Bivalve Shellfish Hygiene Verification

A Seafish / REHIS course

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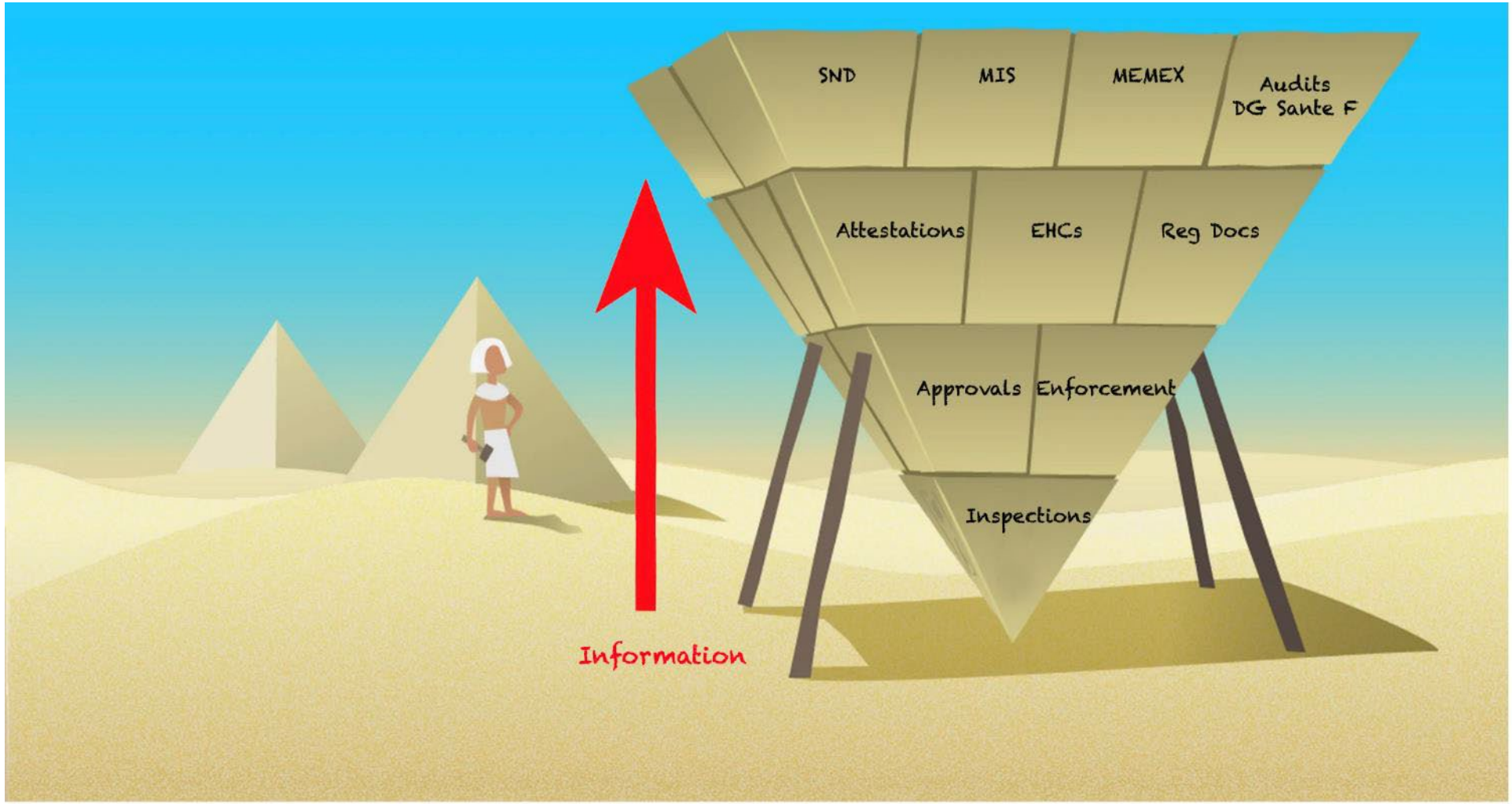
Part Two ~ Bivalve shellfish purification verification

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

Preamble – the criticality of inspecting



Aims

- Assisting industry towards protecting the consumer and with Food Law compliance

Part Two: objectives

- To provide inspection personnel with a greater understanding of what is possible, practicable and reasonable in operating a commercial purification and despatch centre in the UK, so that Official Controls are effective (i.e.. scientific) and result in requirements that are not too onerous or too lenient, but appropriate, balanced and proportionate – and consistent

    - **Official Controls that are effective (i.e.. scientific)**
    - **Enforcement decisions that are not too onerous**
    - **Enforcement decisions that are not too lenient**
    - **Enforcement decisions that are appropriate, proportionate and balanced – and consistent**

Outcomes

- Greater individual understanding of the hazards and the risks, together with effective, balanced, proportionate and reasonable Official Controls and interventions

- Consensus on approach to enforcement

Scope

- All the scenarios are real and have been observed first hand
- They do not represent mainstream or normal practice
- They have been selected to provide selected and idealised learning points

General approach

- **Identify the hazard / high risk activity**
- **Consider content of appropriate**:
    - Regulation
    - GMPG
    - Science
- **Evaluate what is possible / practicable**:
    - Include examples
- **Agree reasonable responses:**
    - Discuss
    - Consider mitigating factors
    - Arrive at consensus/recommendations

