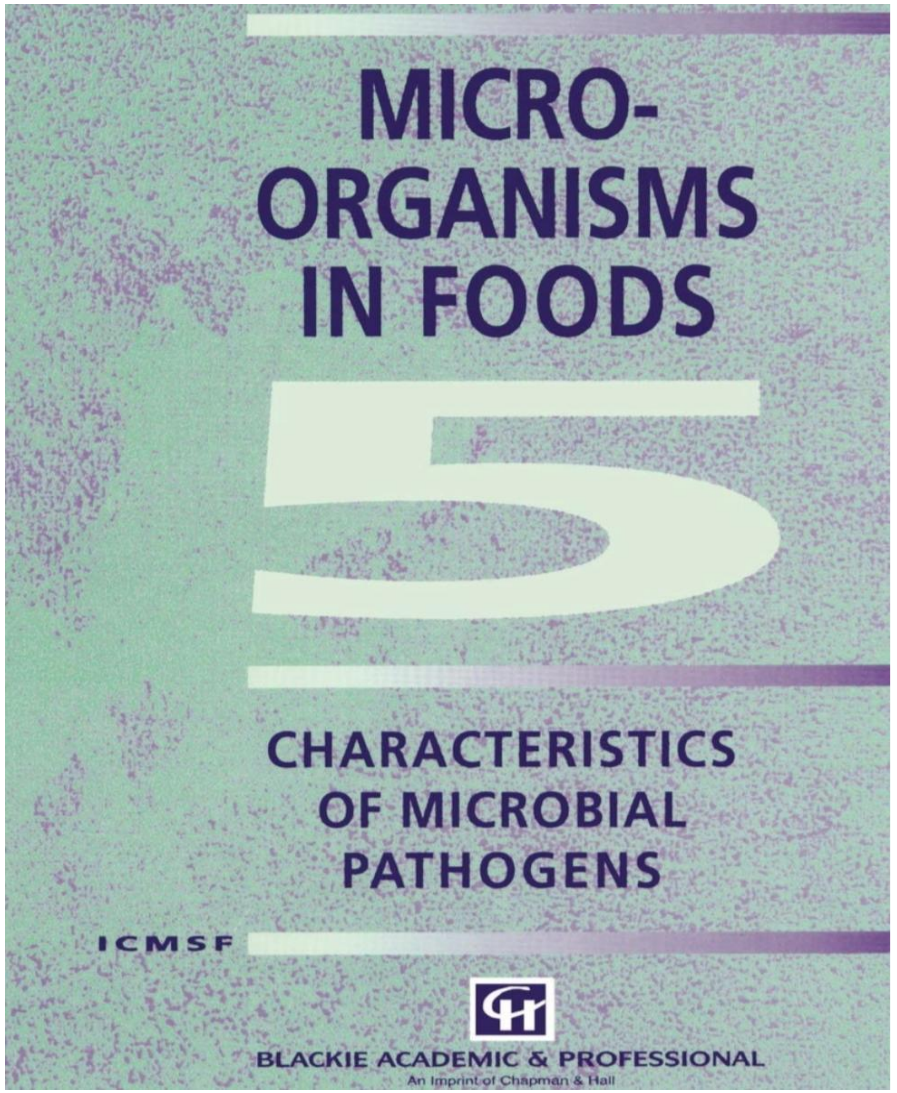
- ***Understand*** and then ***verify*** the complex requirements necessary to ensure successful purification operations
- Ensure ***food safety*** is prioritised
- Achieve a satisfactory result in the exam that will follow this course

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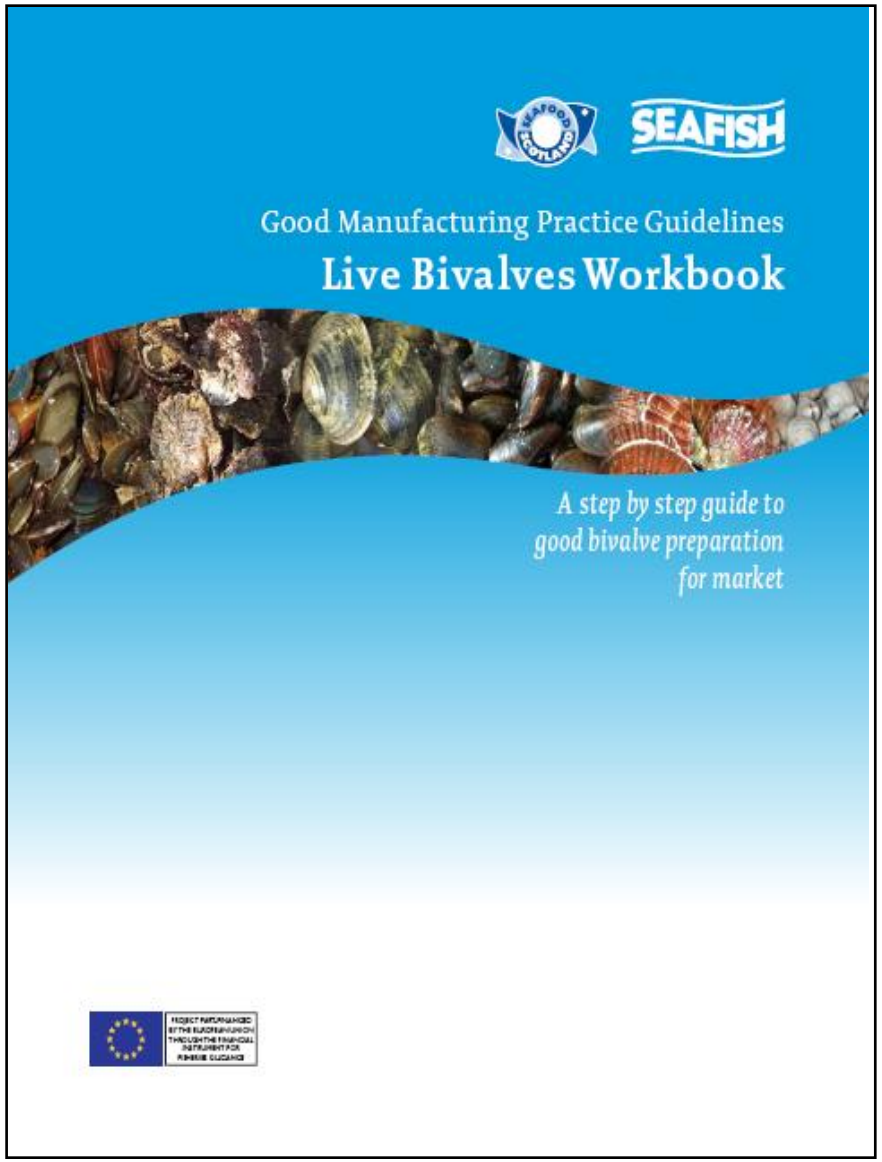
Sources


LISTERIA
Second Edition
Clostridium botulinum
A practical approach to the organism and its control in foods
Chris Bell and Alec Kyriakides
MICRO-ORGANISMS IN FOODS
5
CHARACTERISTICS OF MICROBIAL PATHOGENS
ICMSF
BLACKIE ACADEMIC & PROFESSIONAL
MODERN FOOD MICROBIOLOGY
SEVENTH EDITION
JAMES M. JAY
MARTIN J. LOESSNER
DAVID A. GOLDEN
FOOD SCIENCE TEXT SERIES
Salmonella
A practical approach to the organism and its control in foods
Chris Bell and Alec Kyriakides
E. coli

I.C.M.S.F 5


MICRO-
ORGANISMS
IN FOODS
5
CHARACTERISTICS
OF MICROBIAL
PATHOGENS
ICMSF
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An Imprint of Chapman & Hall

Good Manufacturing Practice Guidelines



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Why is purification needed?











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When do we use purification?

- **A class waters**: min. of 10 samples per year; 80% of sample results must be less than or equal to 230 CFU *E. coli*/100g; no results may exceed 700 *E. coli*/100g.
    - Under current legislation ***no purification needed*** but consider best practice!

- **B class waters**: 230 to 4,600 *E. coli*/100g.
    - Relay / ***purify*** / heat treat.

- **C class waters:** 4,600 to 46,000 E. coli/100g flesh.
    - Long-term relay / heat treat.

- **D class waters:** more than 46,000 E. coli/100g flesh.
    - Prohibited.

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What does purification involve?



- Species and physiological parameters:
  - Biomass
  - Water flow rate
  - Biomass/water ratios
  - Salinity
  - Temperature
- Turbidity
- UV power/wattage
- Ozone/intensive treatment
- Time (42 hours ***or less but only if approved by LA***)
- HACCP study/HACCP Plan (Article 5 of Reg (EC) 852/2004/Reg (EC) 853/2004 & Reg (EC) 178/2002 - Traceability etc

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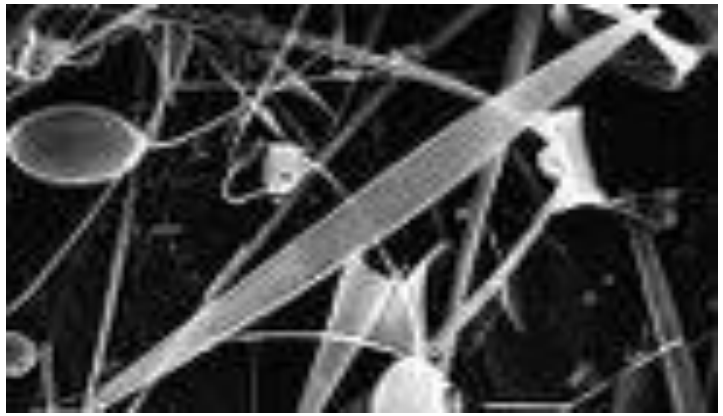
What are phytoplankton?

- Microscopic free-floating algae
- Photosynthetic
- Form large blooms
- Ingestion may be toxic
- Becoming more common?

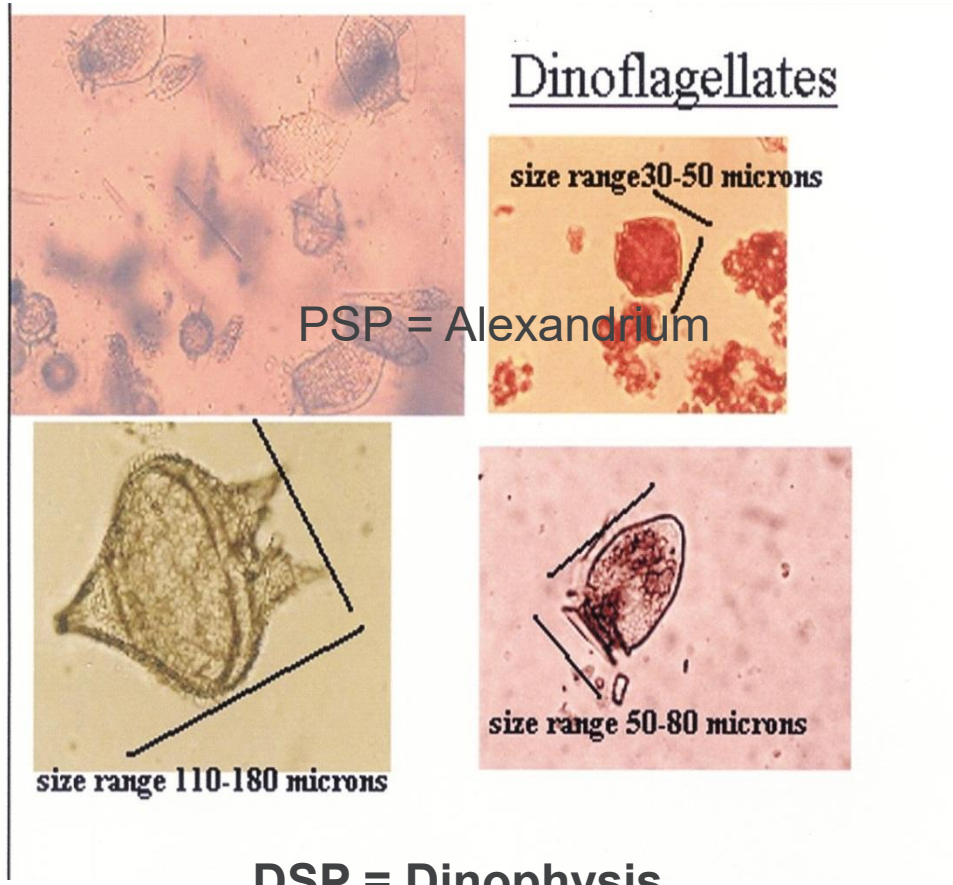
Harmful Algal Blooms (HABs)

- **Phytoplankton** – Dinoflagellates and Diatoms

- **HABs and Biotoxins:**
  - DSP – **Diarrhetic**
  - PSP – **Paralytic**
  - ASP – **Amnesic**



ASP = Pseudo-nitzschia



DSP = Dinophysis

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Classic ‘red tide’ image

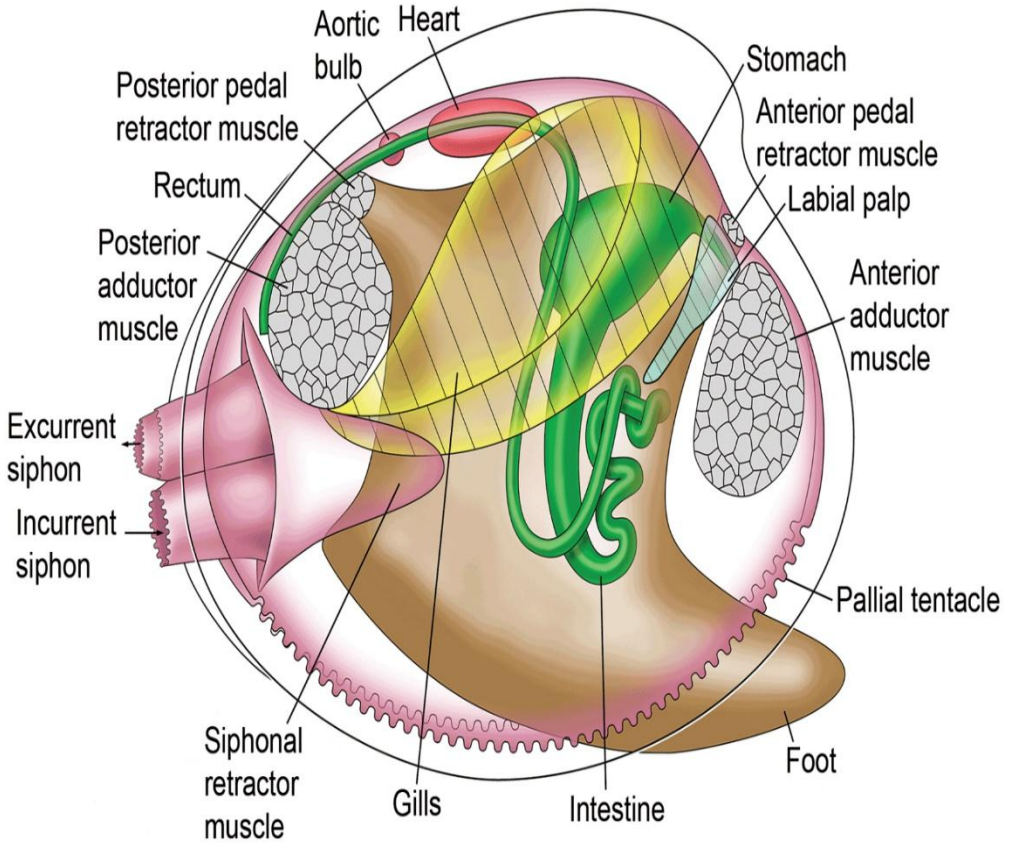


OCV Study - The food, science and technology – Biological and environmental requirements of bivalve shellfish

Bivalve shellfish environmental requirements

In order to purify effectively bivalve shellfish, need:

- Clean water
- Optimum salinity
- Optimum DO
- Optimum temperature range
- No stress or disturbance
- Be able to physically open
- Correct bivalve shellfish to water ratio
- Correct orientation
- Time (42 hours)



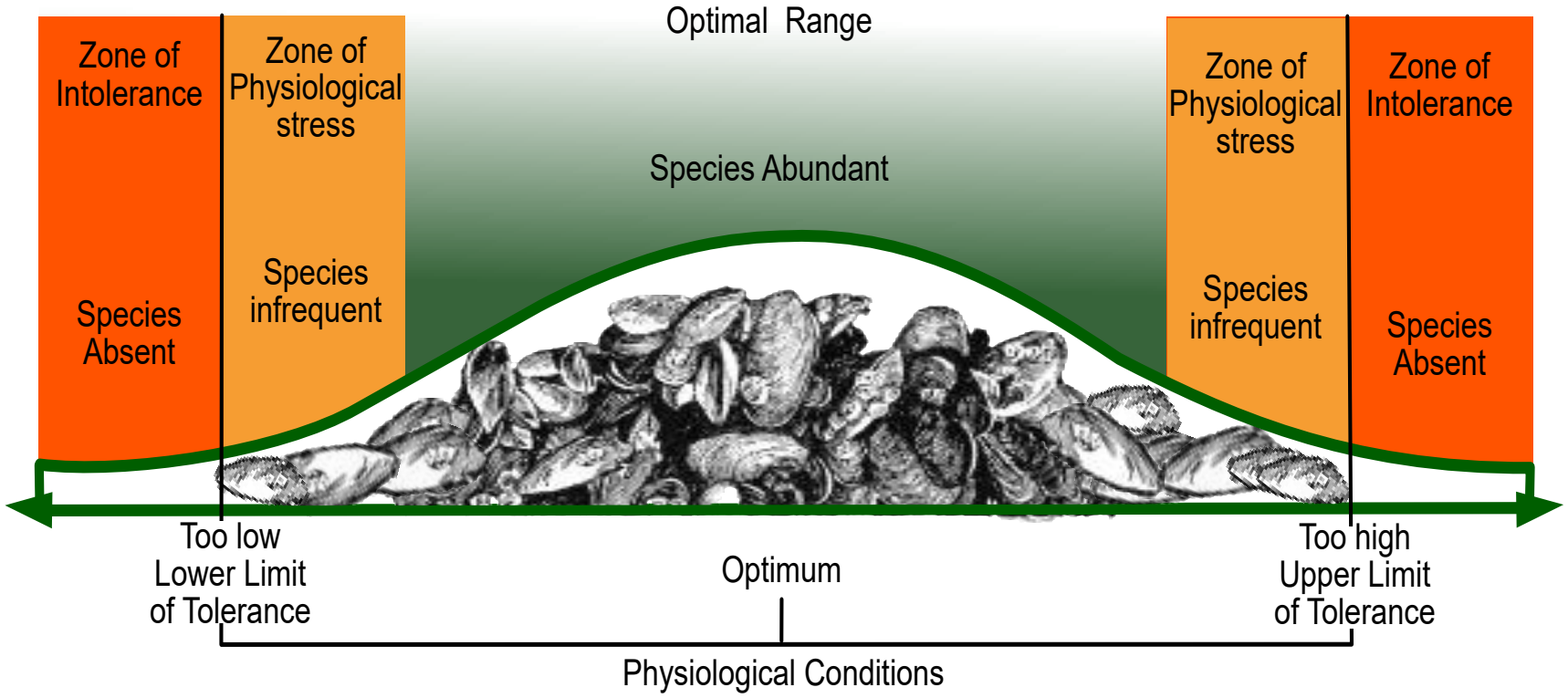
Generalised soft tissue anatomy of an LBM