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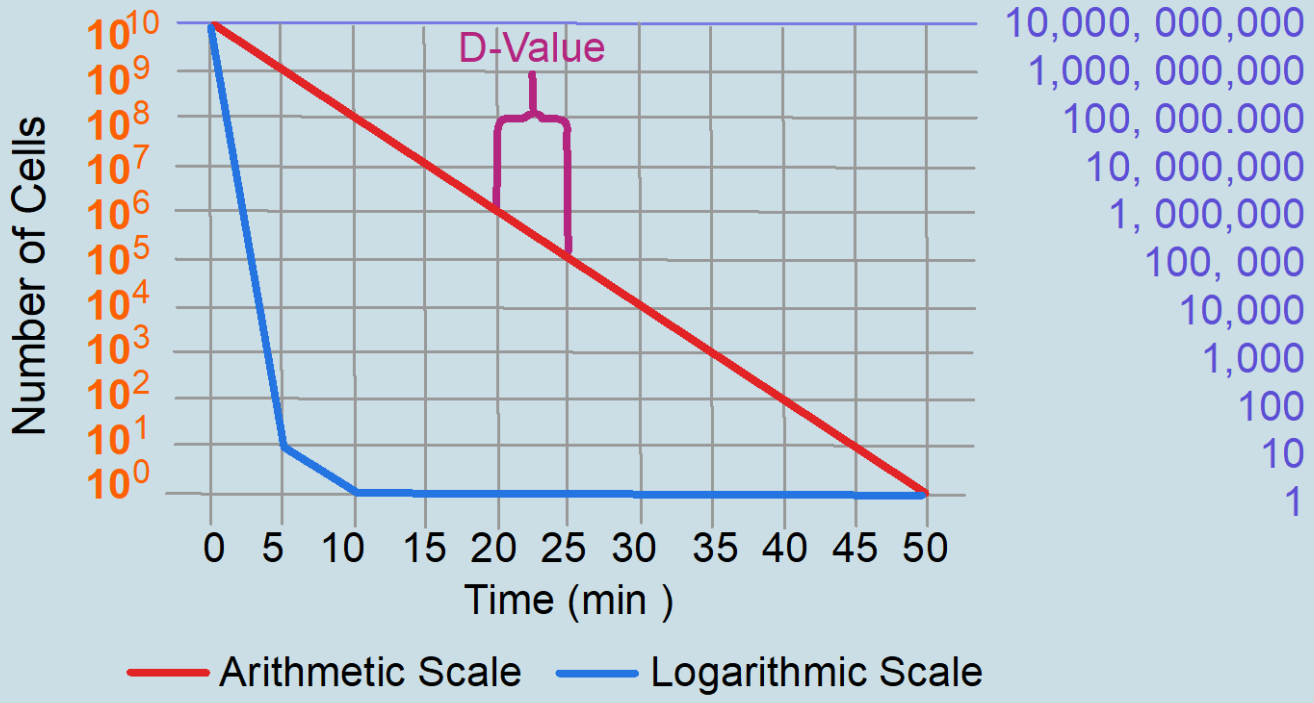
The food science and technology of depuration

- General perspectives on the food science and technology of depuration relevant to Official Controls

Idealised microbial reduction curve



Time (min)	Number of Cells
0	10^{10}
5	10^{9}
10	10^{8}
15	10^{7}
20	10^{6}
25	10^{5}
30	10^{4}
35	10^{3}
40	10^{2}
45	10^{1}
50	10^{0}

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Depuration and bacterial reduction

Table 1. Effect of depuration on mussels artificially contaminated with *Escherichia coli*.

Time (h)	*Escherichia coli* (MPN/100 g)*	*Escherichia coli* (log MPN/100 g ± SD)*	Percentage (%)†
0	7.1×10^5	5.8 ± 0.2	100
4	3.8×10^4	4.6 ± 0.1	5.3
6	4.3×10^4	4.6 ± 0.2	6.1
10	2.0×10^4	4.3 ± 0.2	2.9
16	4.0×10^3	3.6 ± 0.1	0.6
20	9.2×10^3	3.9 ± 0.3	1.3
24	3.0×10^3	3.5 ± 0.2	0.4
30	2.4×10^3	3.4 ± 0.1	0.3
42	5.4×10^3	3.7 ± 0.3	0.8

* Values derived as an average of two independent experiments.

† Percentage with respect to the initial concentration of *E. coli* (time 0).

Acknowledgment - Andritsos N.D. Moschonas G., Roukas, D. Elimination of *Escherichia coli* from Mussels during treatment in a shellfish depuration system. Conference paper November 2016.

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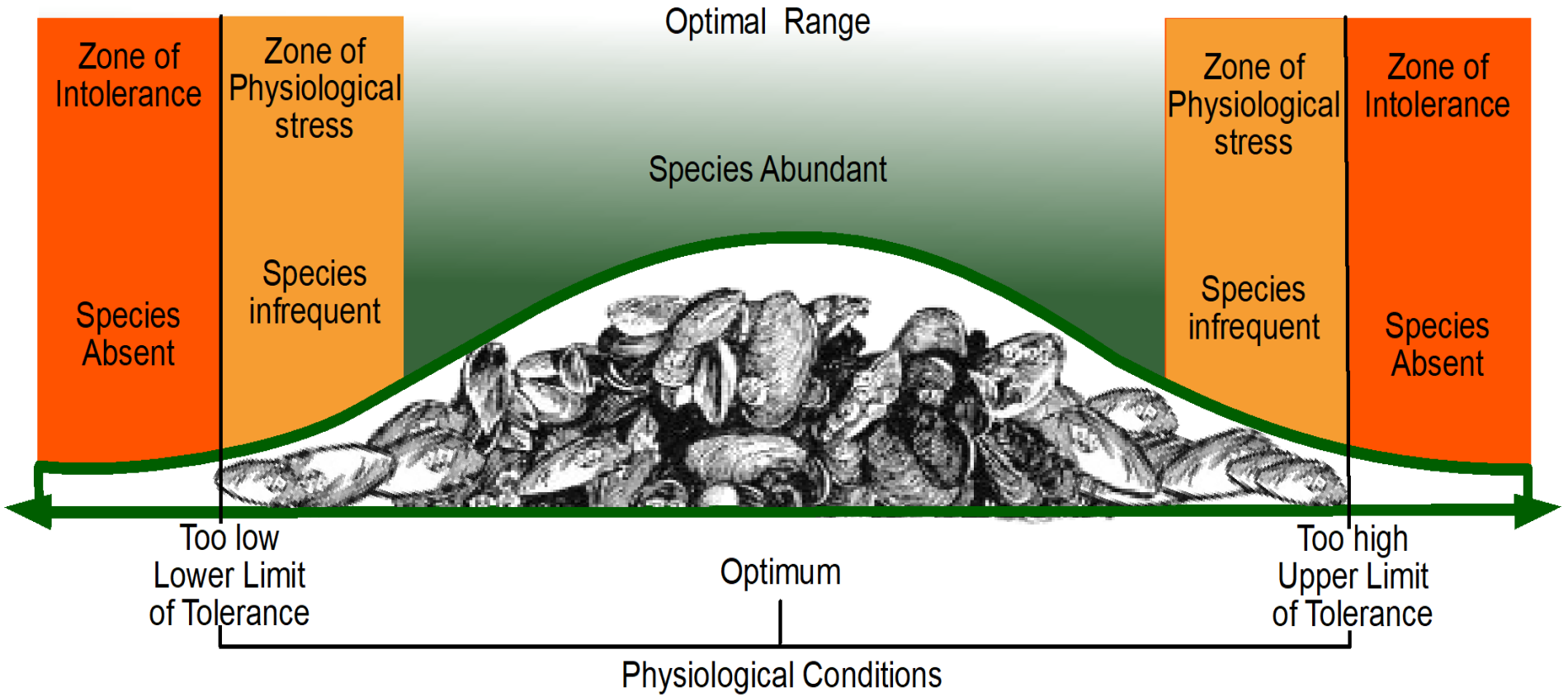
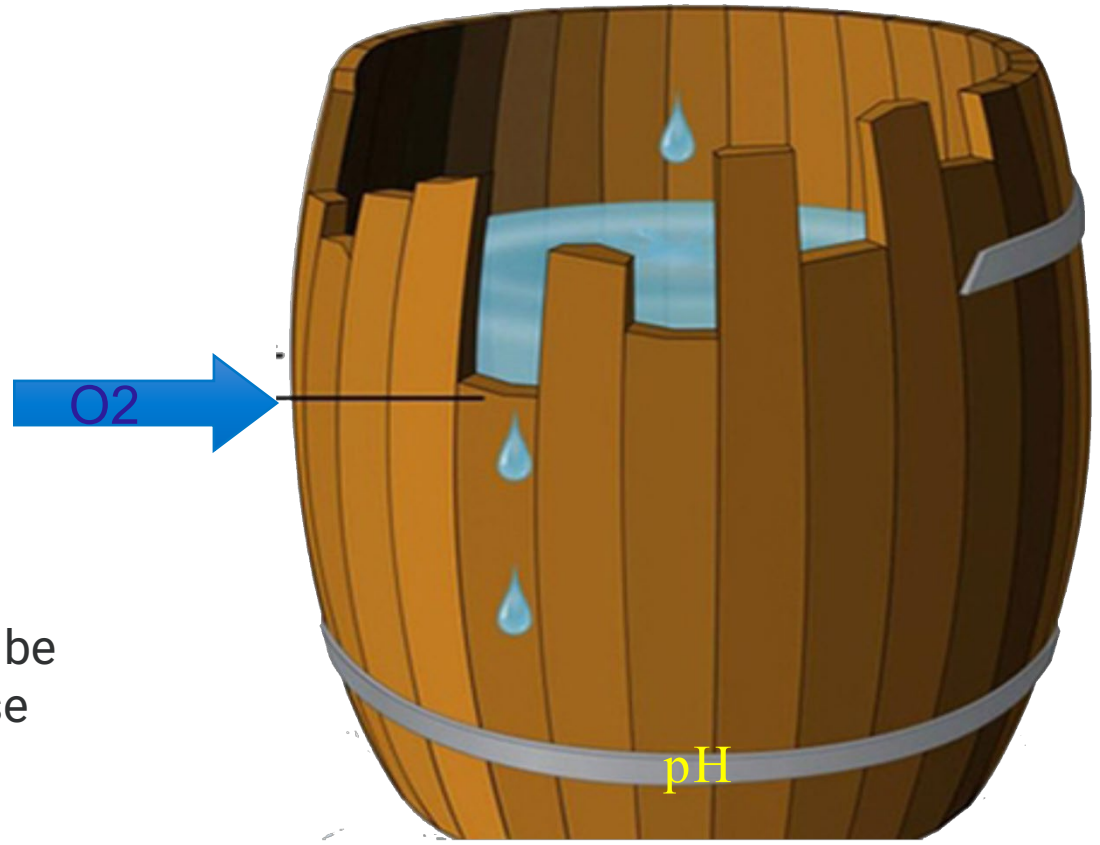
Shelford's Law of Tolerance