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Shelford's Law of Tolerance

W.E.Shelford

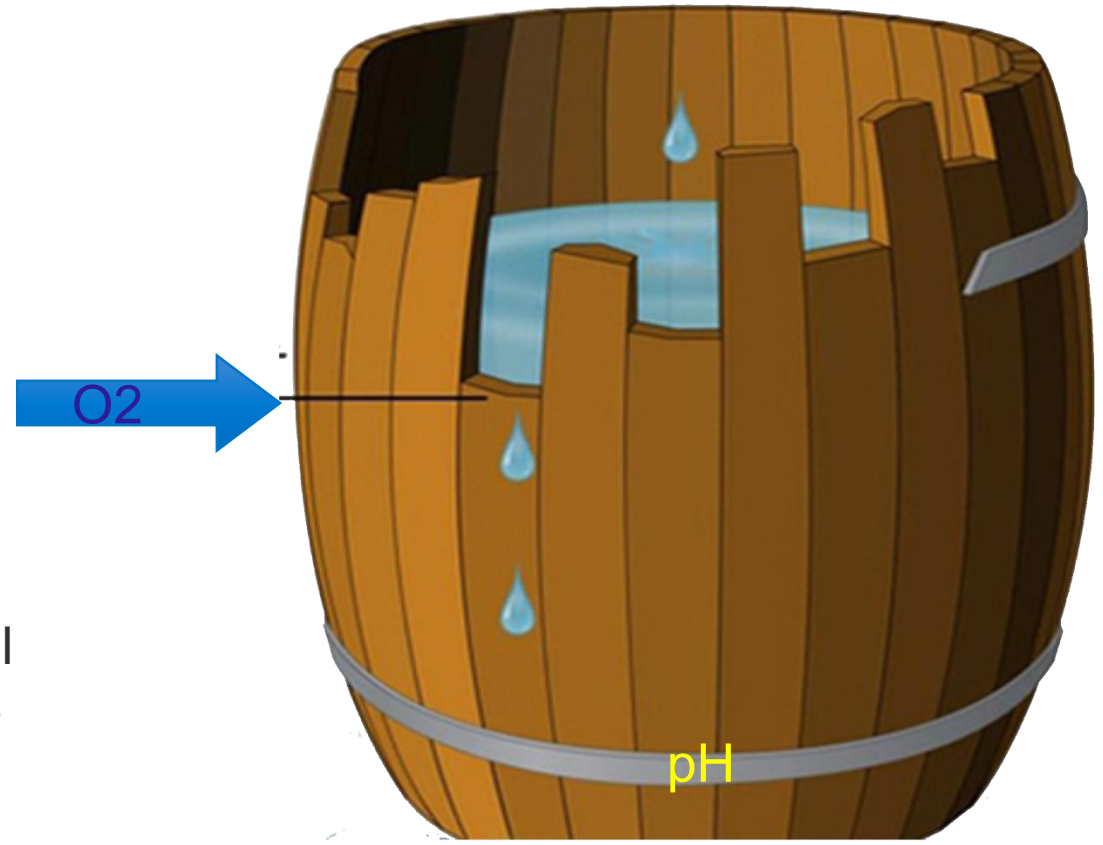




Liebig's Law of the Minimum



Justus Liebig



Metaphor of Liebig's Barrel'. Just as the capacity of a barrel is limited by the shortest stave – Depuration will be limited by the factor in the shortest supply – In this case dissolved O^2

Mussels in a submerged environment open and actively filter feeding



Effects of origin or culture method



- **Example** - **Rope-grown vs. Intertidal mussels:**
  - **Shelf-life** - due to differences in environment, intertidal mussels have ~4 days longer shelf-life

Effects of origin or culture method – continued





- **Example - Rope vs. Bottom cultured mussels:**

  Ability to withstand rough handling -

  - Bottom cultured mussels have thicker shells and so can withstand robust handling
  - Purification tank loading density for bottom cultured mussels can also be greater than rope grown mussels

Know your bivalve shellfish


Mytilus trossulus vs. edulis


Ensis

- You need to know the species for the ID mark (food fraud)
- Understand its biology e.g. subtidal *Ensis* must be re-immersed within 6 hrs. / start depuration within 24 hrs. post harvest

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Temperature vs filtering activity – Pacific Oyster

- Impressive filtering and therefore depuration at **22ºC**
- But spawning induced by higher temperatures – **max is 18ºC**

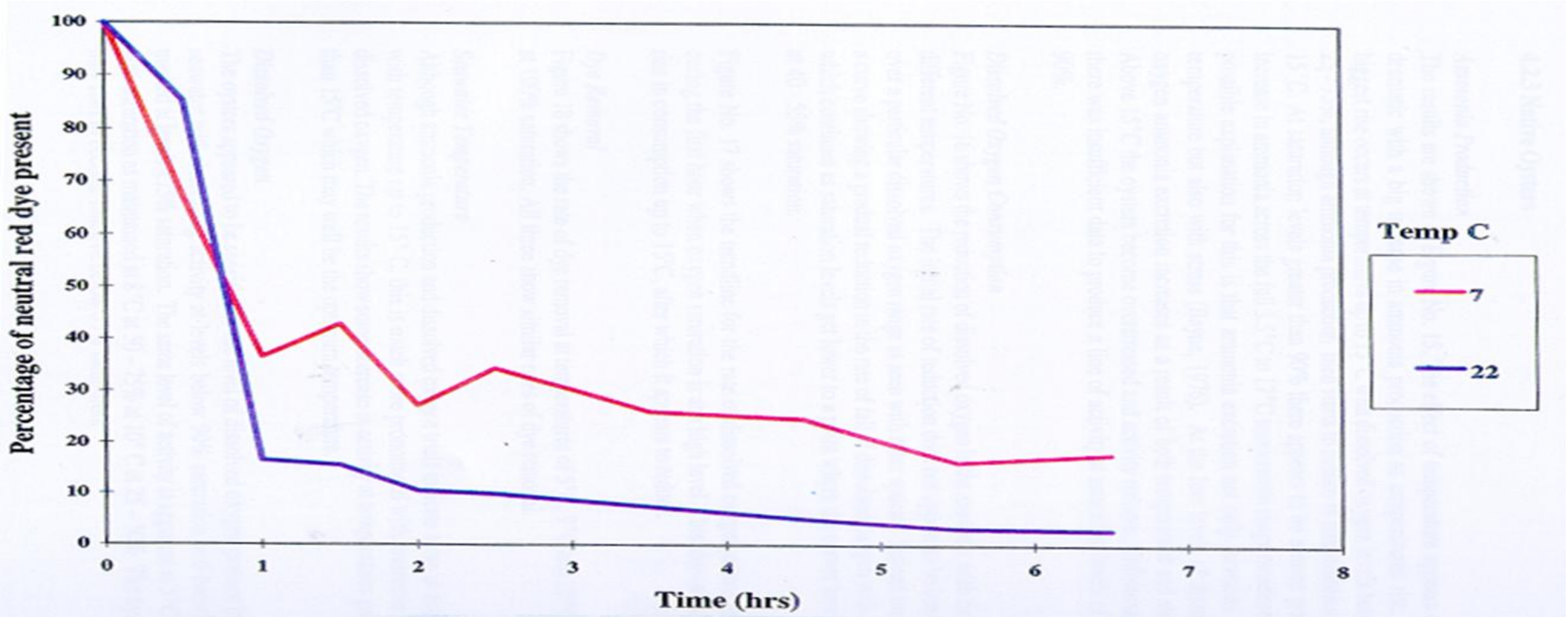


Figure 14 - Pacific Oysters - the reduction in neutral red dye over time at 100% dissolved oxygen and different temperatures

Water temperature - purification and conditioning

Purification Min. T °C		Conditioning °C
Mussels	5 °C	5° - 15 °c
Native Oysters	5 °C	5° - 15 °C
Pacific Oysters	8 °C	8° - 18 °C
Hard Clams	12 °C	12° - 20 °C
Cockles	7 °C	7° - 16 °C
Razors	10 °C	10° - 15 °C

- Understanding differences between purification and conditioning:
  - **Purification** = Legally required control measure
  - **Conditioning** = For operational reasons

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Comparison of reduction rates during depuration

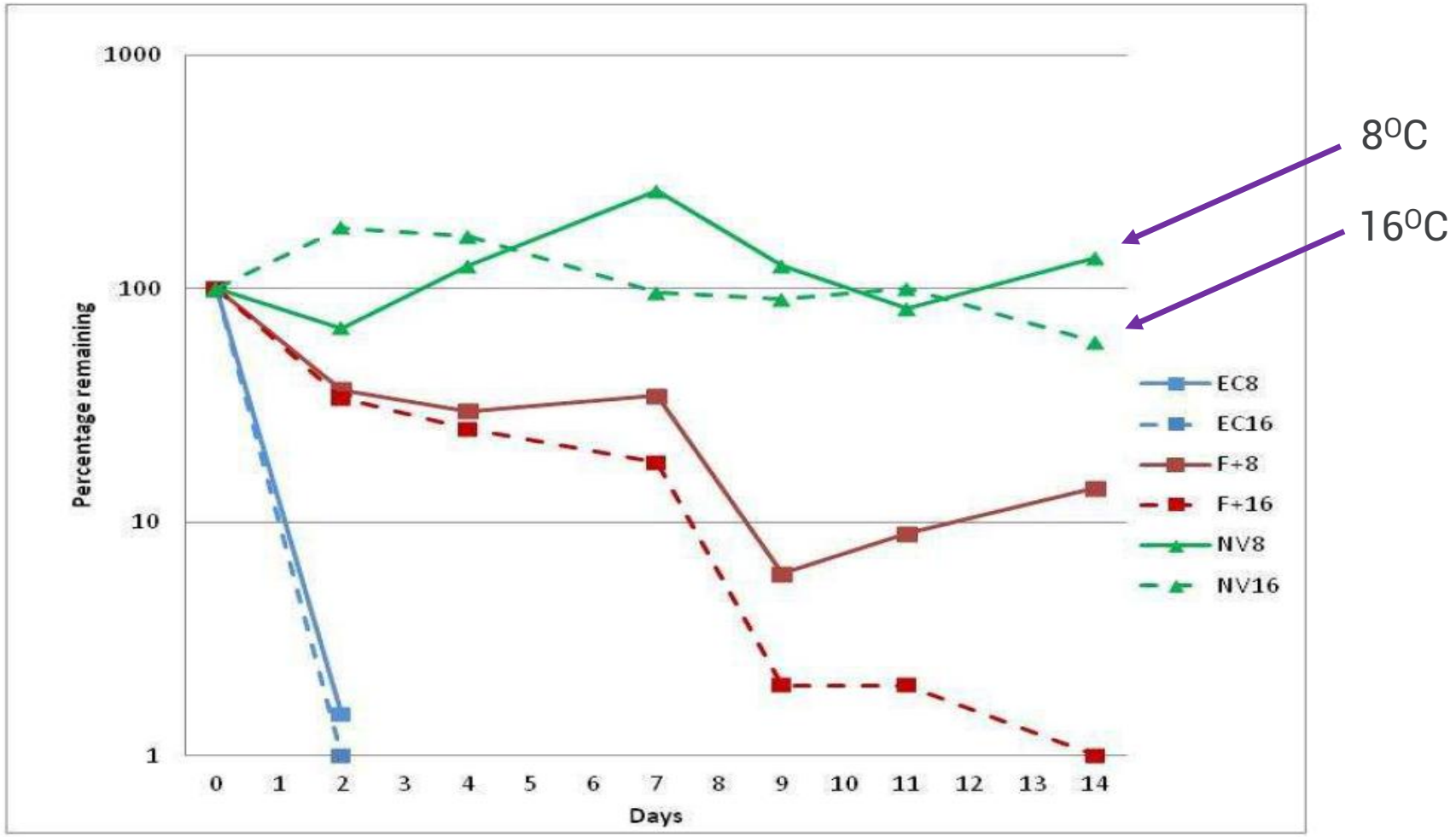


Figure 7. Comparison of *E.coli,* FRNA bacteriophage and norovirus reductions during depuration. Depuration conducted at 8°C (solid line) and 16°C (dashed line). EC = *E. coli*, F+ FRNA Bacteriophage, NV = norovirus. (Each data point calculated from the geometric mean of four replicates).

Source: Cefas study by Anna Neish, 2013

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Minimum salinities for depuration

- Native Oysters 25 ‰
- Pacific Oysters 20.5 ‰
- Clams 20.5 ‰
- Mussels 19 ‰
- Cockles 20 ‰
- Razors 30 ‰

‰ = parts per thousand (ppt)



Mussel raft on Loch Etive with mussels placed at 10-15m depth to avoid low salinity zone – Source: John Holmyard

Good practice: salinity within 20% from where bivalve shellfish gathered. (Source: CEFAS protocol Ver. 8)

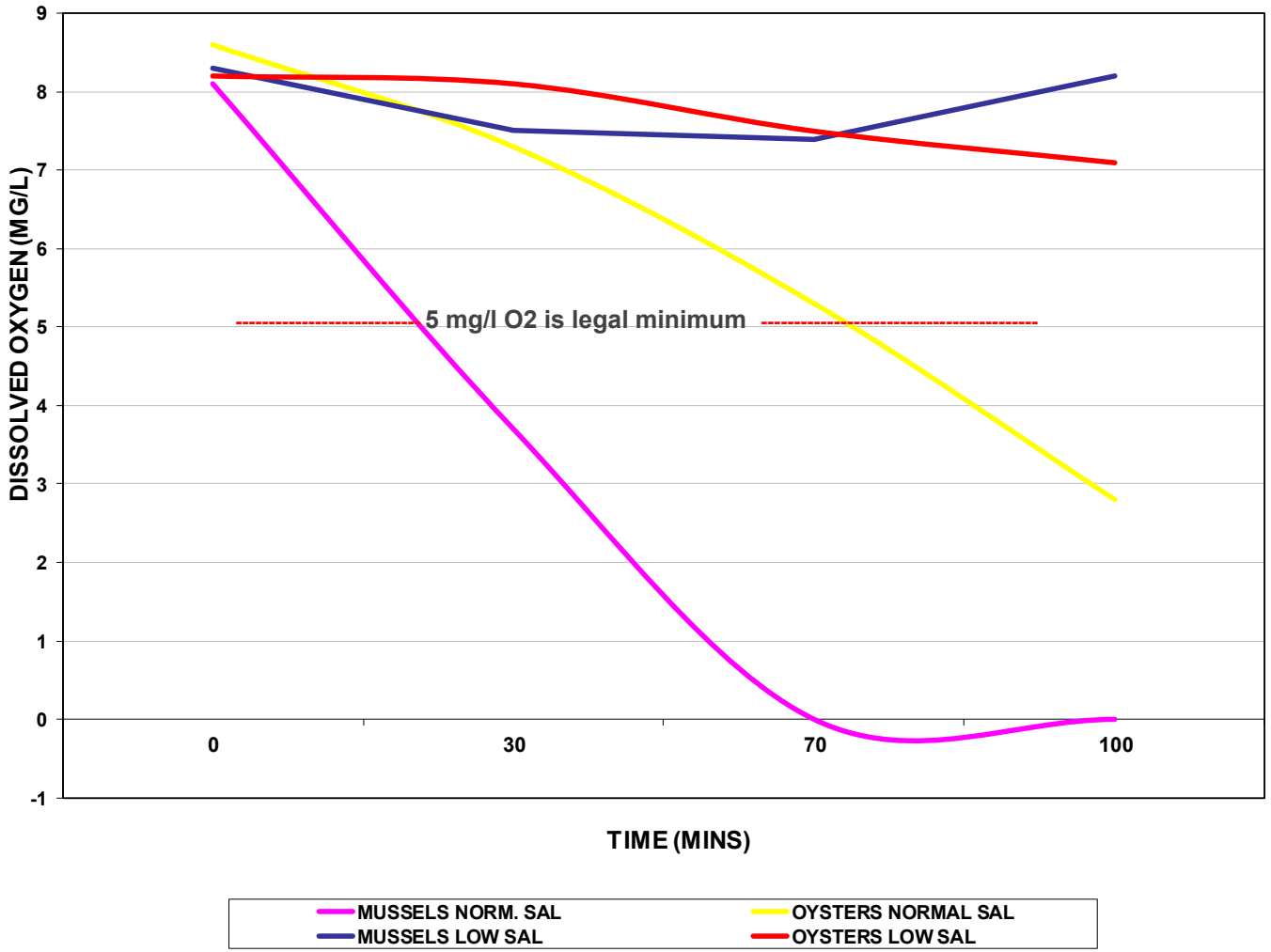
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Verification equipment

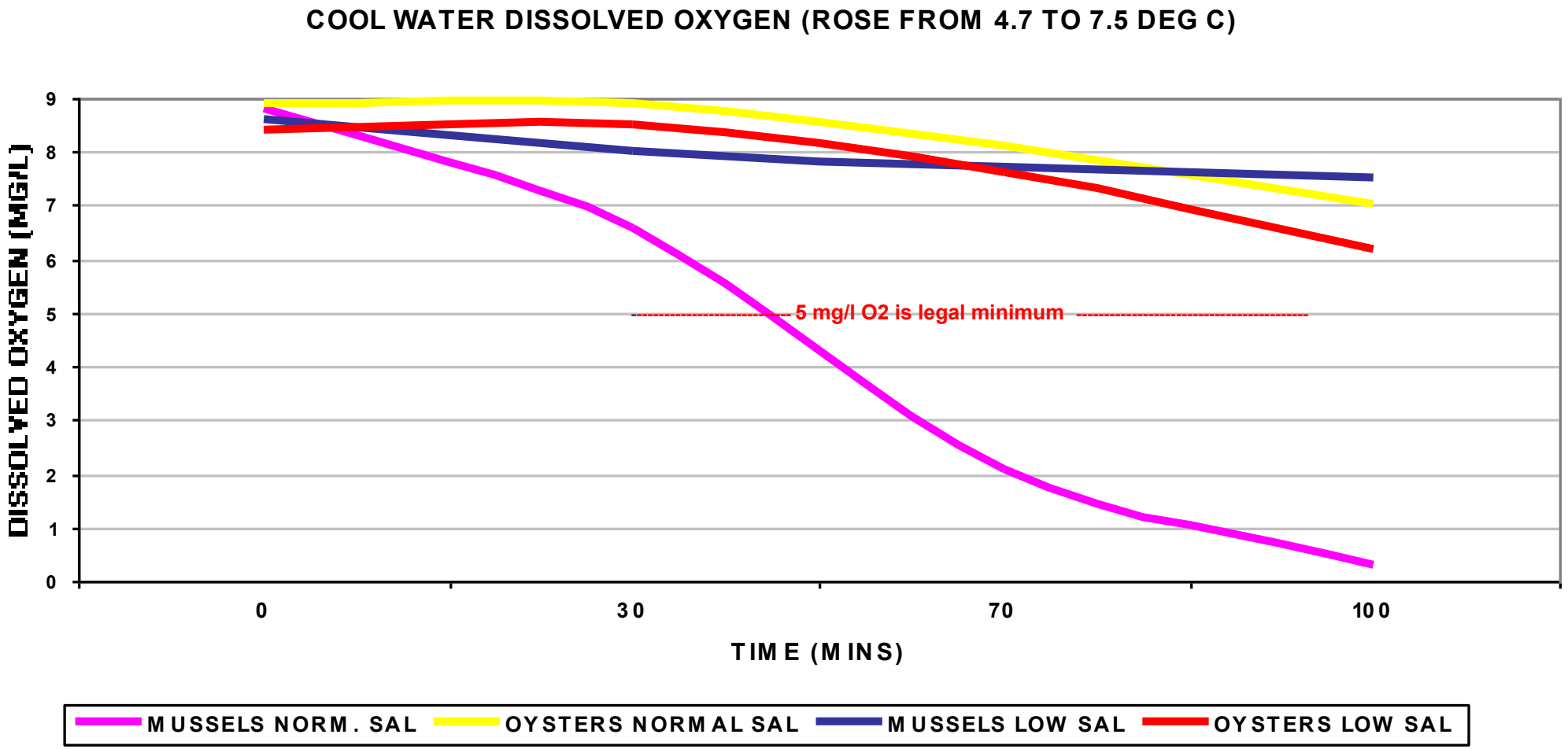
- Thermometer
- Salinity meter/hydrometer
- Dissolved Oxygen (DO) meter
- Flow meter (bucket and timer)
- Turbidity meter
- Other equipment?
  - Test for ozone residues using ozone meter
  - pH meter
  - Ammonia meter
- **Ensure correctly calibrated!**



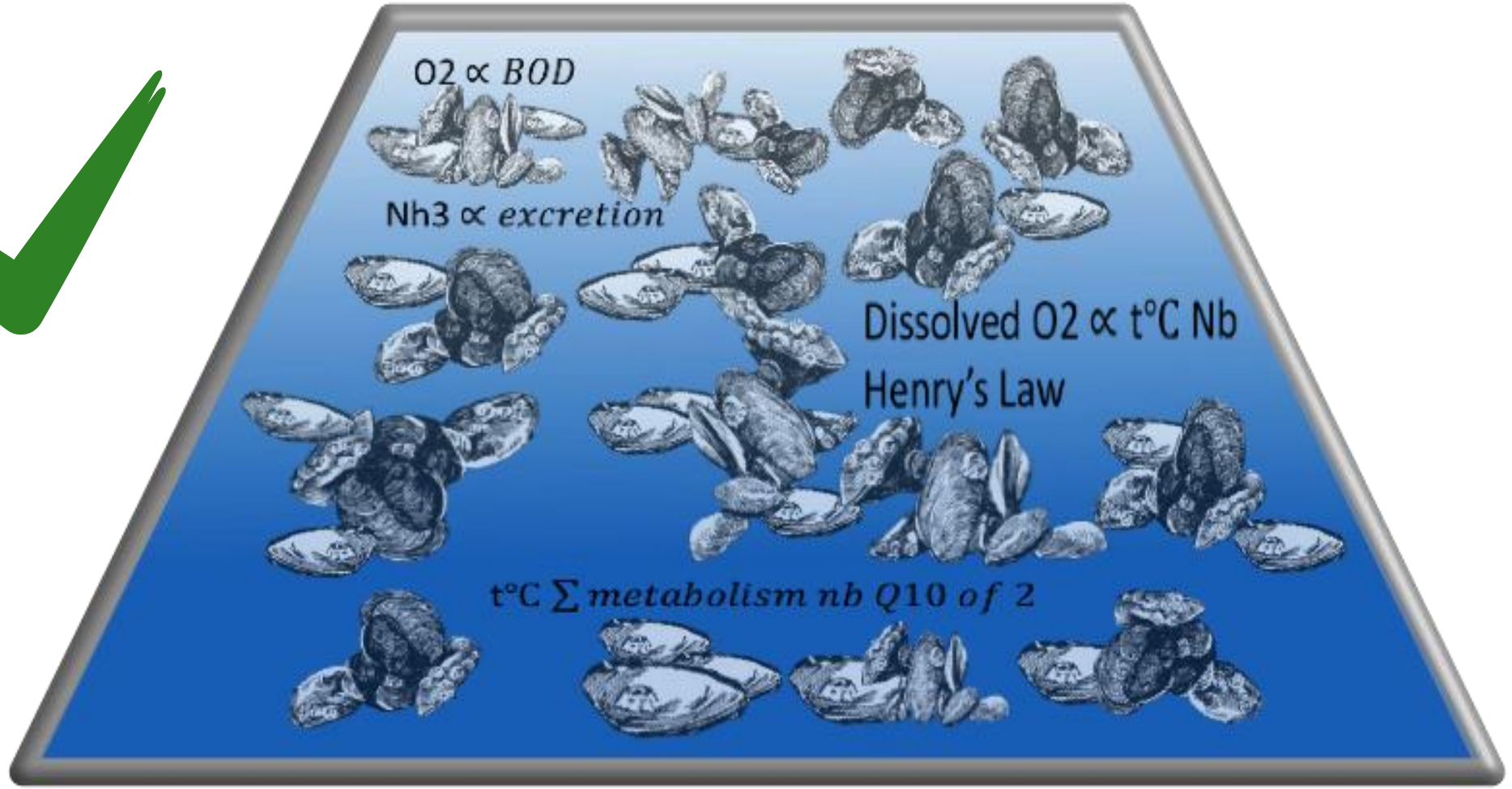
Why you need to check DO, salinity and temperature?



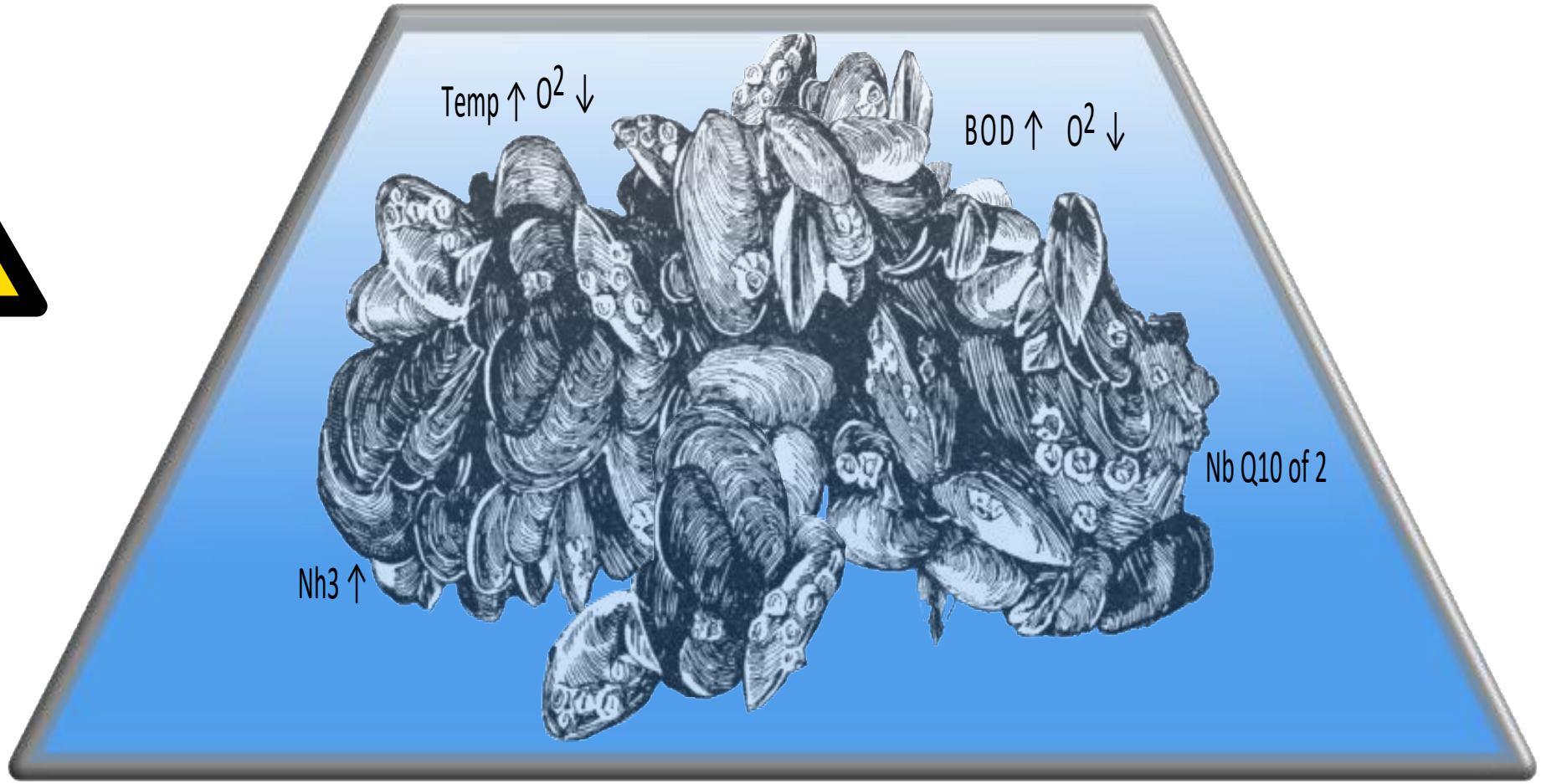
Why you need to check DO, salinity and temperature? - continued



Relationship between biomass: water ratio and physiological parameters



Incorrect biomass: water ratio and physiological parameters



OCV Study - The food science and technology – Depuration tank design and operation

The role of disinfection in seawater

- Why do we need disinfection equipment?
  - To ensure a **clean water supply**
  - To **prevent recontamination** from exterior dirt, faeces on shells and intravalvular fluid
- Consider bivalve shellfish in **clean water**:
  - Bacteria are purged in approx. 2 days
  - Viruses take much longer

Types of disinfection equipment used in purification

- Ozone
- Chlorination
- UV irradiation
- Hybrid systems now also used

What is ozone (O_3)

- Highly reactive form of Oxygen:
- Electrically generated and produced in situ & bubbled through a protein skimmer
- Very unstable gas – can only be stored for 10-20 mins

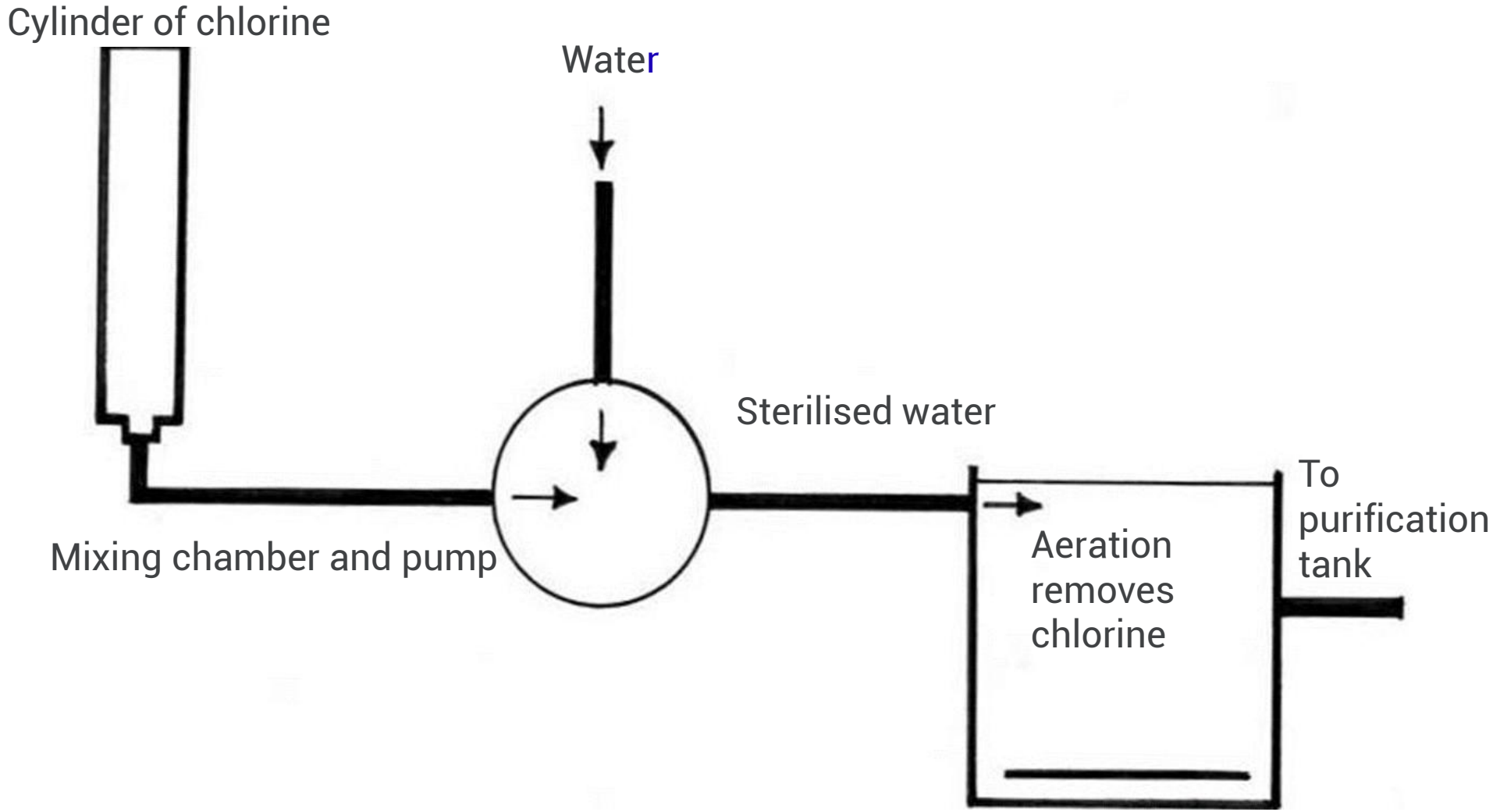
- **Advantages:**
  - Powerful oxidiser - very effective biocide and disinfectant
  - Will treat turbid water
  - Increases oxygenation

- **Disadvantages:**
  - May transform bromides into bromates in seawater!
  - Technically complex to implement although off-shelf solutions now available (Seafish have sample control docs)

See also This Library Guide

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Use of chlorine in purification



What is UV Radiation?

- Germicidal light wavelength is 253.7 nm
- UV damages bacterial & viral DNA preventing replication resulting in cell death.
- As water absorbs some UV, microbes are more difficult to kill in water than in air
- Commercial low-pressure mercury-vapour lamps produce a high proportion UV light



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Advantages of UV radiation

- Proven technology
- Simple to implement and use
- Leaves no taint in shellfish
- Leaves no residual disinfectant

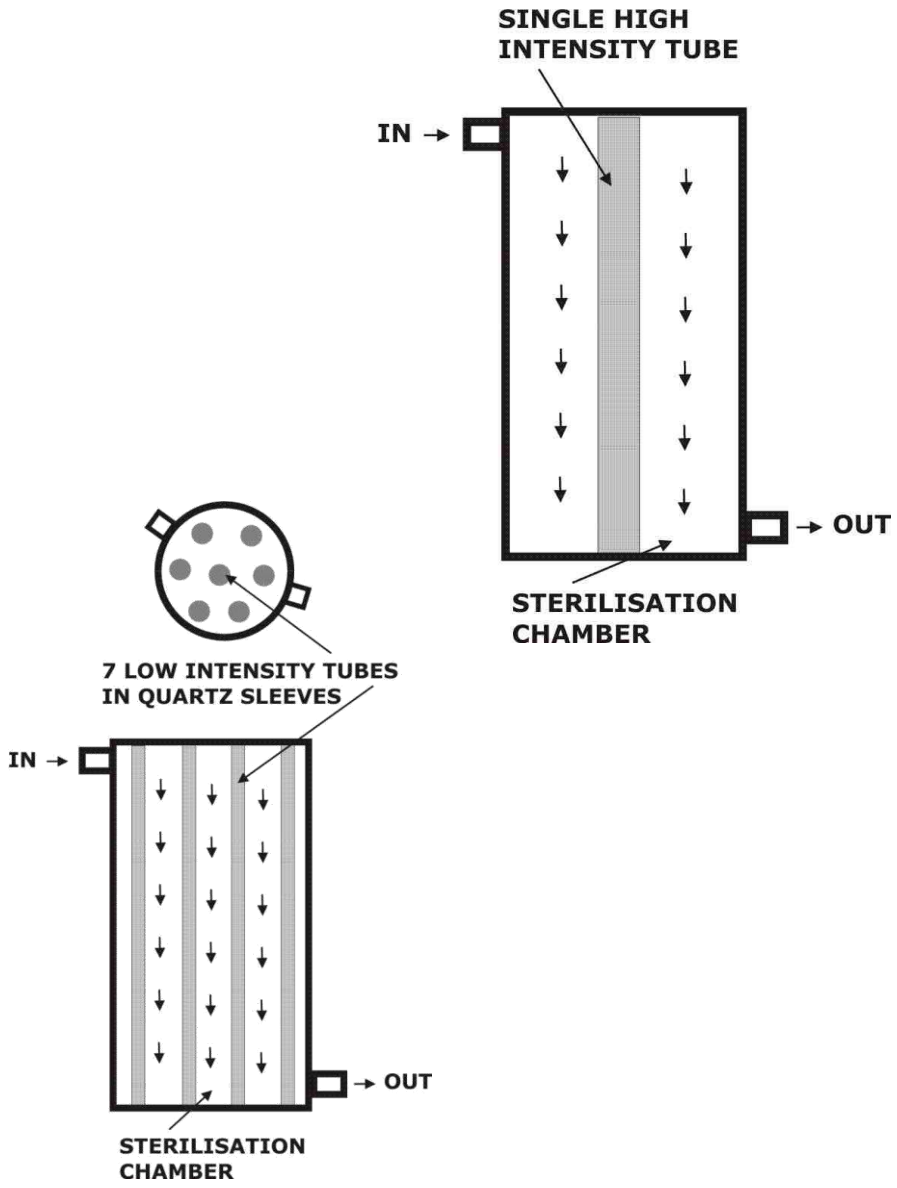


Main approaches to using UV systems

- **Single pass systems:**
  - Water not re-circulated, may be more affected by water supply problems
  - Operator has less control over water quality
  - Intense UV required to destroy bacteria and viruses
- **Recirculation systems:**
  - Many passes through UV bank and so UV can be less intense
  - Allows for greater control of purification conditions

UV lights

- **Wide Chamber:**
  - single high intensity tube
  - 10.45 mJ/cm² @ 2,200 l/hr. = Kill 3 Log (99.9%)
- **Narrow Chamber:**
  - multiple lower intensity tubes
  - 5.29 mJ/cm² @ 2,200 l/hr. = Kill 2 Log (99%)
- For **clear** water only.



Achieving and maintaining the correct UV dose

- **Minimum requirement:** dose must exceed minimum prescribed for a comparable system and must not be less than **10 mJ/cm$^{2.}$**
  - Lamp power : water flow must be correct

- **Note:** West's (1986) recommendation of using not less than 10mJ/cm^2 “one 30w UV tube is sufficient to continuously treat 2,200L of seawater in a re-circulation system" has been used as the basis for system approval in England & Wales since 1980's

How many UV lamps does FBO need?

- **Enough to be effective**!

  - Check with the Seafish standard designs available on website

  or

  - Seek expert help e.g., system or lamp suppliers

Important factors in ensuring effective UV operation

- **Age of the lamp**:
  - Record lamp usage
  - Refer to manufacturer's specifications
  - Replace as part of planned maintenance



- **Turbidity of the water**:
  - **Cleanliness** of the quartz sleeve
  - **Frequency of inspections**



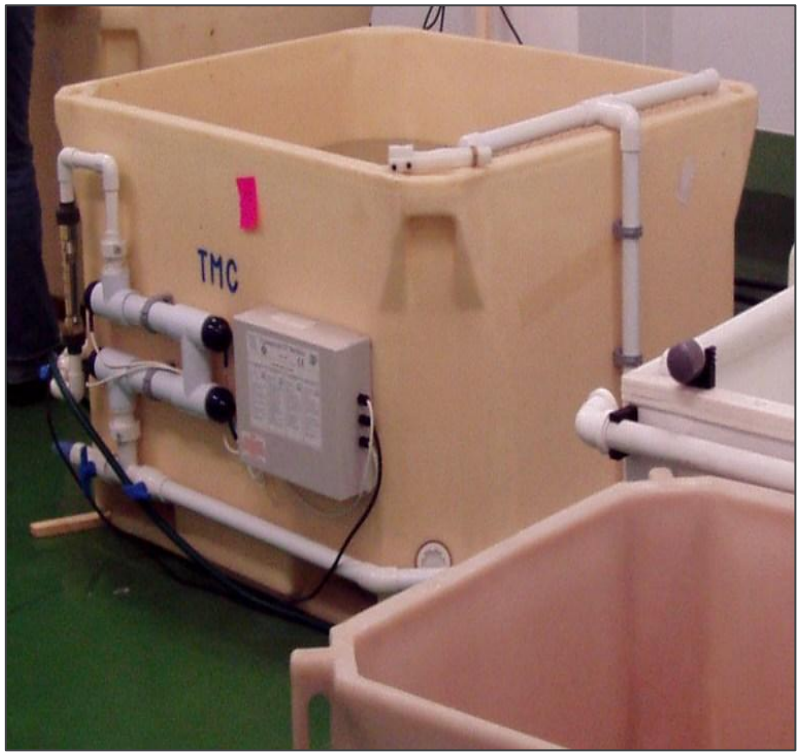
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Seafish standard design purification systems

- **Small scale shallow tank** 90kg mussels
- **Bulk bin system:** Mussels
- **Multi-layer system:** Medium / large scale
- **Vertical** stack system
- **Non-standard** systems - general ops manual

- **Installation:** LA approval, technical inspection and bacteriological challenge testing
- **Advantage:** Operating parameters are **known and proven** i.e. predictable and so less time and cost in obtaining approval
    - "Pre-Validated".