W.E.Shelford



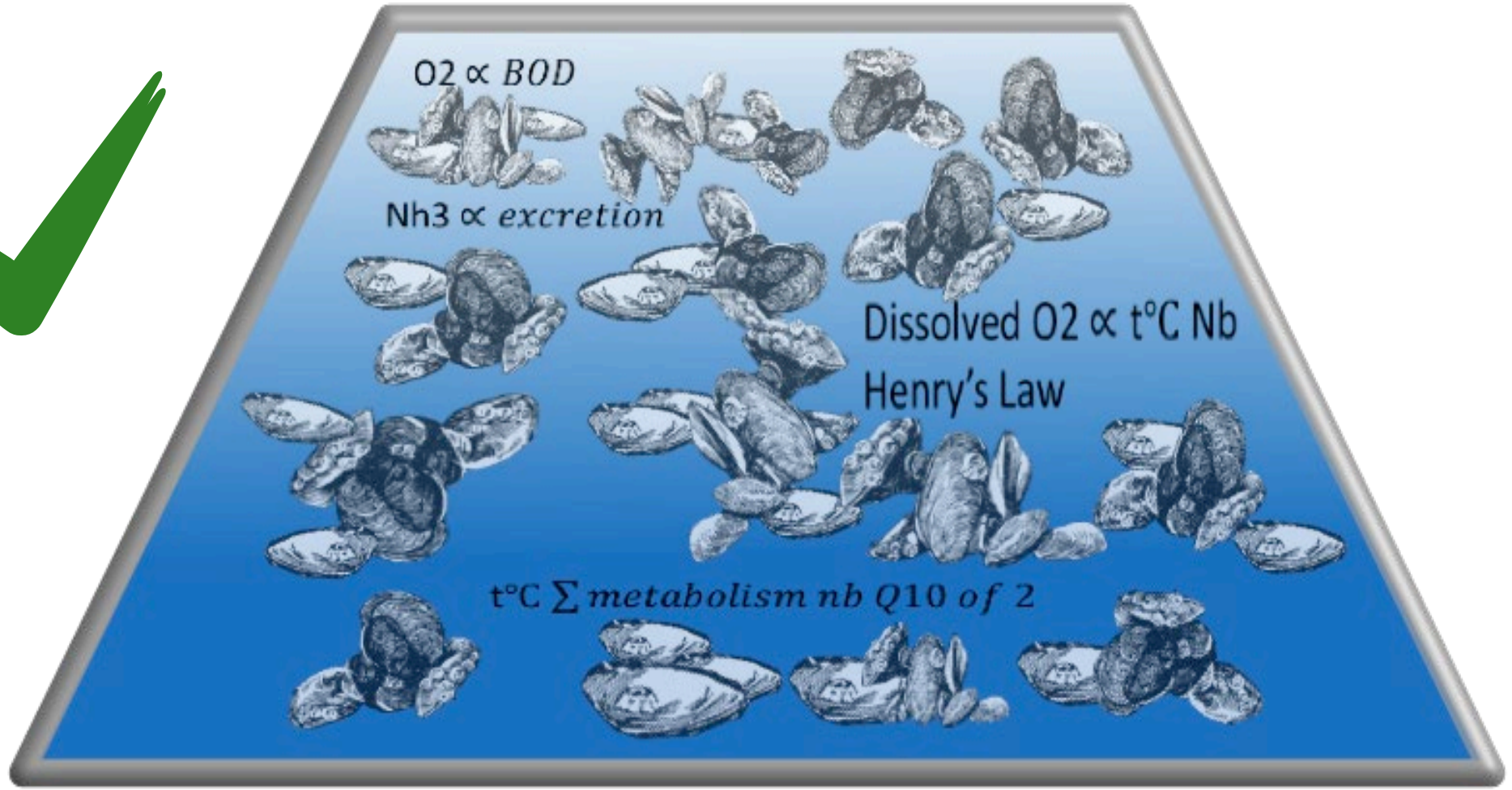
Liebig’s Law of the Minimum

Justus Liebig

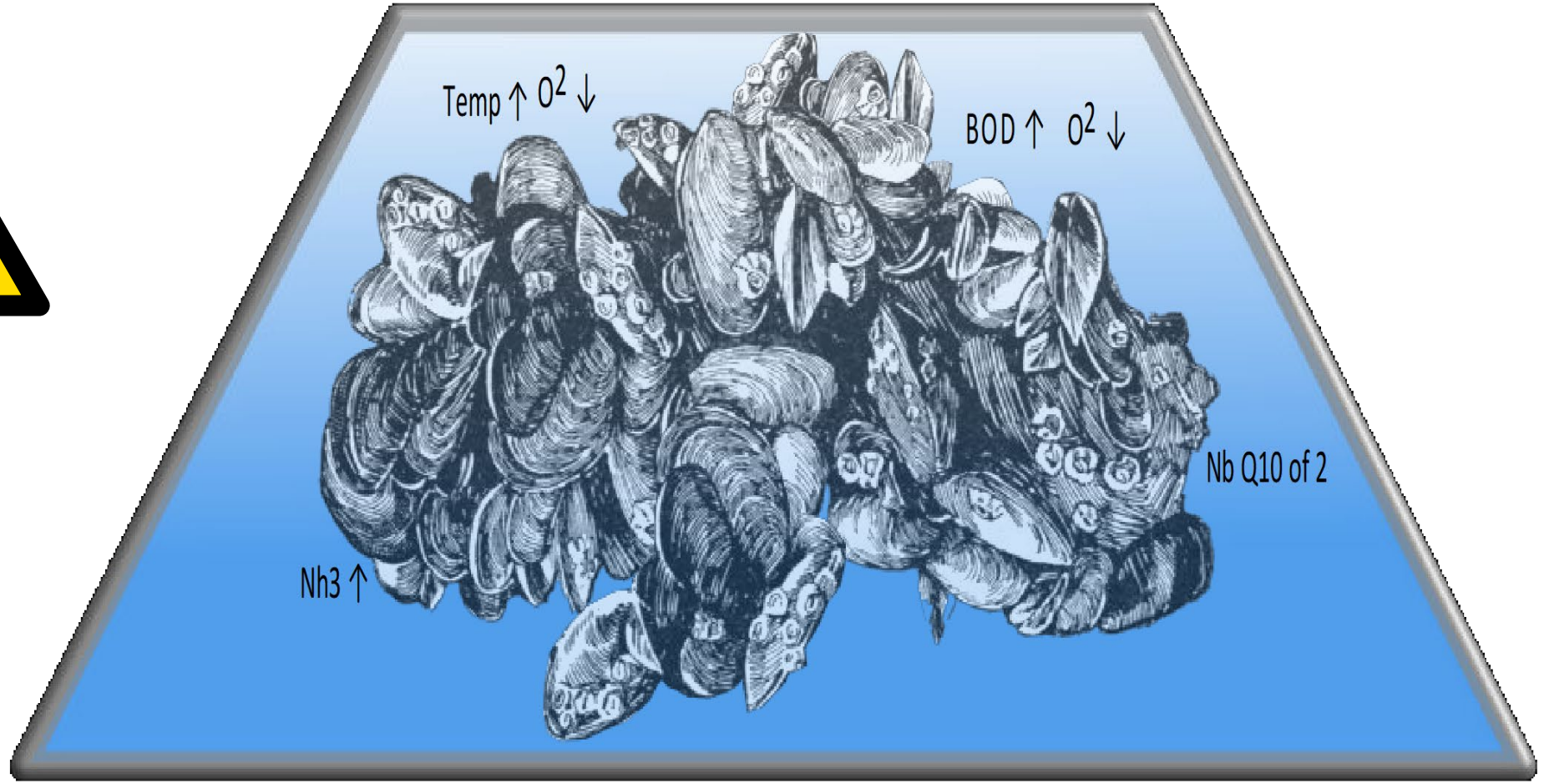


Metaphor of Liebig's Barrel’. Just as the capacity of a barrel is limited by the shortest stave – Depuration will be limited by the factor in the shortest supply – In this case dissolved O^2