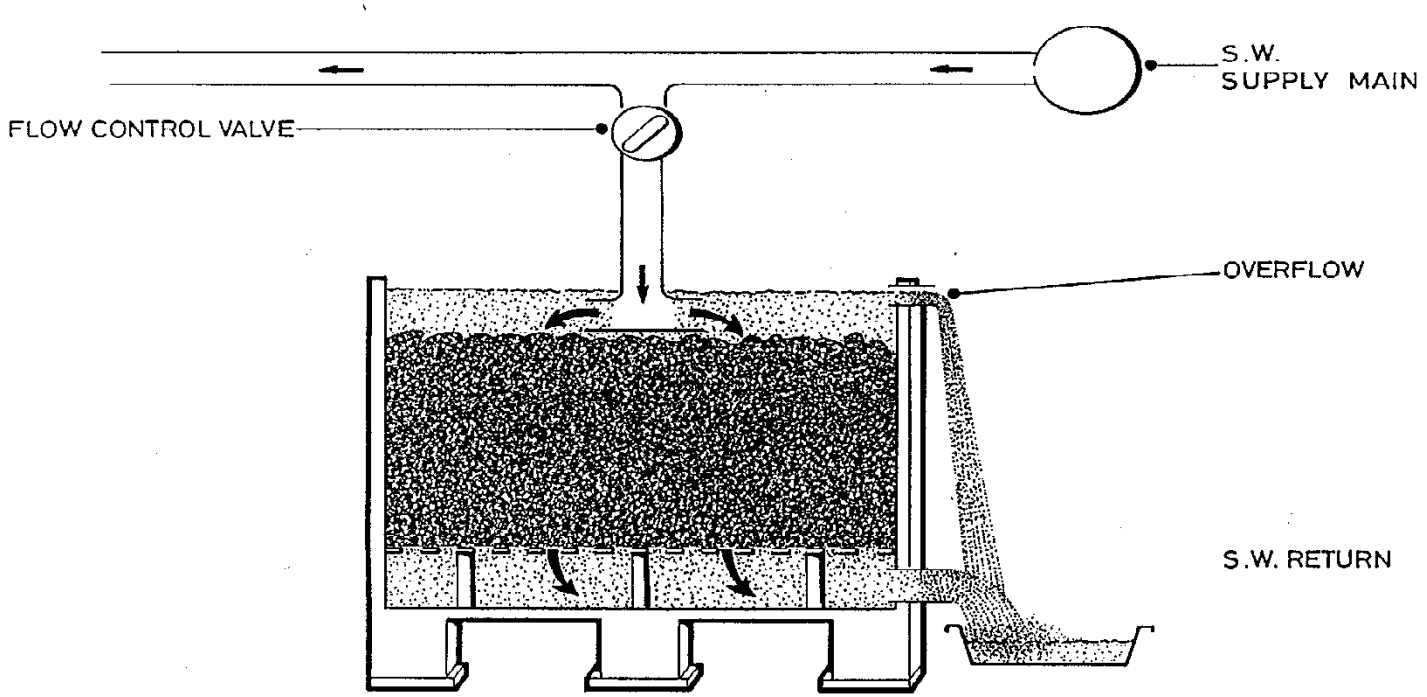
Shallow tank system





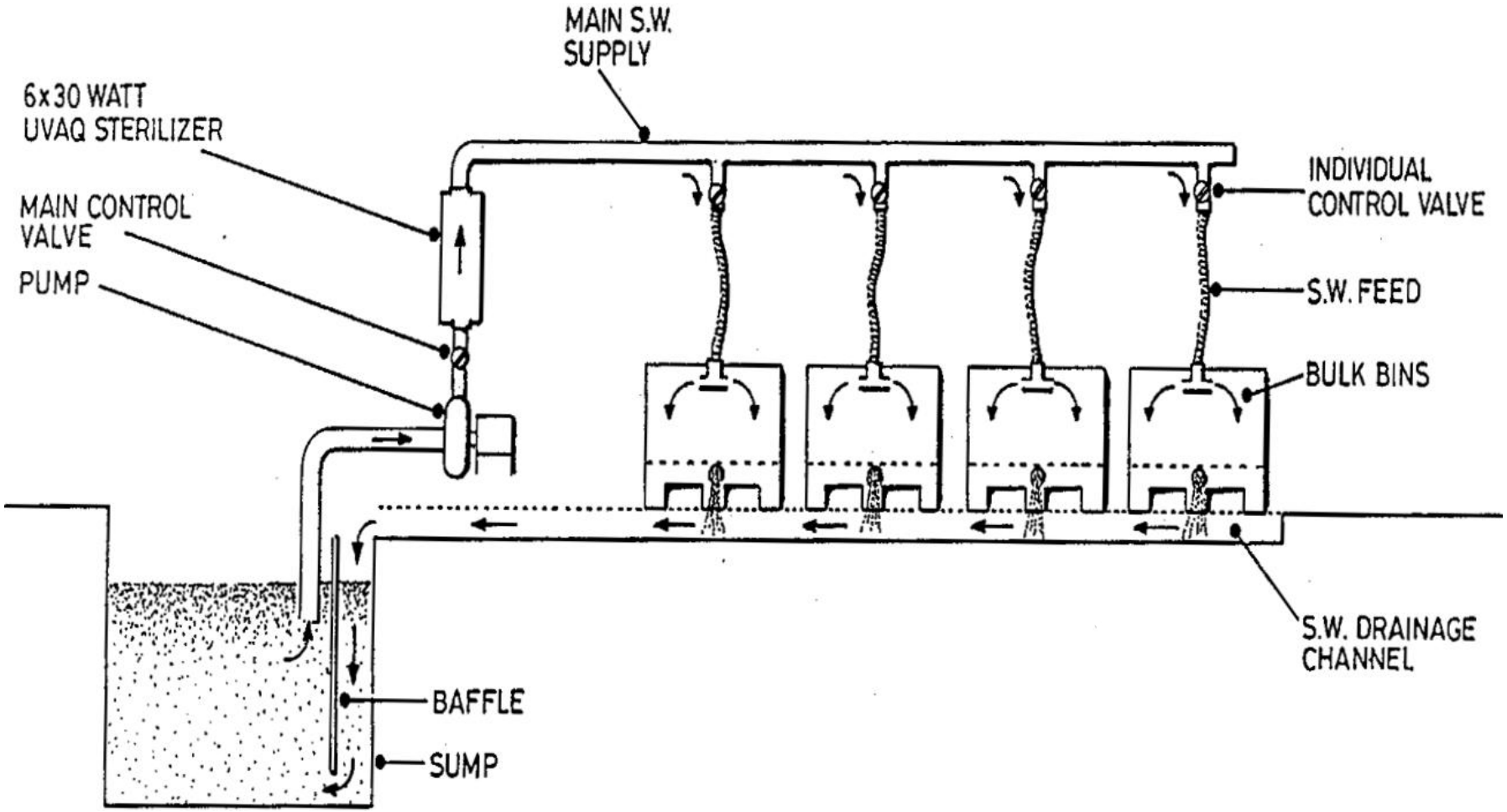


Bulk bin system



- 300-350kg bottom grown mussels vs. 250-300kg rope grown
- Potential for low Dissolved Oxygen in centre of bin
- Downwelling removes pseudofaeces

Bulk bin installation



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Bulk bin system

- Flow 6,500 l/hr. = >50% DO **(or 5 mg/litre)**
- 300kg Mussels (only!)
- 32mm outlet aperture
- Down welling carries detritus to the base of container
- Sump allows settlement of detritus carried over side
- Water enters below the surface – minimises disturbance



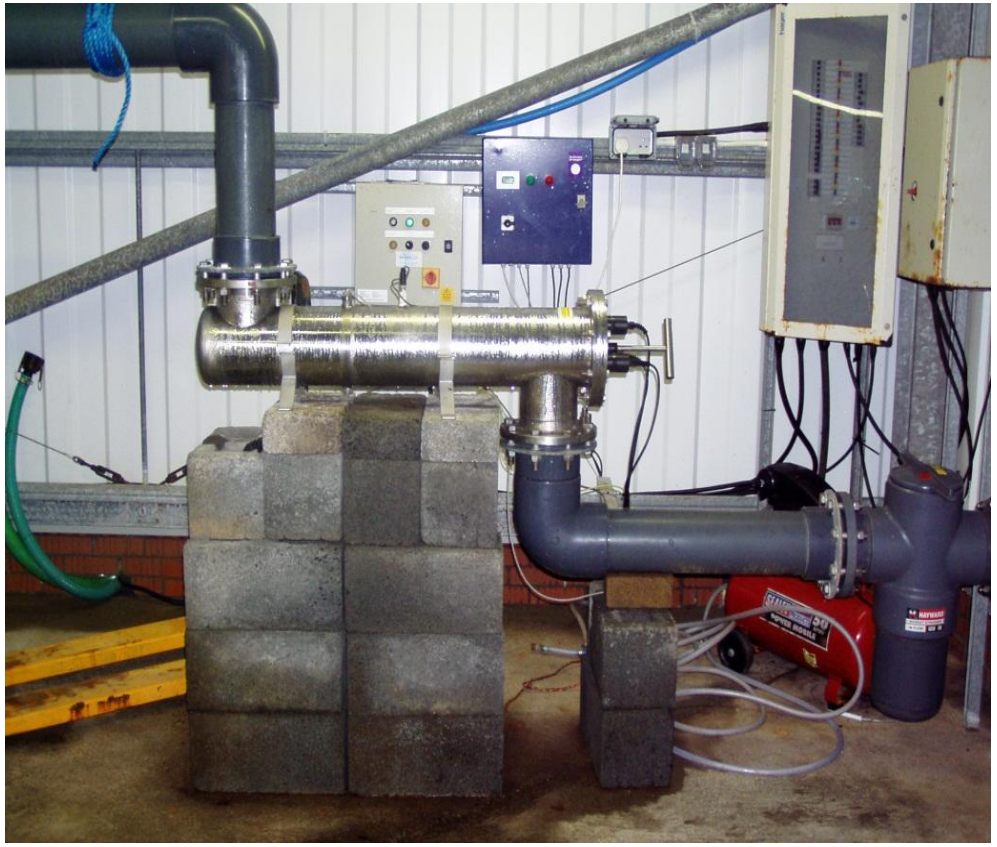
If you want to know that you are getting 6,500+ litres into a tank per hour…

32mm diameter hole = 6,500 litres

- **Q = C (Pi D2/4) (2gH)*0.5**
  - Q = Flow required
  - C = Non dimensional coefficient
  - D = Orifice diameter
  - g = Gravitational constant
  - H = Head
- ***So*** – if a 32mm outlet is emptying at full-bore and the overflow is just running then you have 6,500L per hour!

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Bulk bin system





Medium scale multi-layer system



Vertical stack system

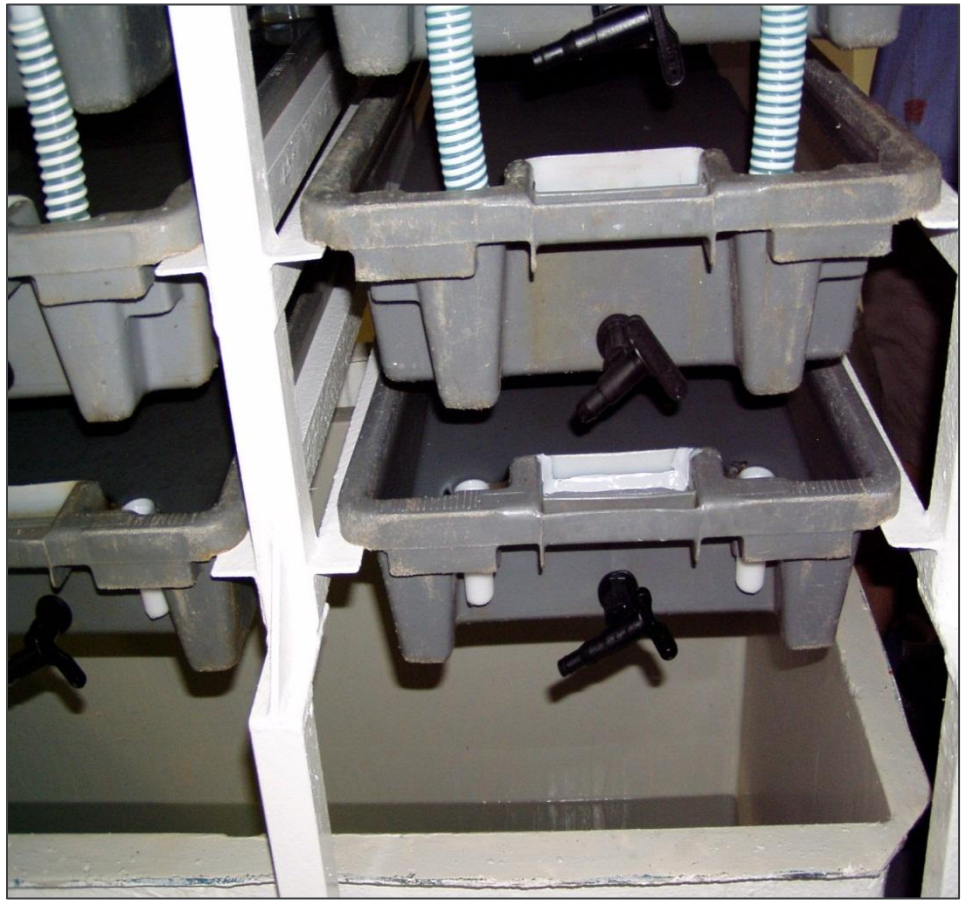




Stack system allows single tray removal

Useful for small to medium sized producers - also useful for storage after depuration





Multi-layer system – non-standard design



Is cleanliness of tank exterior an issue?

Note the (potentially) hazardous chemicals next to tank.

Other images…



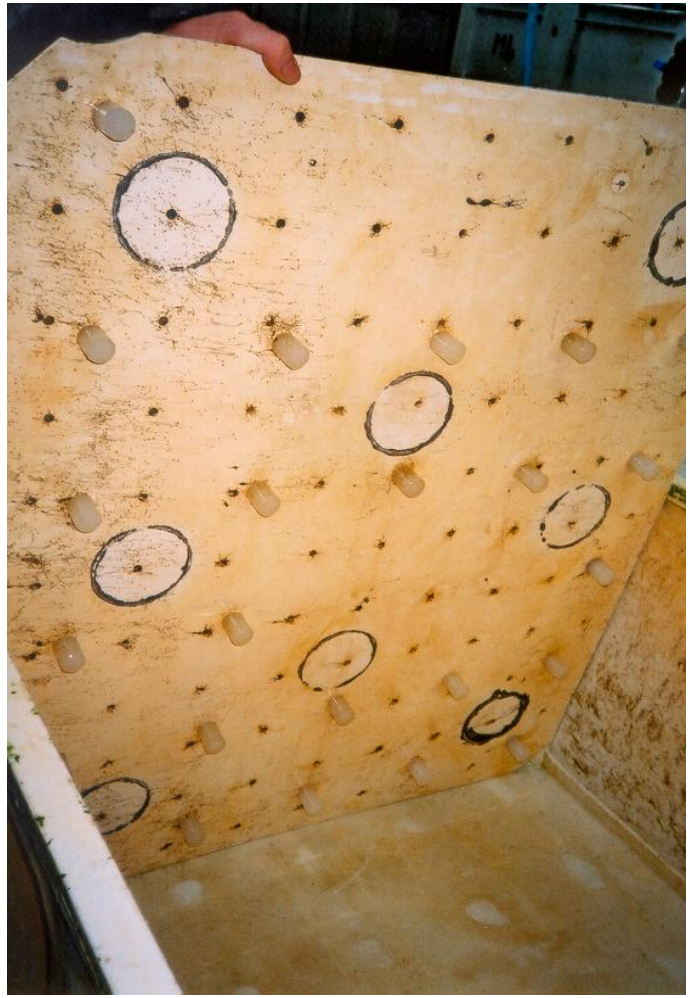
- Consider how you would verify/change the UV bulb operation during a depuration cycle?

Other images continued

- Trays of mussels loaded and waiting to be depurated in a multi-layer system
- Clean mussels and lack of debris on tank floor - show not yet purified
- Mussels need to rinsed after tank drain down



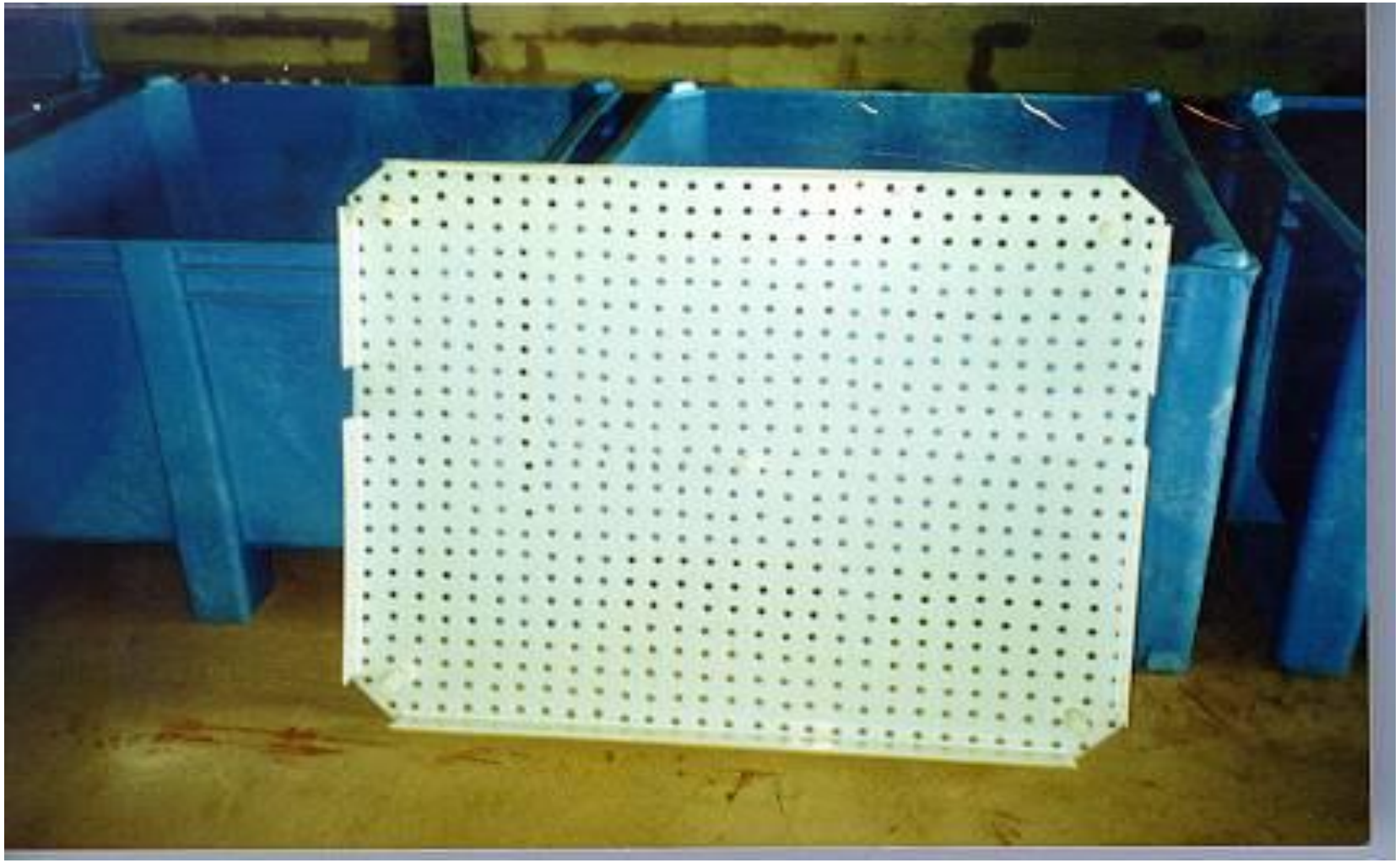
Keeping the mussels out of the detritus

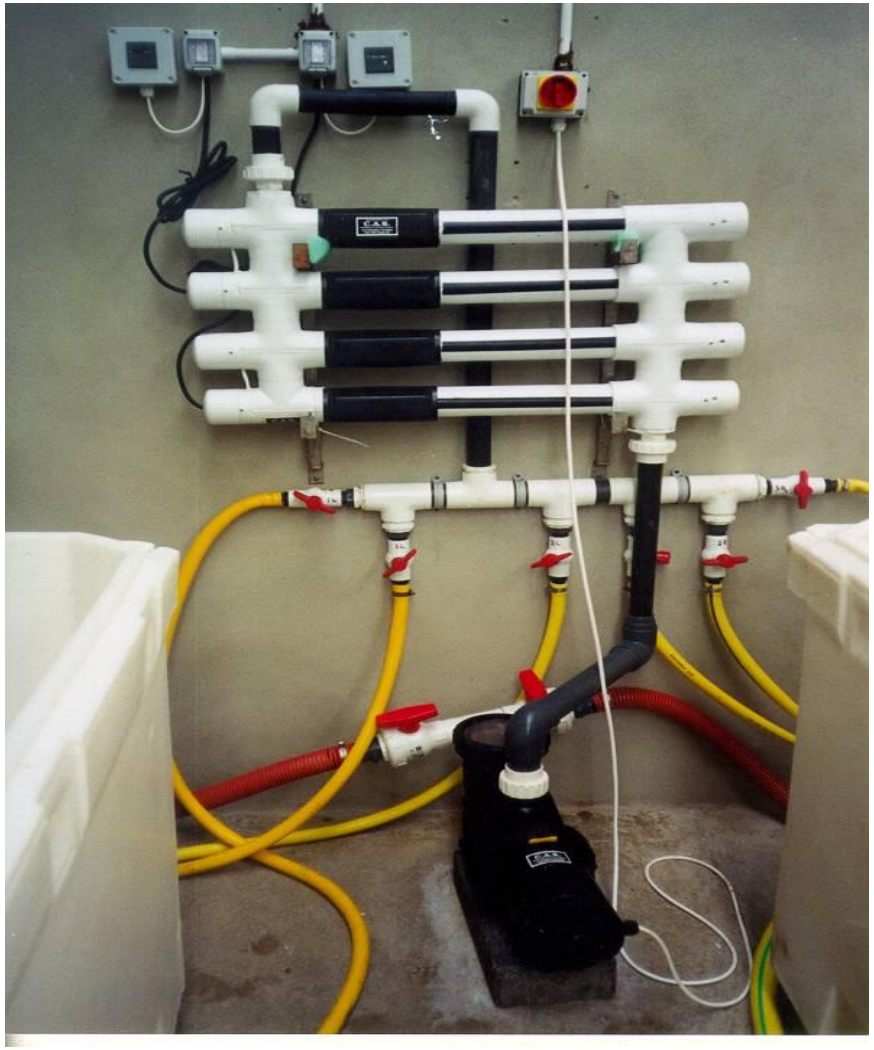




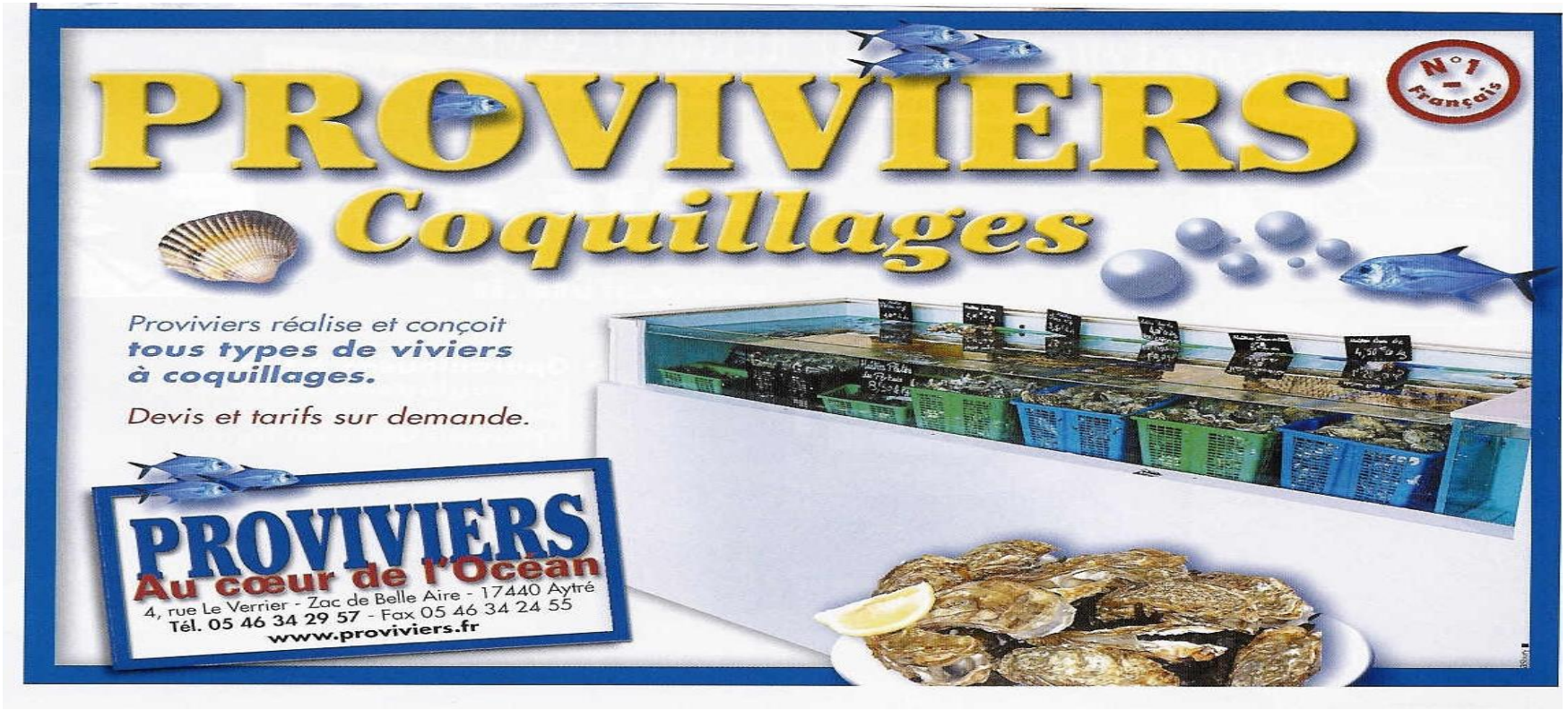
Difficulties in removing byssus threads

Clean sump screen from bulk bin system





- Catch basket in pump required cleaning and so was a potential source of contamination
- Difficult to check UV operation on this system



FSA: "**Conditioning may only** be carried out **in approved dispatch/purification centres**. Re-immersion of live bivalve molluscs [*bivalve shellfish*] for human consumption in display or storage tanks, e.g. in a retail establishment, **is not permitted**."

OCV Study - The food science and technology – Bivalve shellfish loading density, oxygenation considerations and re-use of seawater

Density, examples of other considerations

Minimum height above each layer of bivalve shellfish:

- hard clams & oysters = 30mm
- mussels = 80mm (shallow tray)

Small scale shallow tank system tray stacking:

- 3 layers of oysters, mussels and cockles - total of 6 trays per tank
- 2 layers hard clams - total of 4 trays per tank
- 1 layer of razor clams – total of 2 trays per tank

Density/loading – other considerations

- Allow expansion and movement of bivalve shellfish
- Consider total loading of system
- Settlement of detritus must be possible so that it can be removed
- **Single** bivalve shellfish species only per depuration tank/system

Re-use of seawater

- **Examples:**

- **Artificial Seawater** (Large scale tanks):
  - 6 litres water = 1 kg bivalve shellfish + 10% make-up = **4 weeks** normal life of that water batch

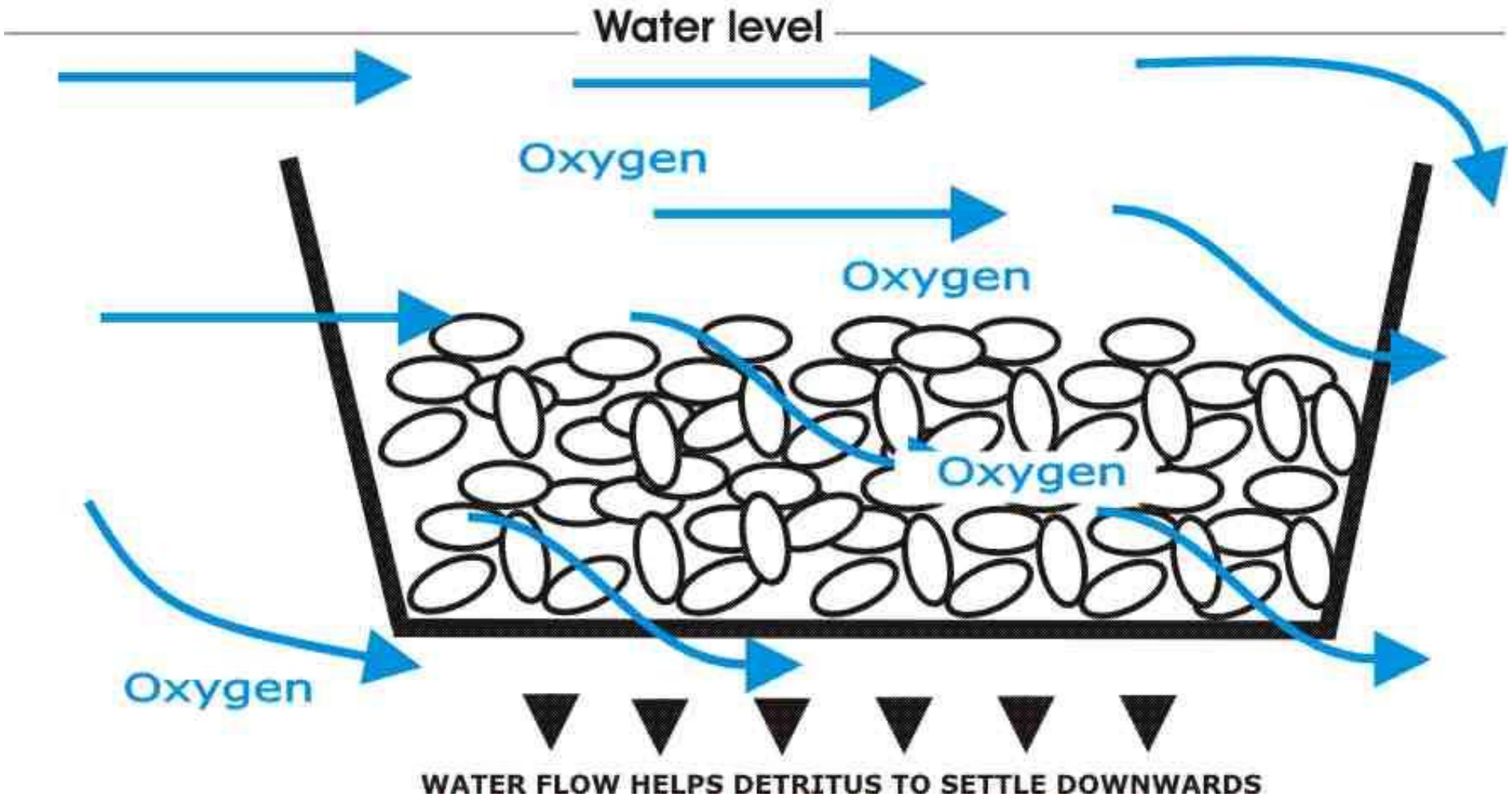
- **Natural Seawater:**
  - Normally **2 weeks** unless adverse weather conditions when 4 weeks for small scale systems

- **High Density** (Medium scale tanks):
  - 3 litres water = 1kg bivalve shellfish + 5% = **3 cycles** life of that water batch max

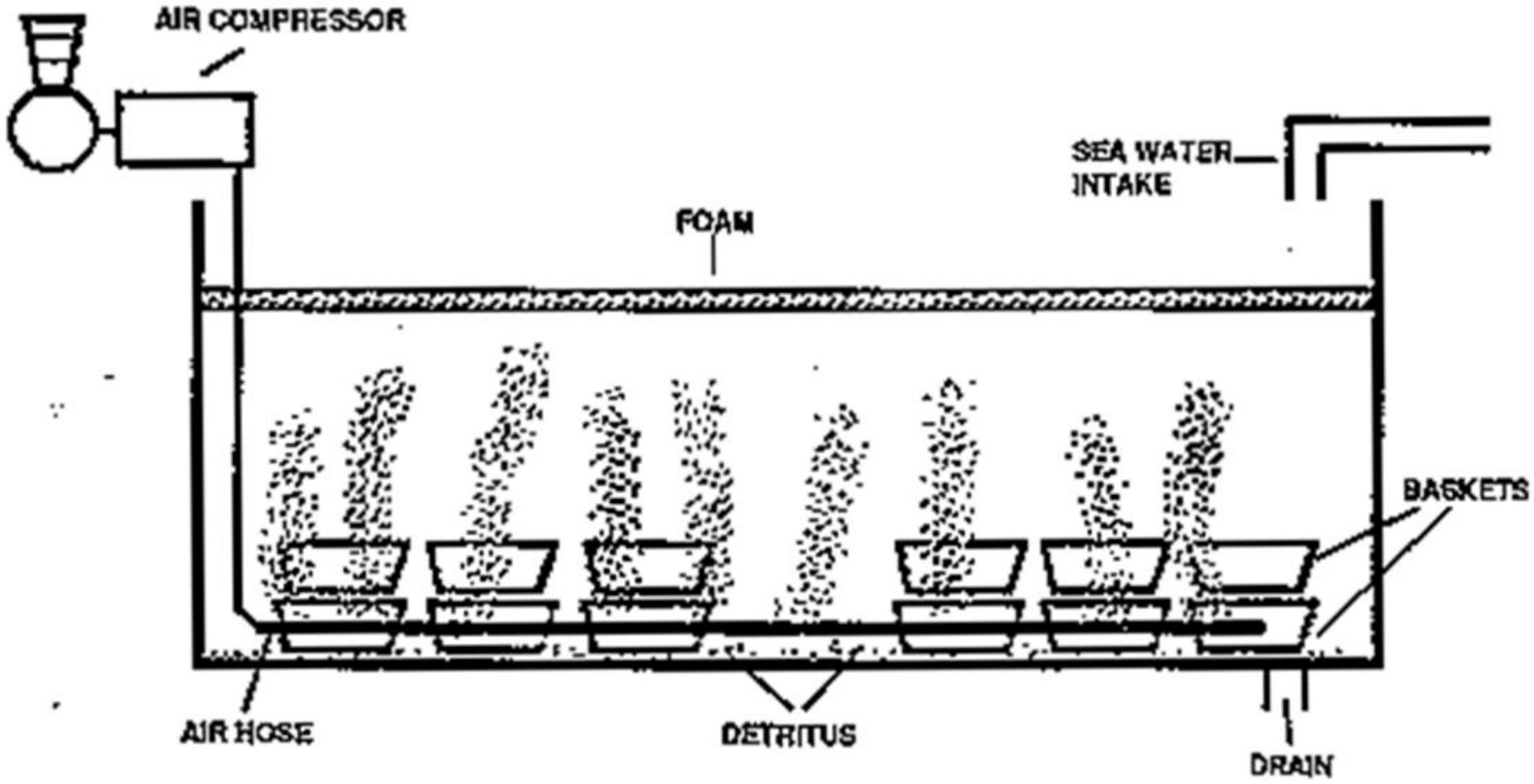
- **Visual checks**:
  - foam, bivalve shellfish action, smell NH_3

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Ideal oxygen supply

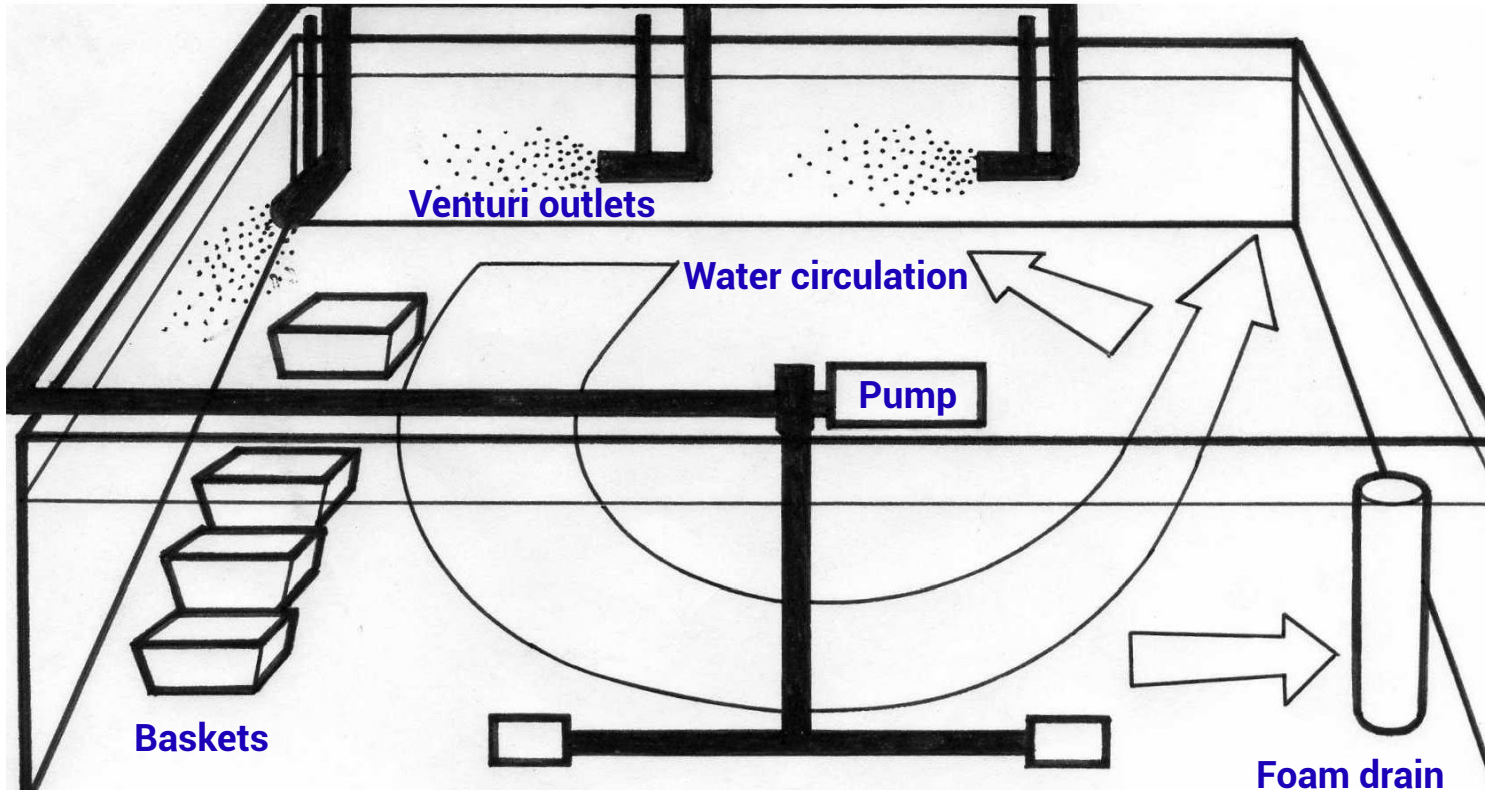


Purification tank with bubble aeration



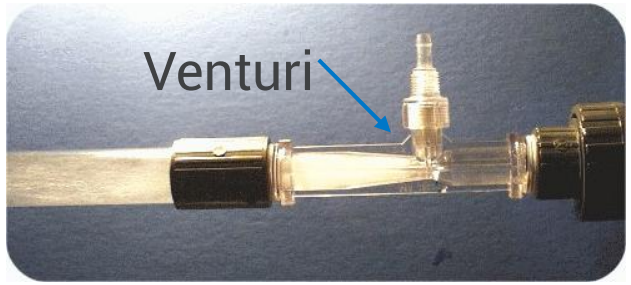
What are the flaws in this design?