Relationship between biomass: water ratio and physiological parameters



Incorrect biomass: water ratio and physiological parameters



Inspection techniques

- General perspectives on inspection of depuration establishments

Presentation overview

- EU Regulation 2017/625 and the Food Law COP - ‘Official Control Verification’
- ‘A more educated scientific approach’
- Scope of the inspection
- OCV triangulation and GAP analysis
- Official Control ‘*FSMS Study*’
- The ‘mass balance’
- Evidential triangulation
- Structure of the inspection
- Summary

The nature of Food Law on depuration

- 178 establishes the scientific nature of Food Law.
- Regulation 2017/625 **requires that all Official Controls are effective.**
- “The purification system must allow live bivalve molluscs rapidly to resume and to maintain filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated…The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre”
- **And little else!**

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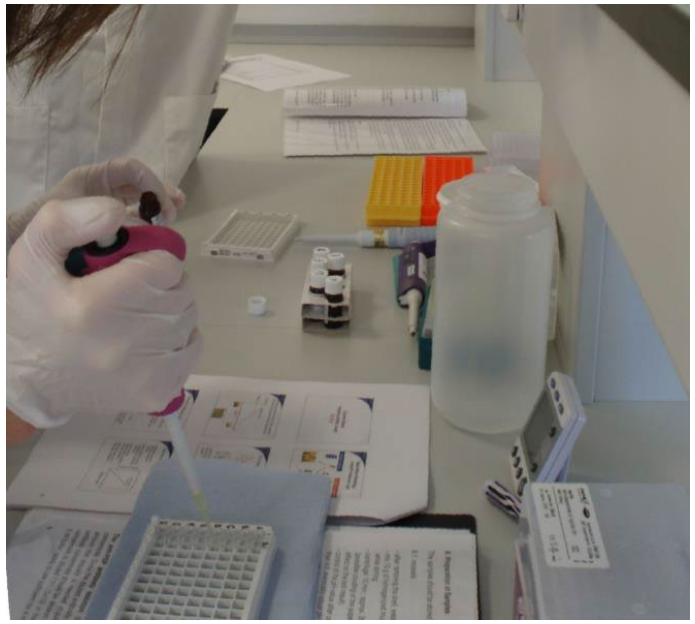
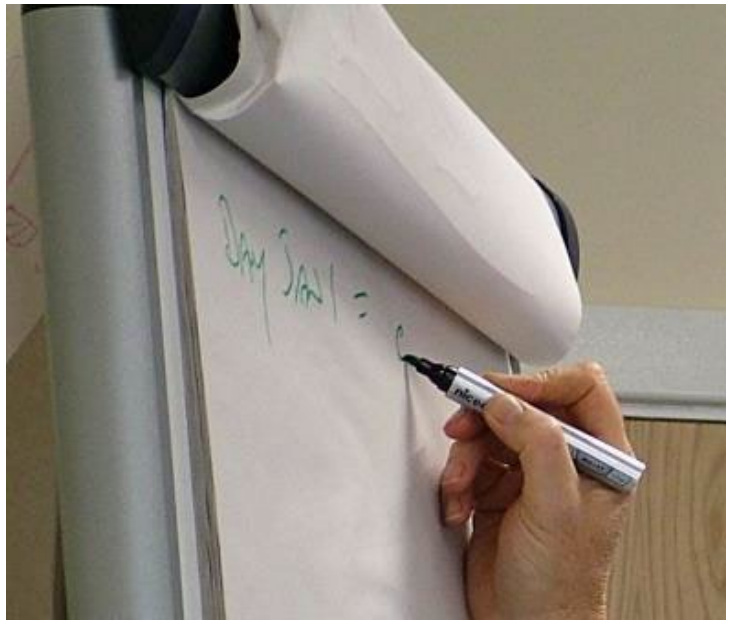
A regulatory metric?

"…Evidencing a cause and effect relationship between level of compliance and public health outcomes is a difficult task and is not currently available for the UK".

- Alison Gleadle FSA 2011

“A more educated scientific approach”- Sheriff Cox





A food safety metric?

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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'Contributory factors' (PI.I.M.S) and 'hazard mapping'

- All outbreaks were 'hallmarked' by an association between hazards & certain steps in the process

- Epidemiology - 'Contributory Factors' - **P.I.I.M.S** and **P.I.G.S.** E.g:
  - **P** Presence of inherently contaminating hazards
  - **I** Introduction of hazards via direct contamination
  - **I** Introduction of hazard via a cross-contamination pathway
  - **M** Multiplication of hazards.
  - **S** Survival of hazards at…

Consideration of the hazard, the process step and the contributory factor associates the hazard to a process step in a way relevant to foodborne disease - 'hazard mapping'