Air supplied via water intake



What are the flaws in this design?

Venturi online video



Aquamerik.com

Water flow rate examples

- Typically, 20L/1kg/hour for mussels @ 15°C
- 2L/1kg/hour for oysters @ 21°C
- Bulk bin system: 108L per minute = 6,500L per hour
- STS: 20L per minute = 1,200L per hour

Bivalve shellfish handling

- **Proper planning prevents poor performance of the bivalve shellfish**

- **How do we get them ready?**
  - Identify and check batch identity
  - Grade / clean
  - Weigh and place in containers
  - Check tanks are clean and ready
- **Complete appropriate documentation**.

  Inc:
  - The registration document
  - FCMS entries e.g. weight/positively release tanks to process

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Stressed bivalve shellfish

- **What causes stress to bivalve shellfish**?
  - Low oxygen levels
  - Temperature or salinity outside of range
  - Rough handling before, during or after purification
  - Other shocks

- **Stressed bivalve shellfish will:**
  - **Fail to depurate**
  - Have reduced shelf life
  - May even die in the tank

Bivalve shellfish handling

Do this

- Inspect and grade
- Remove duds, mud balls etc
- Handle gently
- Protect from heat

Do not do this!

- Mix batches
- Have dead or different animals in tanks
- Throw or clump
- Stand in sun
- Expose to contamination

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Post purification treatment

- Tank drain slowly and completely
- Lift animals out – **avoid resuspension of detritus!**
- Wash - how?
- Inspect
- De-clump if needed*.
- Weigh and bag up
- Label
- Store / despatch
- Clean tanks
- Complete appropriate documentation
- Inc:
  - Registration document.
  - FCMS entries e.g. batch/lot identity to ensure traceability inc. internal/clean tank, records.

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How do we know it’s working?

- **It's working if…**
  - The **bivalve shellfish open their shells**
  - Moderate foam appears on top
  - The lamps are on
  - Lots of water is passing through the system

- **It's not working if ….**
  - The bivalve shellfish **don't** open their shells
  - You disturb or handle them when they are in the tanks
  - You place more bivalve shellfish in the tank after the start time

Stage 11 – Validation of the FCMS and systems

Methods and techniques of validation



- **WHO Codex, CAC/GL 69-2008 '*Guideline for the Validation of Food Safety Control Measures':***
  - Outlines 5 broad categories of validation activity
- **Scientific literature review**
- **Scientific studies (valid re the '*scientific method*'):**
  - Microbiological '*challenge testing*'
  - **Pre-production trails:**
    - Collection of production date (limited 3-6 weeks)
- **Mathematical modelling**
- **Surveys e.g. of consumer understanding of labels:**
  - Need for scientific validity (e.g. questionnaire design)
- **Other & allied methods:**
  - Statistical analysis
  - Reference to legal prescriptions
  - Reference to industry standards & codes of practice
  - Expert advice

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Challenge testing

- Challenge Testing:
  - Laboratory assays of trails that mimic actual process conditions
- Frequently use surrogate microorganism (benign with similar susceptibilities):

Inoculate known quantity of surrogate

↓

Operate process – SOPs

↓

Enumerate



FCMSs/Risk management and record keeping

HACCP

- **Hazards:**
  - Something with the potential to cause harm

- **Significance:**
  - A hazard that has been analysed for significance (probability x severity) and epidemiology.

- **Critical Control Points (CCPs):**
  - Points within the purification process flow where hazards are eliminated or reduced to an acceptable level
  - Not every step in the process is critical!

- **Hazard Analysis Critical Control Points:**
  - A food safety management system

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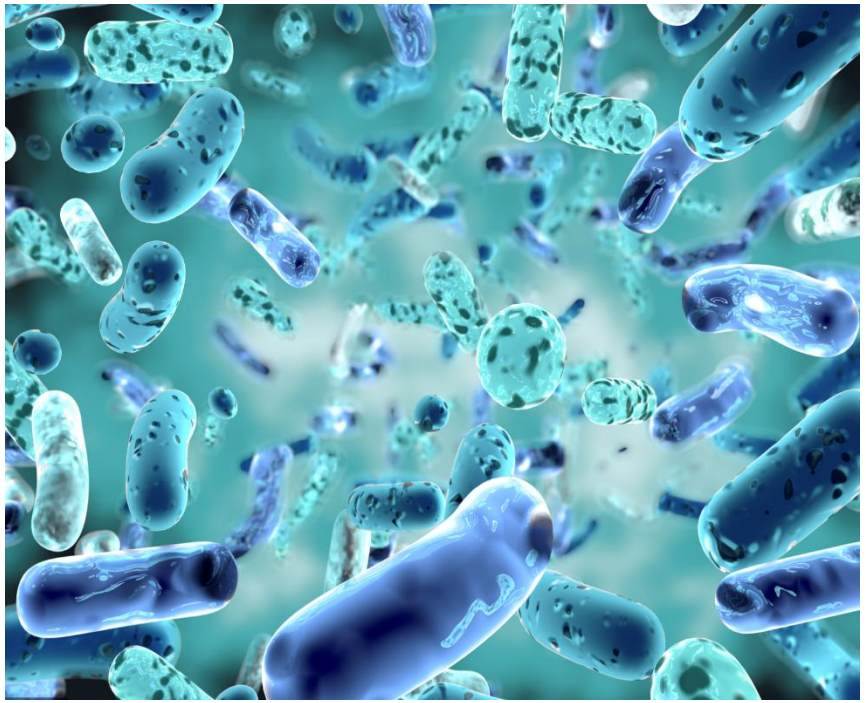
Stage 6 of the HACCP study – Hazard identification & analysis

Bacteria

Significant bacterial pathogens in bivalve shellfish

- **Salmonella spp – 12%***
    - serious illness for months
    - E.coli spp

- **Other bacteria include:**
    - *Clostridium perfringens*
    - Bacillus species
    - Campylobacter species
    - *Staphylococcus aureus*



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Viruses

Significant viral pathogens

- Source of contamination is normally sewage
- **Norovirus** - severe gastroenteritis
- **Hepatitis A** - serious illness
- Current depuration times **are <u>not</u> long enough** to remove viruses

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Sewage as a contaminant

- Sewage contaminated filter-feeding bivalve shellfish (oysters, mussels, clams) are recognised vectors of food poisoning

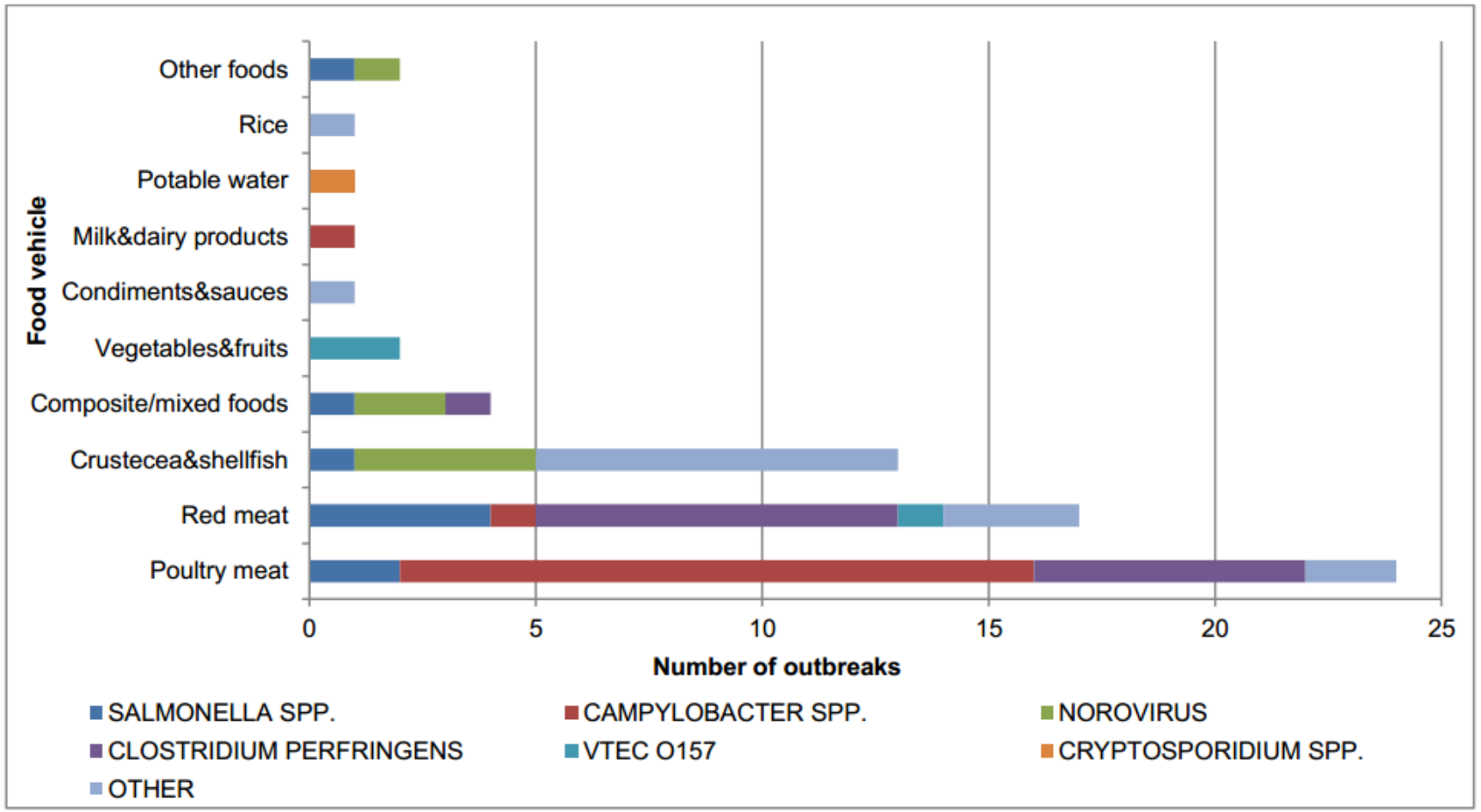
- Water companies are actively working with industry to mitigate the impact of significant pollution events – but have also incurred significant criticisms

- Water companies are not the only source of sewage contamination e.g. leaking septic tanks, diffuse pollution

Outbreaks in England and Wales

PHE Gastrointestinal Infections Data

Summary of eFOSS *data*, 2013

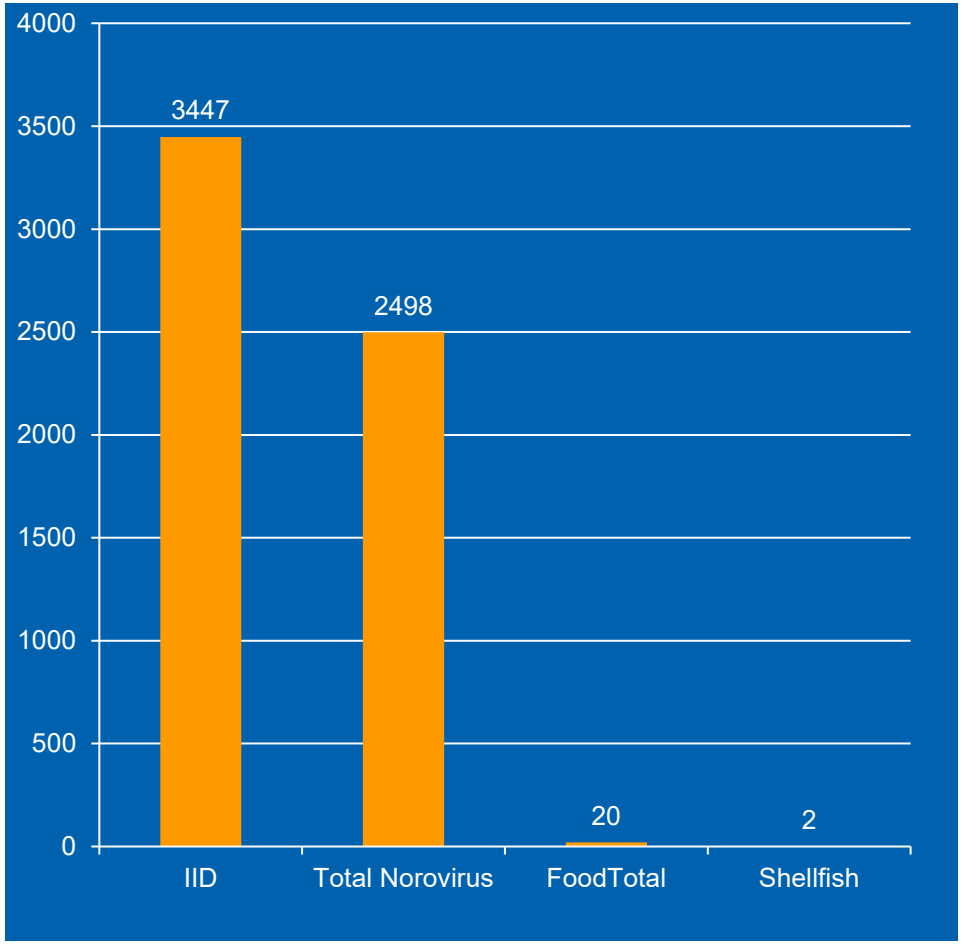


www.gov.uk/guidance/foodborne-and-non-foodborne-gastrointestinal-outbreaks-surveillance#surveillance-reports

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Food poisoning statistics

Total Infectious Intestinal Disease (IID) outbreaks in Scotland 1996 to 2011 – Health Protection Scotland.



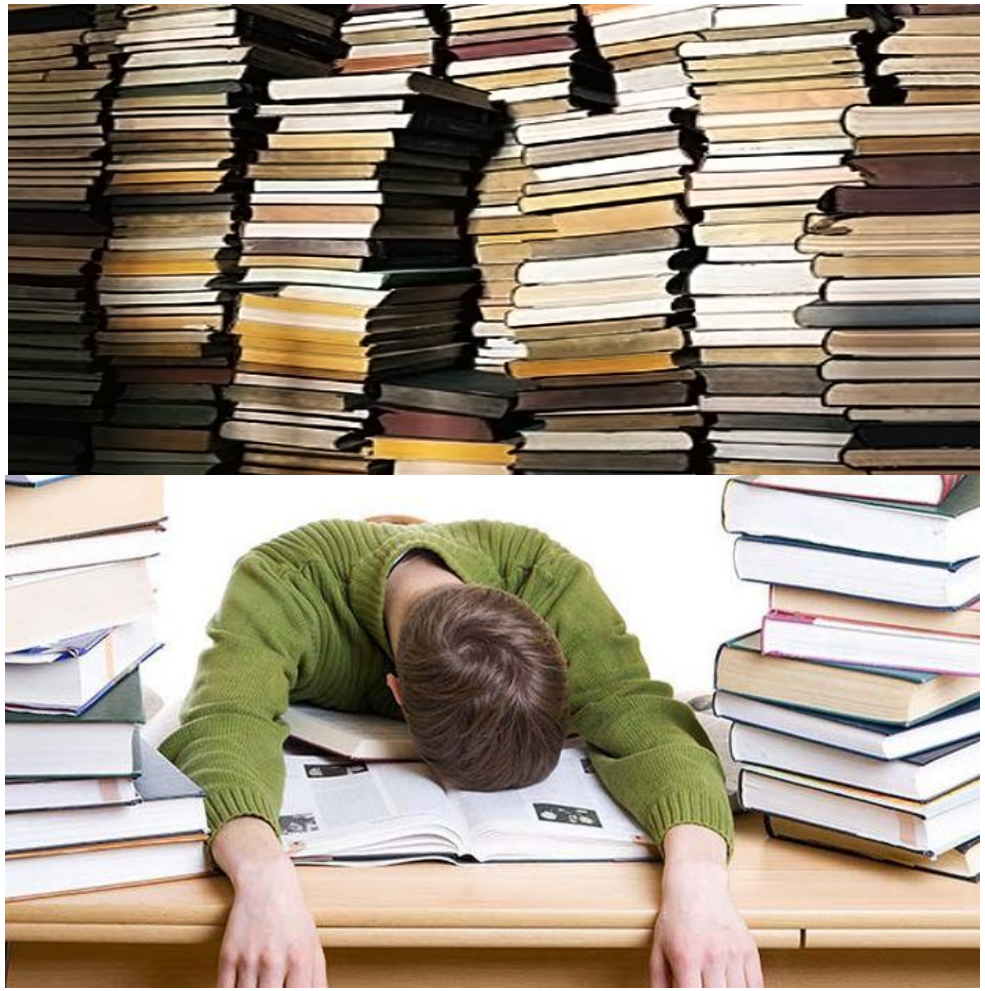
- Almost **3500** in total in the period
- Almost **2500** caused by **Norovirus**
- Almost **2500** NOT caused by **food**
- **20** caused by **food**
- **2** caused **by bivalve shellfish**
- **Why do people always blame the bivalve shellfish?**

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Correlation ? -*E. coli* and Norovirus

- There is no permanent relationship between the levels of *E. coli* and Norovirus
    - Although there appears to be a site-specific relationship
    - Food poisoning outbreaks from viruses have occurred even when *E. coli* levels were very low
    - The absence of *E. coli* does not guarantee low viral levels
- They have different behaviours in the sea and in bivalve shellfish e.g. length of viability and potential for binding within bivalve shellfish

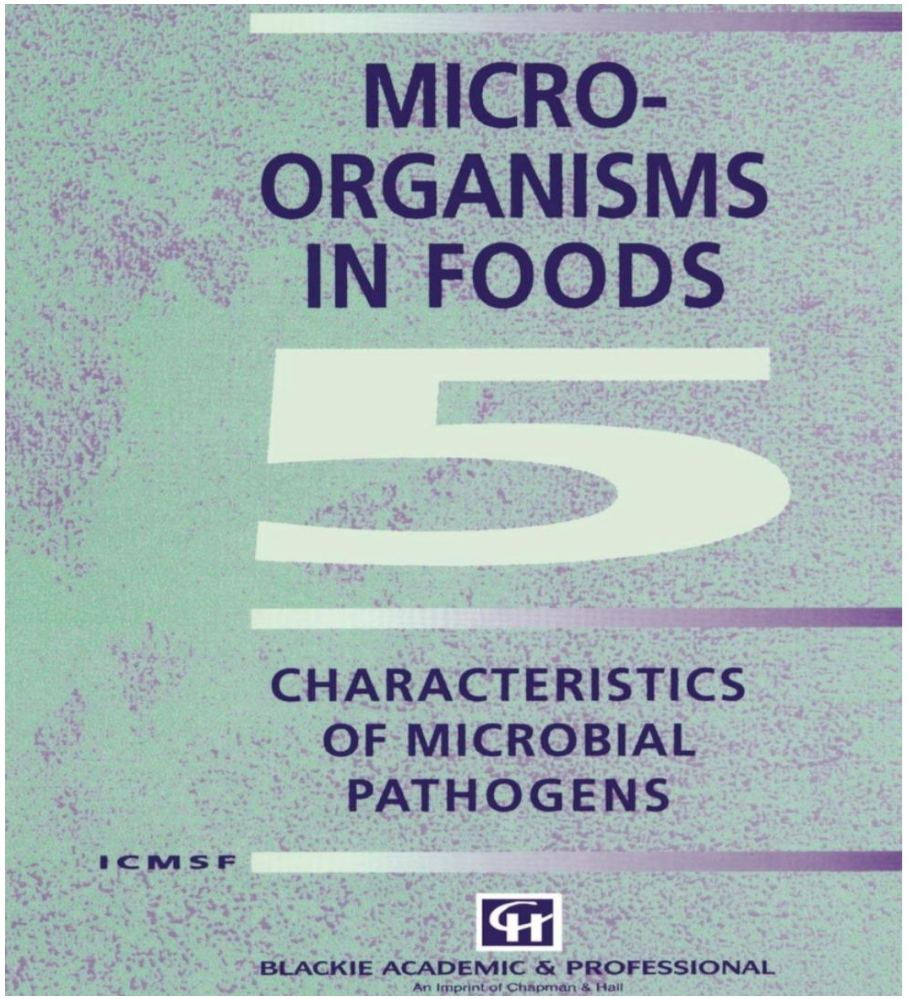
Stage 6



We are considering the potential to cause harm:

- **Potential** - is an absolutely key aspect.
- **Anything!** - with the potential to cause us harm must be considered

I.C.M.S.F 5


MICRO-
ORGANISMS
IN FOODS
5
CHARACTERISTICS
OF MICROBIAL
PATHOGENS
ICMSF
BLACKIE ACADEMIC & PROFESSIONAL
An Imprint of Chapman & Hall

Stage 6 - A structured approach

There must be a logical relationship between identified hazard and the control measure

List

- **"List all potential hazards" (i.e. what are the hazards?)**

Hazard analysis 1

- Significance? – **what/which** are the significant hazards? (i.e. "likely occurrence" & "severity"?)