The PFD becomes predictive of the chain of events leading to food borne illness

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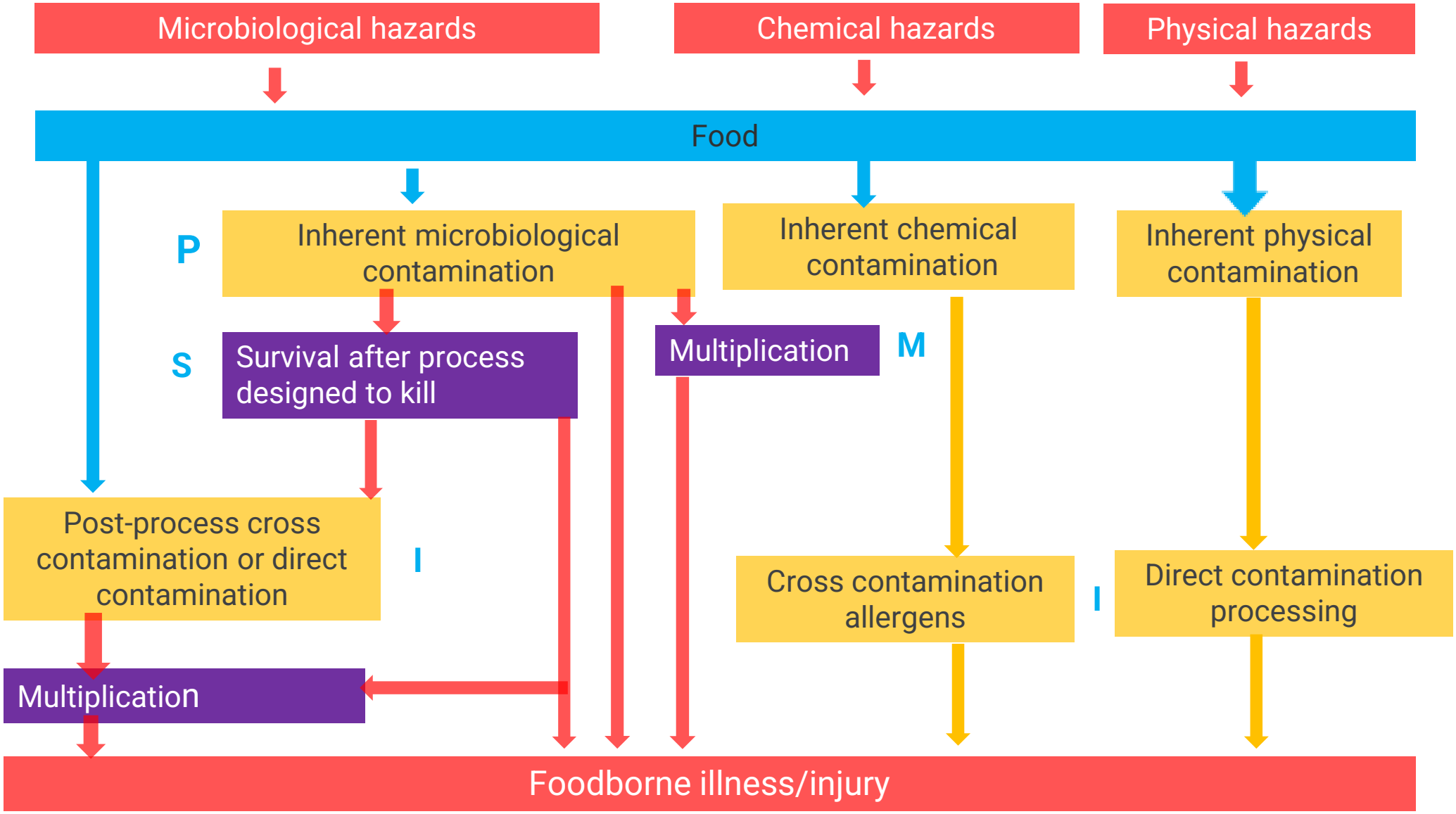
Foodborne illness – culmination of chain of events