Hazard analysis 2

- Map hazards to process steps by considering "*contributory factors*" – associate hazards to steps as relevant - presence/introduction/multiplication/survival of hazards? (i.e. **where/when** hazards are occurring?)

Hazard analysis 3

- Cause/source(s) and vectors(s)? (**why** the hazards occur and why they occur at particular steps?)

Control measures

- Control measures? (**what** control measures can be applied?)

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Stage 6 - A structured approach



*1 6 W 1 H

Structured & Epidemiological 6W 1H *1 Approach to Step 6/Principle One:- Hazard Identification & Analysis Chart

= Inductive

= Deductive

1. What has been the epidemiological history of this product/process?_____

_____

_____

3. What (if any) are the contaminants/hazards?_____

_____

Process Step Number & Description (Where & When?)	Identification/ List Classify What?	*2 Significance (Risk) (What?) Refer to Risk Quadrant etc LxS			Epidemiological Relevance Descriptor 3* (P.I.M.M.S) (Contributory Factor/ Manifestation of Hazard Qualitative Approach) (How?) *4	Causation/Source (Why?)	Control Measure (What we need to do to eliminate or reduce the hazard to an acceptable level?)

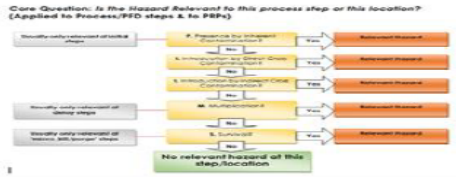


*2 Risk Quadrant

*3 Mnemonic - P.I.M.M.S/P.I.M.S/P.I.G.S

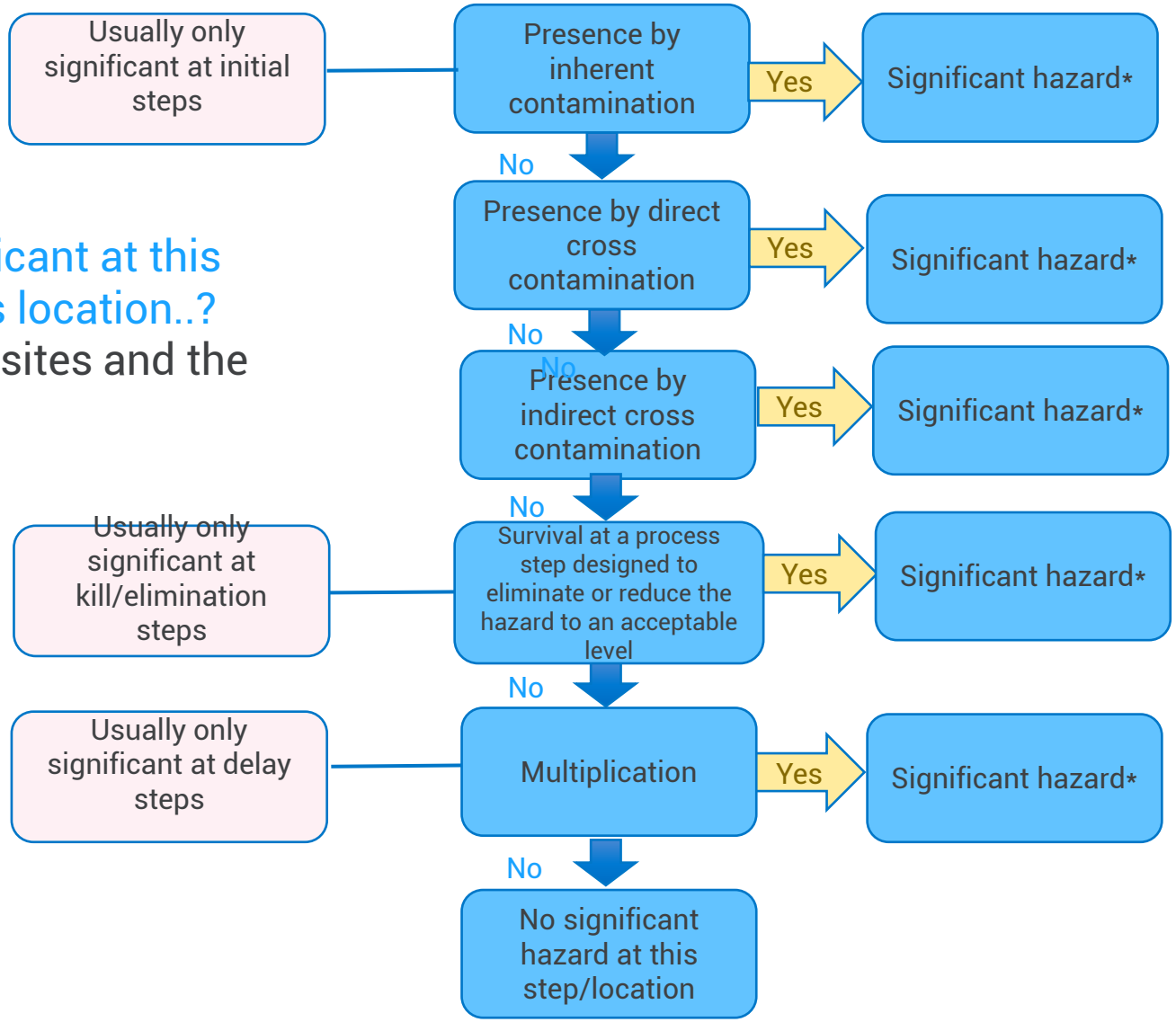
P =Presence by inherent contamination
I= Introduction by direct contamination
I= Introduction by cross contamination
M= Multiplication
S = Survival

*4 P.I.M.M.S Algorithm



Hazard mapping – an algorithm

Is the h*azard* significant at this process step or this location..?
(applied to prerequisites and the process flow):



* Significant at that process step/location in epidemiological terms

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Contributory factors – contamination and source – ‘presence’





Contributory factor – introduction contamination

- Cross contamination:
  - ***from another source***
- Recontamination:
  - ***after purification***



Contributory factor – multiplication

- Temperature and time control
- Throughout the process



Stage 6 demonstration

Process step number & description (where & when?)	Identification/ list classify (what?)	*2 Significance (risk) (What?) Refer to risk quadrant etc	Hazard mapping - contributory factor (epidemiological relevance/association)3* (P.I.M.M.S)/(P.I.G.S) (How?) *4	Causation/Source (Why?)	Control Measure (What we need to do to eliminate or reduce the hazard to an acceptable level?)
1 Receipt of LMBs	Salmonella spp	20 - High	Presence	Contamination & Source	Approved suppliers - Operating Validated & Verified HACCP, Provenance is classified waters SOPS re Class A/B waters, Time & temperature controls. Refer SOPs XXX, YYY, ZZZ
//	E.coli STEC spp	25 - High	Presence	//	//

Contributory factor – survival

Failures of depuration:

- Incorrect biomass to water ratio
- Failure to submerge
- Incorrect processing parameters



Hazards and inadequate controls



- Inadequate environmental information
- Lack of information on source of bivalve shellfish
- Leaving lying around
- Exposure to further contamination
- Temperature abuse
- **<42 hrs. without LA approval**
- Stress

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Considerations with reduced purification cycles

- **Species** – e.g. differing filtration rates between species and with changing environmental variables (such as temperature)
- **Time of year and associated contamination risks** - e.g. when higher levels of norovirus are present in the population (*Note*: requires assessment of bacterial and viral contamination risks)
- **Recent weather** – e.g. heavy rainfall events
- **Recent official control monitoring results** – i.e. classification results
- **Other information** - e.g. pollution events, algal toxins

Appropriate control measures

- Insist on registration document / unique batch number for **EVERY** batch:
  - (e.g. prod. area/Julian date/tank no.)
  - Reg. 178: batches separate, identifiable
- Move directly from transport to protected storage or preparation area

Stage 6 exercise

- Group to carry out Stage 6 is relation to designated process steps

Algal toxins

Bivalve shellfish poisoning

- **DSP** (Dinophysis – Okadaic Acid):
    - Mild symptoms - rapid onset
    - Common in rich fertile water
    - Numerous outbreaks
    - Symptoms < 30mins
    - Diarrhoea, nausea, vomiting, abdominal cramps and chills
    - Recovery in 3 days

Alert level for phytoplankton in seawater = equal to or > 100 cells/litre.

- **Regulatory limit for DSP:**
    - for diarrhetic shellfish poison, 160 micrograms of Okadaic acid per kilogram flesh

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Bivalve shellfish poisoning

- **PSP** (Alexandrium – Saxitoxin):
  - 1987 Central American village = **187** cases **26** dead
  - Onset **0.4 - 2** hours
  - Tingling lips – numbness, drowsiness, staggering, fever, rash, paralysis of airways, death, **NO** antidote
  - Supportive therapy is the rule - survivors recover fully

Alert level in seawater = > 0 cells/litre

- **Regulatory limit for PSP:**
  - for paralytic shellfish poison, 800 micrograms of Saxitoxin per kilogram flesh.

Note: Forms cysts resting / over wintering stage in the environment

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Bivalve shellfish poisoning continued

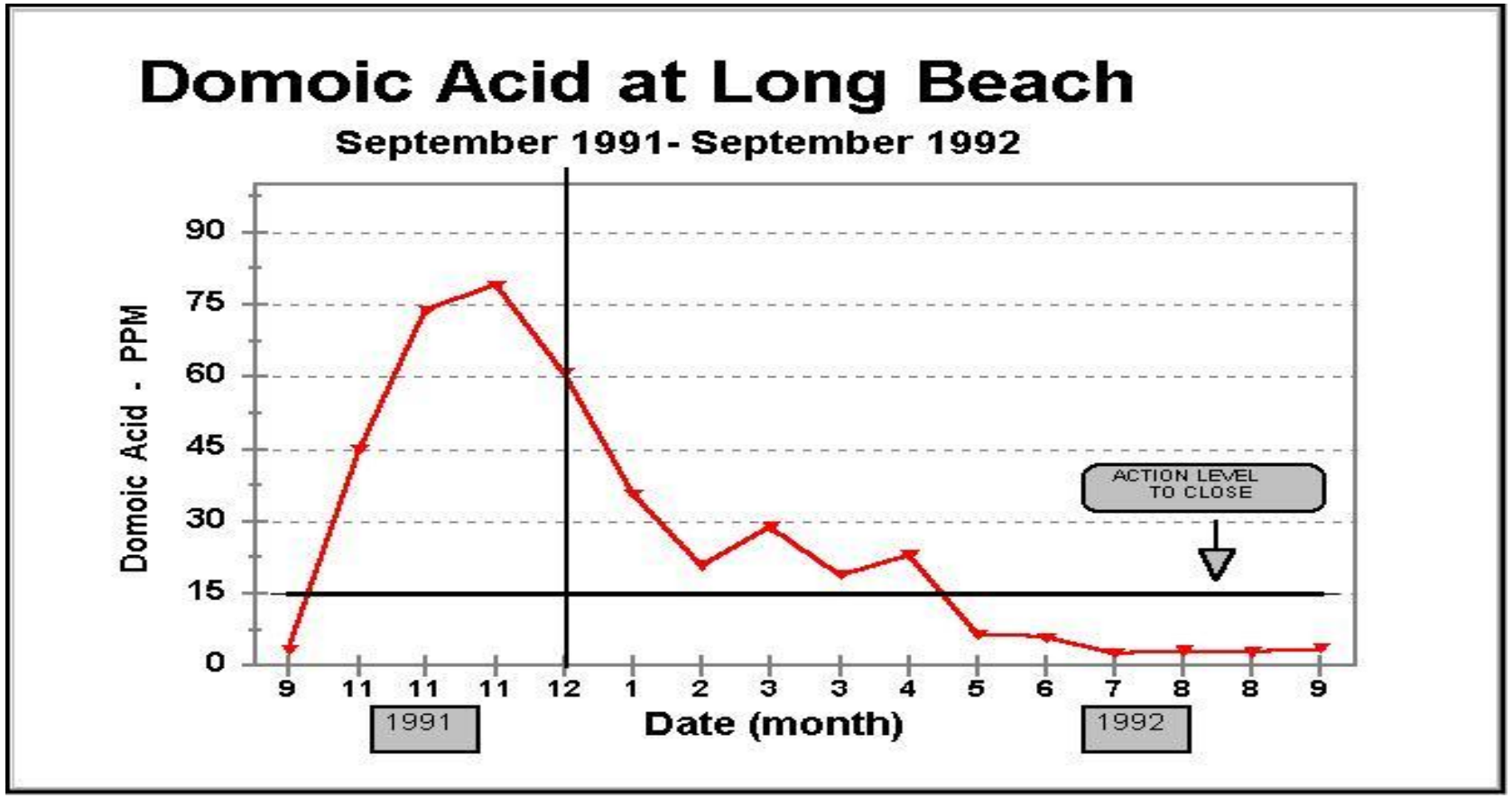
- **ASP** (Pseudo-nitzschia – Domoic Acid):
  - Fatal outbreak in **Canada 1987**
  - Domoic acid identified
  - Gastrointestinal and neurological disorders
  - Gastro-enteritis **< 24hrs**
  - Nausea, vomiting, cramps, diarrhoea
  - **<48 hrs**. dizziness, headache, seizures, disorientation, permanent short-term memory loss
  - Respiratory difficulty
  - Coma and **DEATH**

Alert level in seawater = equal to or >150,000 cells/litre

- **Regulatory limit for ASP:**
  - For amnesic shellfish poison, 20 milligrams per kilogram flesh

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Long term problem



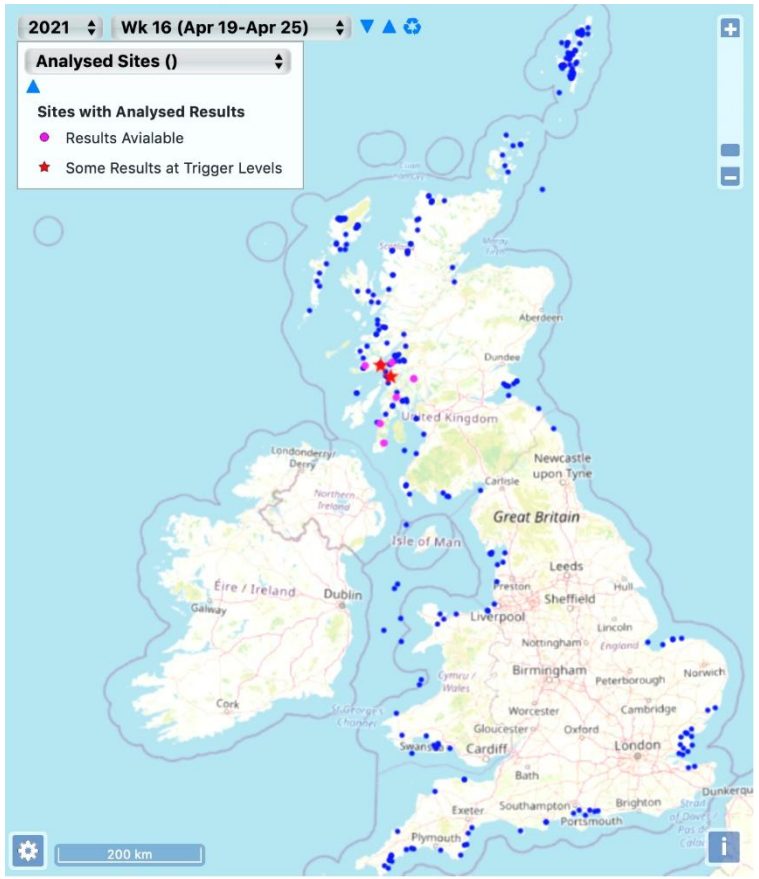
Domoic Acid (ASP) in flesh samples was above action level for 9 months

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Monitoring and testing for HABs

- **Sources of information:**
  - EU member states, through LAs, must monitor for toxin producing plankton in bivalve shellfish production / relaying areas, and for biotoxins in live bivalve shellfish
  - FSA/FSS websites
  - Predictive monitoring – Project ShellEye now has a subscription-based service: https://www.shelleye.org/

- **Testing procedures:**
  - Based on flesh and water samples
  - Specialist labs / in-house labs / field test kits
  - Chemical testing now replaced animal testing (MBA) for **all** species (was effective 1st May 2012 as per FSA)



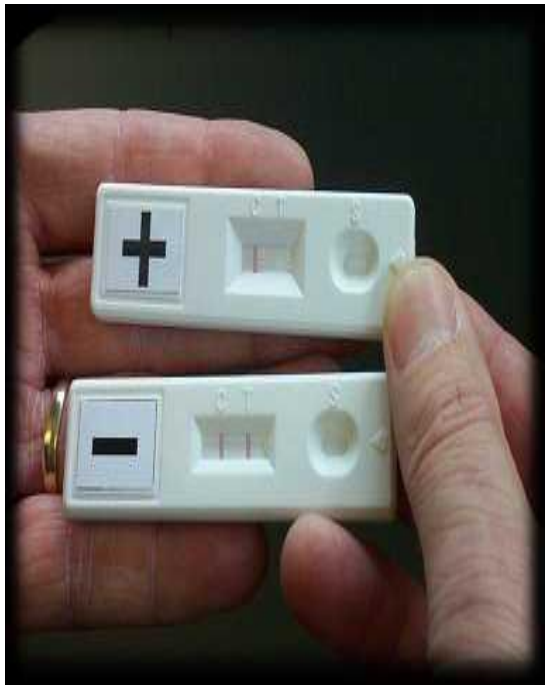
What can industry do about HABs?

- **What to do**:
  - More intensive and rapid testing now possible
  - Practicality of moving bivalve shellfish?
  - Avoid harvesting until all clear given

- **Monitor**:
  - Know your area
  - Historical data
  - Know your suppliers!
  - **End product testing** – due diligence!

- **Cooperation -** Work with LA and other local businesses, share data and manage collective risk

- **The future** – depuration with probiotics?



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Stage 12 – Documentation of FCMSs

Stage 12 documentation

- Retain **ALL** documents of:
  - The HACCP study/HACCP plan
  - The validation study
  - Site schematic – layout/process flows/water flows/waste flows/personnel flows
  - Deliveries records – traceability and provenance
  - Registration documents – traceability and provenance
  - Batch numbers – lot marking
  - Processing records

  ✓Loading density, O2, temp, salinity, pH, turbidity, activity, duration of depuration (start and finish).
  - Distribution – traceability and provenance
  - Approvals documents and EPT as may be required for Step 11 –i.e. verification

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Documents

- All referenced to original movement document (batch coding/lot mark)
- Permanent movement authorisation, use batch number
- Chronological order
- Diary of events
- Cleaning and disinfection maintenance

Example record sheets

- Bivalve shellfish reception

- Purification system operation:
  - CEFAS standard systems sheet
  - CEFAS ozone systems sheet

- Product dispatch

- Bacteriological testing

What other types of records are needed as part of a HACCP based permanent management system?