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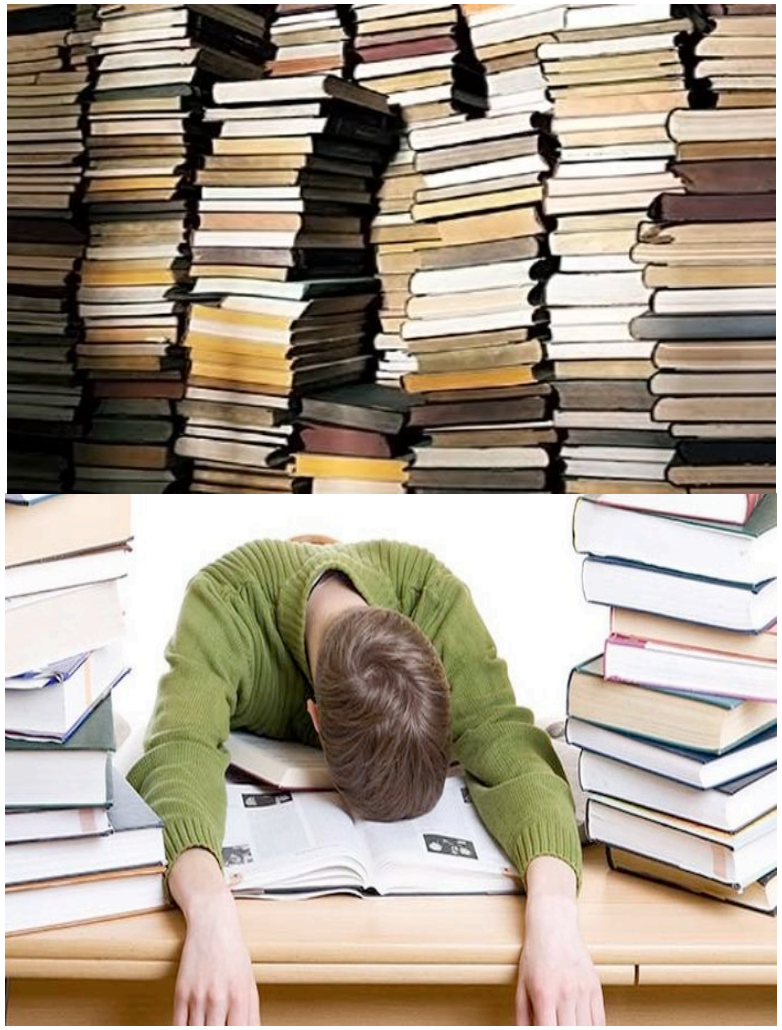
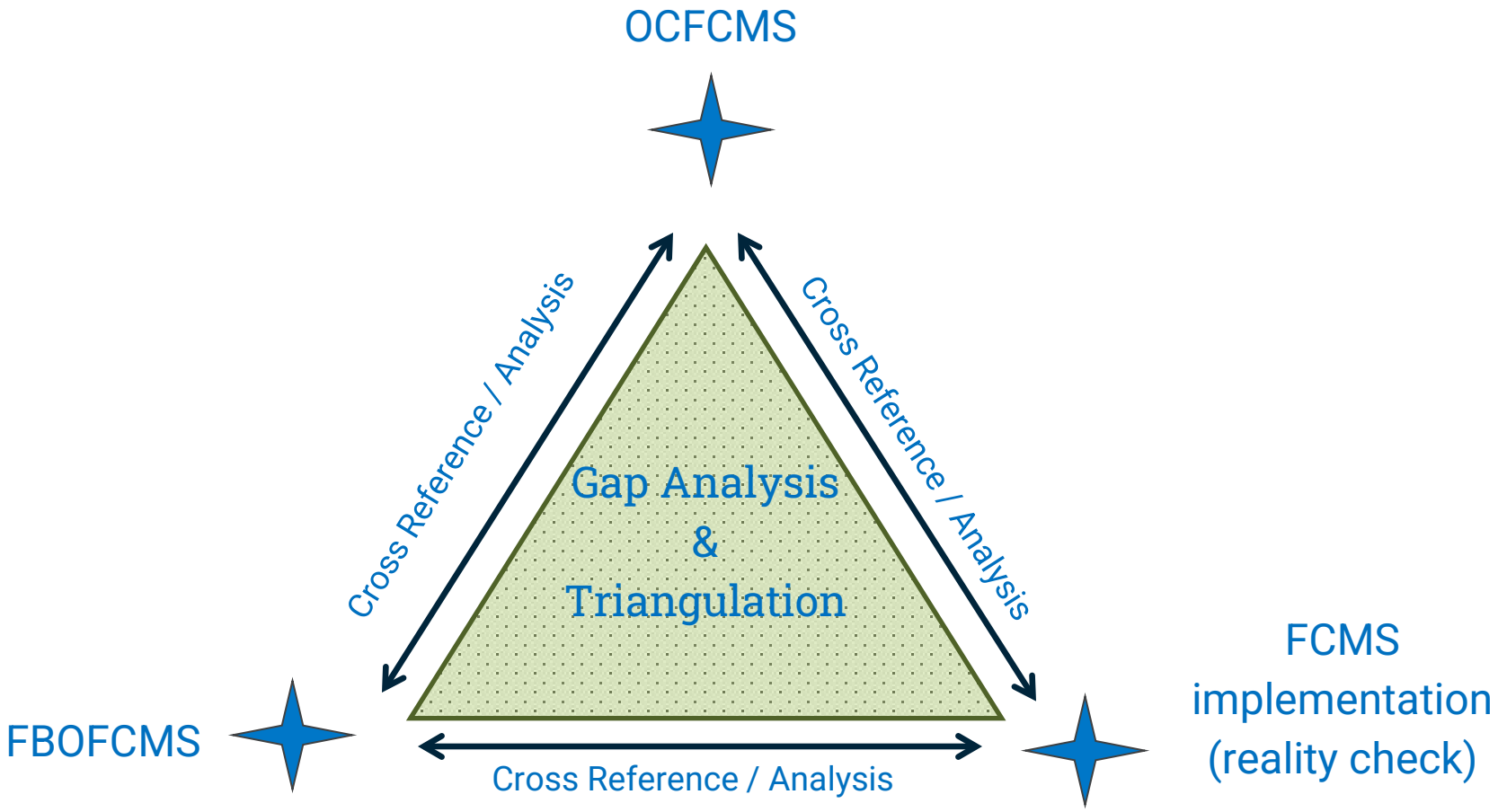
Literature review