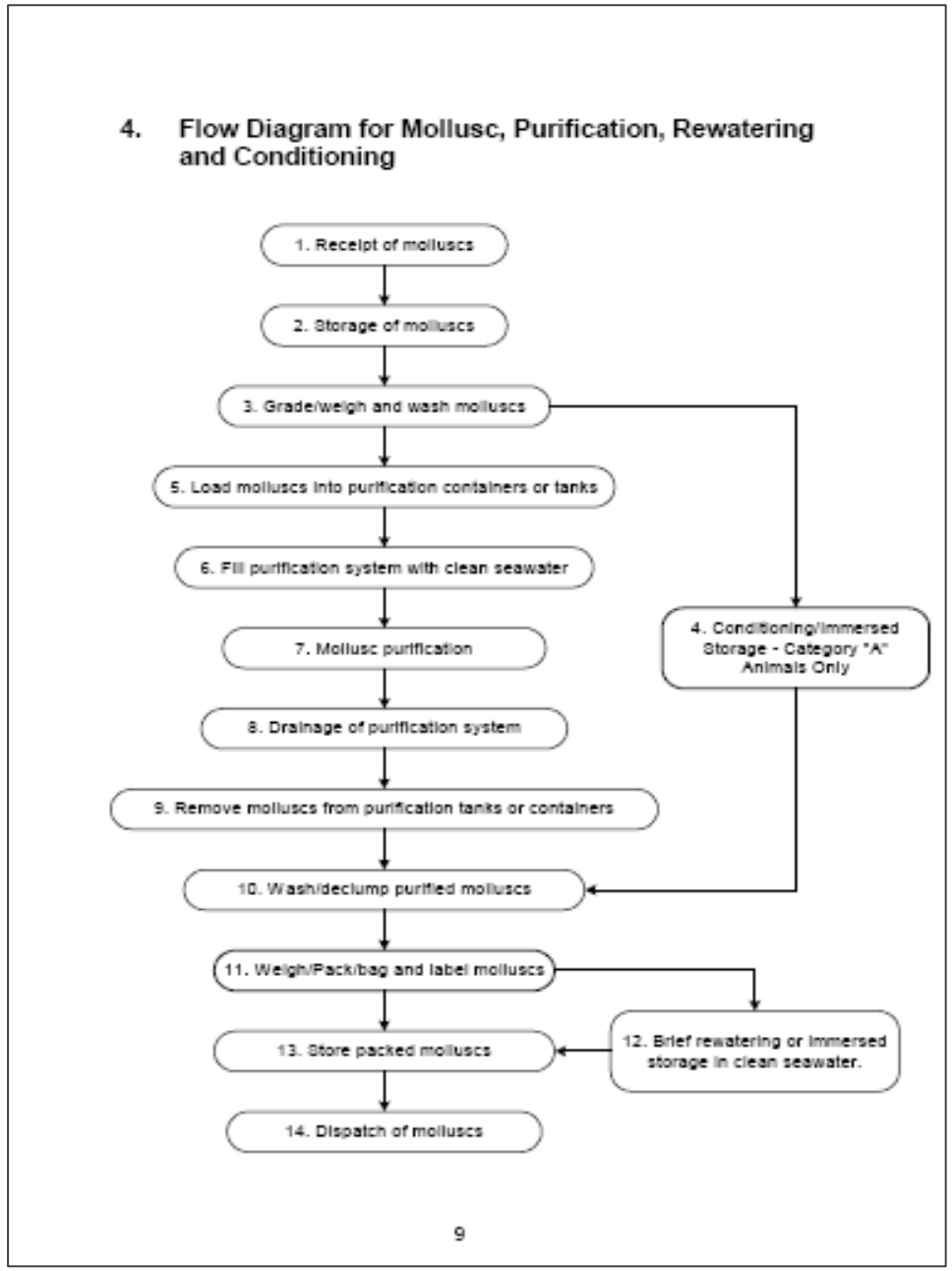
Permanent Management Procedures (PMP) based on HACCP are required

- 852/2004 *as amended*
- Change of business ownership requires **reapproval**…
- Useful tool now available: **https://myhaccp.food.gov.uk/**
- Seafish have an updated model **HACCP plan/guide**

42 hour vs. reduced purification times

- From **Nov. 2016**, FBOs allowed to apply alternative purification times (***see Seafish handout***)
- FBO **must prove** that systems remain effective and operate under an appropriate HACCP-based system
- FBOs must consider all relevant hazards, including viral as well as bacterial contamination
- **Evidence** must be provided to LA that time period is effective and EPS are met
- Use of reduced periods must be **under constant review** as part of a HACCP-based system and time periods increased if threat levels change/increase

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Some resources for FBOs can be found in the **Seafish Training Academy website:**

– ***Bivalves Library Guide***

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Don’t forget

- Live bivalve shellfish are a high care food product

- Staff should be instructed to report any food safety issues to management

- Due diligence ... Take all reasonable precautions:
  - Follow industry best practice (use GMPG)
  - Monitor and record
  - Train and supervise staff
  - Keep up to date

Legislation

Any questions? Any examples?







Food Safety Law

- Food Safety Act 1990 (UK):
  - Regulation 178/2002/EC

- Retained EU Regulations 2017/625 and 2019/627

- Includes primary production and ‘live' food as well as food products

Food Safety Act 1990

- **Offence:**
  - ‘unsafe or unfit’
  - Not of ‘nature, substance or quality’ **demanded by the consumer.**
  - Falsely or misleadingly describe food

- **Defence: ‘due diligence’:**
  - **took all reasonable precautions …**

EU Food Hygiene Regulations

- Regulation 852 – 853 – 854 of 2004 (***updates due in 2019 - Official Control Regulation (EU) 2017/625 as per FSA, Feb. 2018***)
- Duties of Food Business Operators
- Lays down basic hygiene requirements
- Permanent management procedures based on HACCP

Legal definition of clean water

- **Clean** - means that it does not contain any:
  - harmful micro-organisms
  - harmful substances
  - biotoxins in quantities harmful to health

- Turbidity less than 15 NTU (legal definition vs. guidance)

- No detectable *E. coli*

- Seawater, brackish, fresh

End Product Standards EU/853/2004

- They must have **organoleptic characteristics** associated with freshness and viability, including shells free of dirt (***see Seafish handout***)
- An adequate **response** to percussion and normal amounts of intra-valvular liquid
- *E. coli*, **less than 230 E.coli/100g** in flesh and intra-valvular liquid (tested by MPN)
- Salmonella, **absence** in 25g

End Product Standards – continued

- They must not contain marine biotoxins in total quantities (measured in the whole body or* any part edible separately) that exceed prescribed limits

  – (**see previous End Product Testing handout for limits**)

Seafish Biotoxin Guidance Note

- **Note:** Seafish maintain that testing of tank and post-purification product by the regulator is **not** End Product Testing (EPT)

- Periodic checks that tanks continue to work effectively and EPT **are** the responsibility of industry

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Legal requirements for dispatch centres (EU Reg. 853/2004)

- When handling live bivalve shellfish, you **must not:**
    - cause contamination of the product or
    - affect the viability of the bivalve shellfish
- Before dispatch, the shells of live bivalve shellfish **must be** washed thoroughly with clean water
- Live bivalve shellfish **must only come from**:
    - a Class A or B / B-LTC production area
    - a relaying area
    - a purification centre
    - another dispatch centre, includes dispatch centres onboard vessels

Traceability documents

- **Registration document** – tracks movement of bivalve shellfish from harvester to final distributor:
  - Copies kept at each stage in distribution chain
  - Section VII, Chapter I of Regulation 853/2004

- **Identification mark** – produced by final distributor for use by retailer:
  - This applies to all retail packs irrespective of final destination
  - Section I, Annex II of Regulation 853/2004

- ***Greater scrutiny of compliance in the future!***

The registration document

Must contain at least the following information:

- (a)(i) the gatherer's identity and address
- (ii) the date of harvesting
- (iii) the location of the production area described in as precise detail as is practicable or by a code number
- (iv) the bivalve shellfish species and quantity
- (vi) the destination of the batch
- (b) In the case of a batch of live bivalve shellfish sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:
  - (i) the location of the relaying area

And ……

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The registration document – Continued

- (ii) the duration of relaying
- (c) In the case of a batch of live bivalve shellfish sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:
  - (i) the address of the purification centre
  - (ii) the duration of purification
  - (iii) the dates on which the batch entered and left the purification centre

Identification mark

- Live bivalve shellfish must be labelled before leaving the dispatch centre

- Information must include:
  - Common and scientific name
  - Date of packing
  - Durability mark or ‘these animals must be alive when sold’

- Centre ID needs to be within an oval shape

- Linked to registration document

Now known as
Identification Marks

HEALTHMARK
BATCH CODE 75
PACKED ON 25/03/09
USE BY 31/03/09
5 030098 700266
80/90 x 96 Pacific Oysters
Live Bivalve Molluscs (Crassostrea Gigas)
From The
All Molluscs
in accordan
XYZ Ltd., The Shore
EEC.E T. AD002/D/PC
WARNING: These animals mu

HEALTHMARK
CODE 75
PACKED ON 25 MAR 09
USE BY 31 MAR 09
5 030098 700266
80/90 x 96
Pacific Oysters
XYZ Ltd., The Shore
EEC.EST. AD002/D/PC
Live Bivalve Molluscs (Crassostrea Gigas)
From The U.K.
All Molluscs have been purified and are processed
in accordance with EC Directive 853/854
WARNING: These animals must be alive when sold

Jersey Oyster
La Ferme, La Grande Route des
Sablons, Grouville, Jersey JE3 9FE
Tel: +44 (0) 1534 850440
Date of packing /
Date de conditionnement:
UK
JY007D
EC

SLF
UK
Clams specialist
Scan with QR reader for shellfish care
The Generator Business Centre
Unit D – 95 Miles Road - London CR4 3FH - United Kingdom
Tel. 0044 798 4425 907 - Fax. 0044 208 6718 515
Email: info@saggiomo-luxury-food.com Websites: www.slf-uk.com
Despatch Country: UK. The temperature of transport and preservation must not jeopardize the quality of the product. Depurated shellfish to be consumed preferably cooked. At the wholesales and restaurant keep the temperature to a maximum 6° C. Weight to correspond at the moment of sale (tare 10 gr.).
PACKED DATE STATED ON THE BACK.
UK MT 024 EC
WARNING: THESE ANIMALS MUST BE ALIVE WHEN SOLD
www.

Training

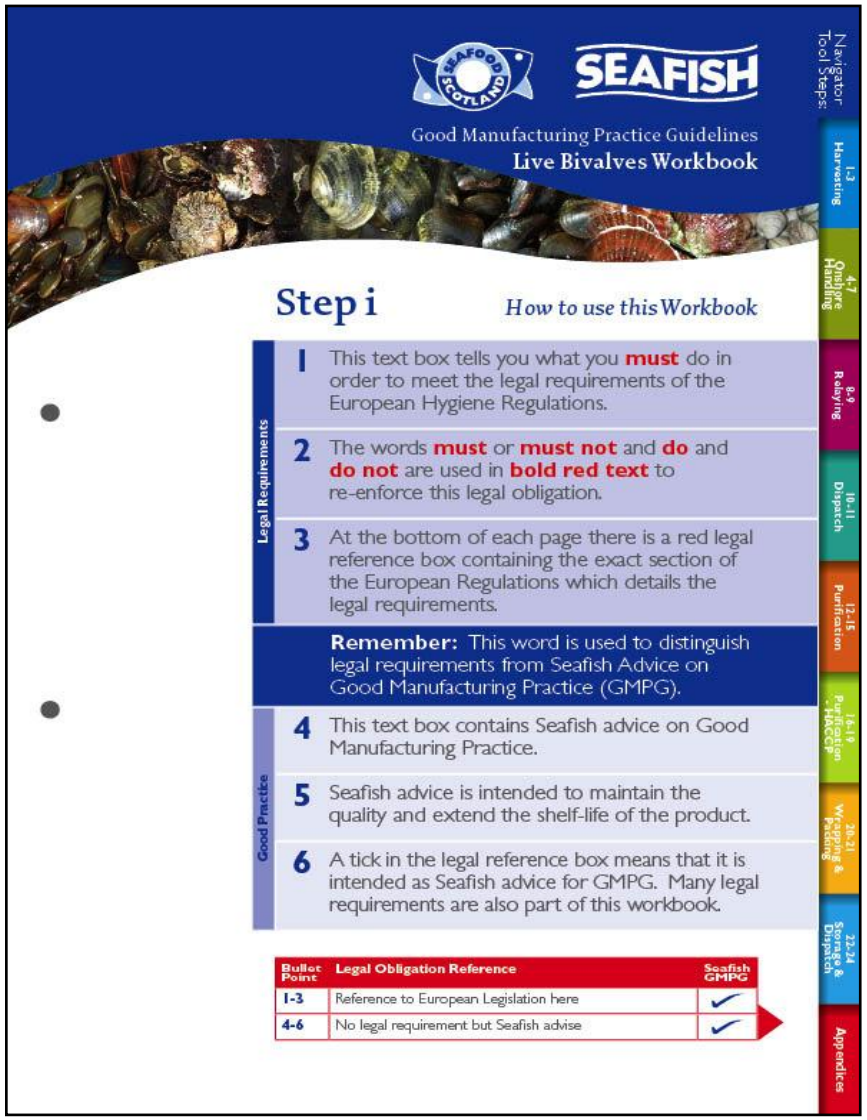
- Regulation 852/2004, annex II, Chapter XII

- Requires food handlers to be *supervised* and *instructed* and/or *trained* in food hygiene matters **commensurate** with their work activity:
  - **Who will supervise and instruct the manager?**

- Requires staff responsible for food safety management to be trained in HACCP

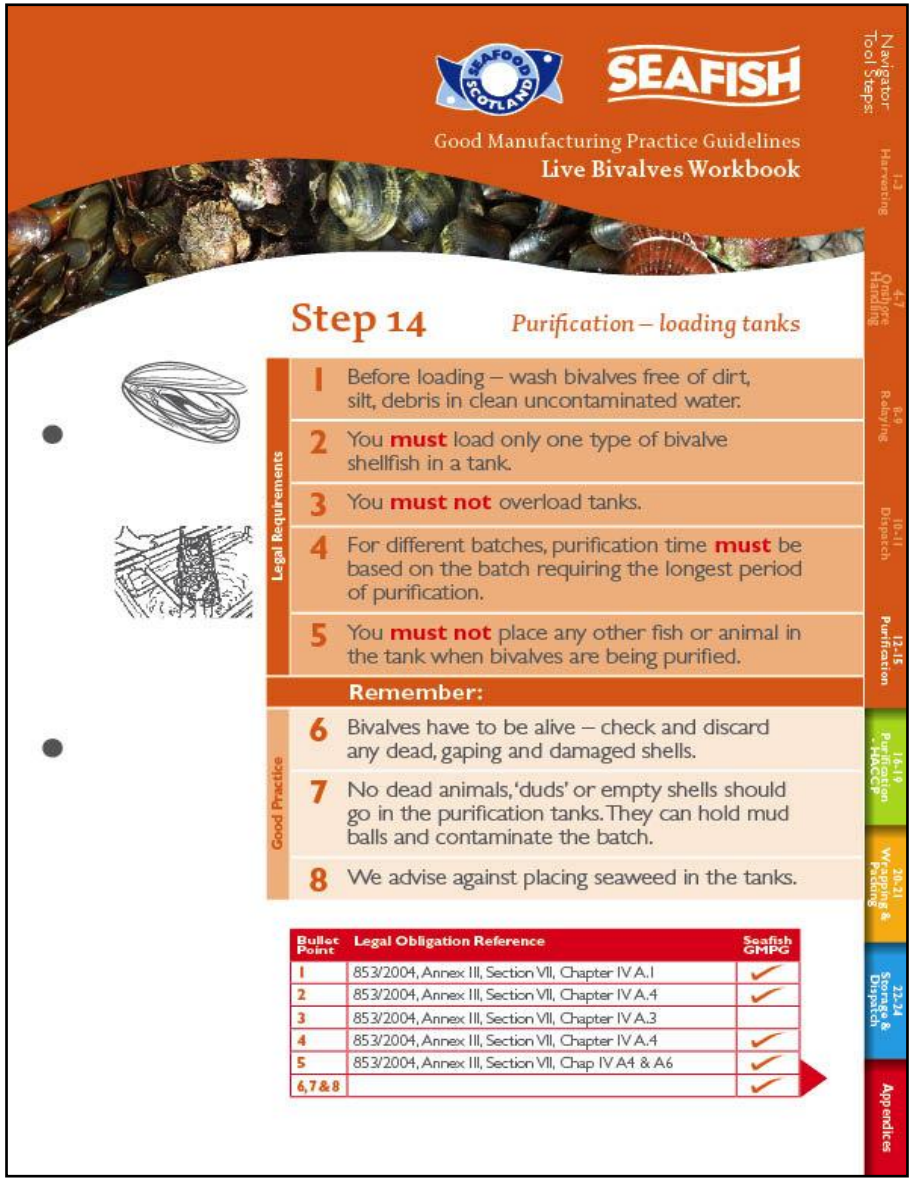
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Good Manufacturing Practice Guidelines continued



- Simply illustrates '**must do's**' with '**nice to have'** / Seafish Good Practice
- Seafish advice goes further than legislation to protect market and consumer needs
- Each step in production from harvest to dispatch
- Relevant to workstation

Good Manufacturing Practice Guidelines step 14



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Good Manufacturing Practice Guidelines
Live Bivalves Workbook

Step 14 *Purification – loading tanks*

Legal Requirements

1. Before loading – wash bivalves free of dirt, silt, debris in clean uncontaminated water.
2. You **must** load only one type of bivalve shellfish in a tank.
3. You **must not** overload tanks.
4. For different batches, purification time **must** be based on the batch requiring the longest period of purification.
5. You **must not** place any other fish or animal in the tank when bivalves are being purified.

Remember:

Good Practice

6. Bivalves have to be alive – check and discard any dead, gaping and damaged shells.
7. No dead animals, 'duds' or empty shells should go in the purification tanks. They can hold mud balls and contaminate the batch.
8. We advise against placing seaweed in the tanks.

Bullet Point	Legal Obligation Reference	Seafish GMPG
1	853/2004, Annex III, Section VII, Chapter IV A.1	✓
2	853/2004, Annex III, Section VII, Chapter IV A.4	✓
3	853/2004, Annex III, Section VII, Chapter IV A.3	
4	853/2004, Annex III, Section VII, Chapter IV A.4	✓
5	853/2004, Annex III, Section VII, Chap IV A4 & A6	✓
6,7&8		✓

Navigator Tool Steps:
Harvesting
Onshore Handling
Relaying
Dispatch
12-15 Purification
Appendices

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Illegal harvesting

The real problem!

News Article on illicit harvesters - 29/05/12



Illicit harvesters…



Sources of guidance and support

Sources of guidance and training

- FSA/FSS Delivery Teams
- SFELC Seafoods OCs Working Group – through FSS
- Seafish approved training (for FBOs):

Seafish approved trainers

Seafish approved courses

- Environmental Health Officers are the first point of contact for matters concerning food safety

Any questions?



Seafish update

- Training opportunities for industry:
  - BVP Operations course: available by remote delivery on demand
  - BVP Management course: must have completed the BVP Operations course first
- Contact Seafish for more information – onshore@seafish.co.uk .
- Sign up for the monthly seafood industry training newsletter **here.**

Exam

- Online multiple-choice test.
- Based on exam of 20 questions sat by FBOs who require 75% to pass
- The BSHV exam is:
    - 25 questions
    - open book
    - 100% pass mark
    - can be retaken multiple times
    - your link will be emailed to you and must be passed within one week of completing the course
    - REHIS/Seafish qualification based on attendance, participation of both part one and part two and successful completion of the exam

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End of part one

Thank you

Here to give the UK seafood sector **the support it needs to thrive.**