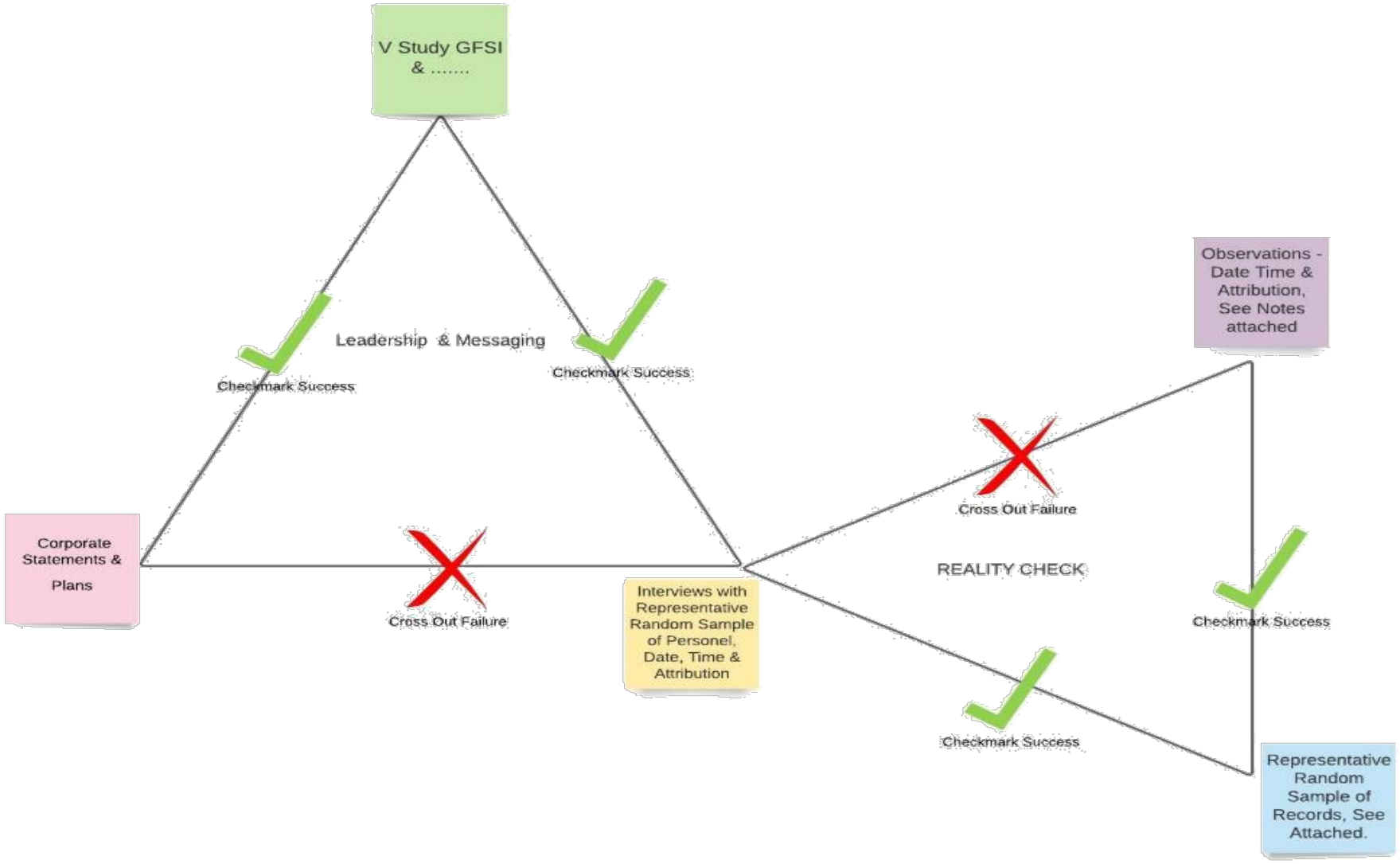


- Research required!
- Food science technology of depuration
- Microbiology of depuration
- Epidemiology of depuration
- Sources: Seafish/CEFAS/FSA/FSS WHO-CODEX

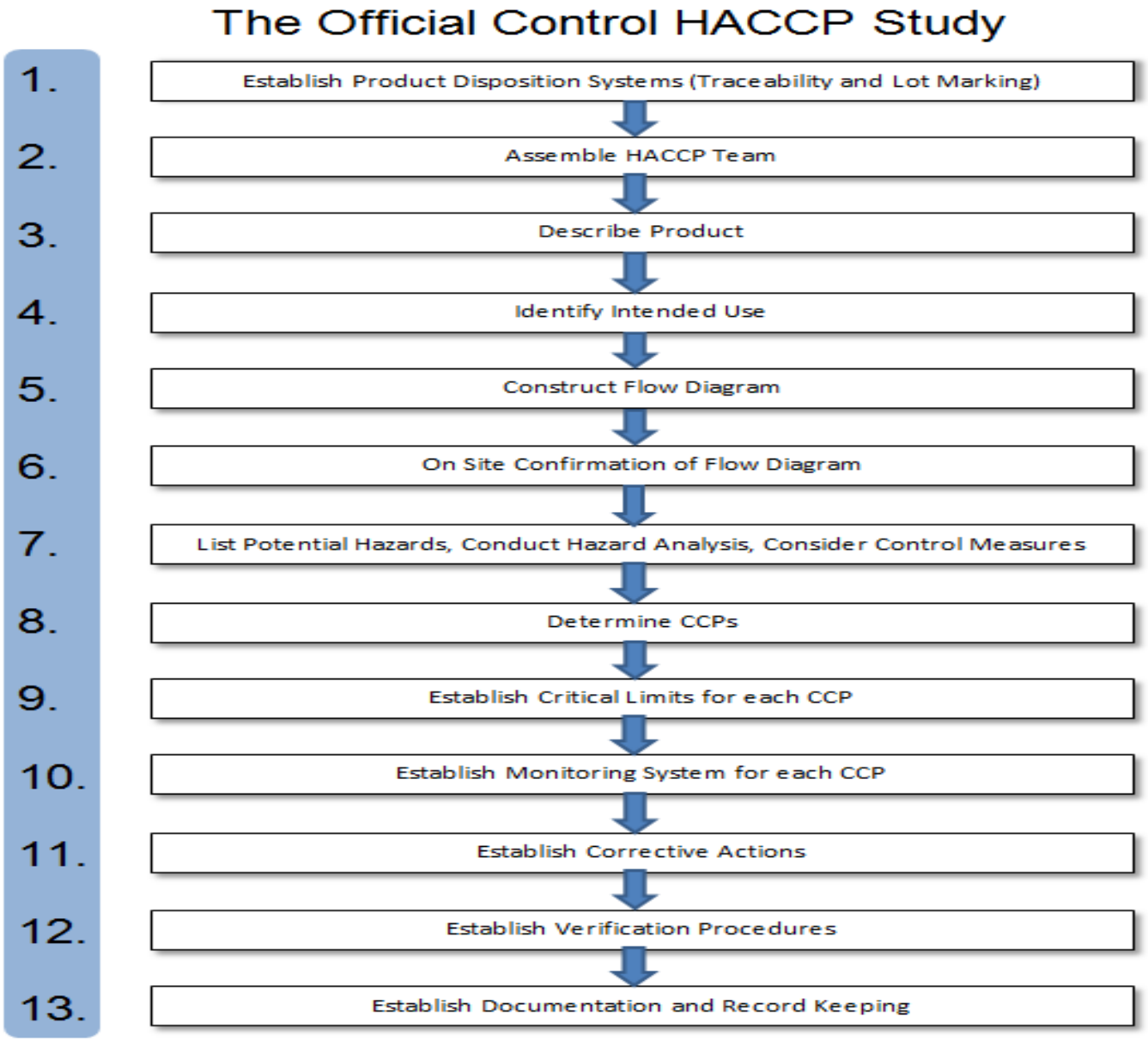
Official Control Verification



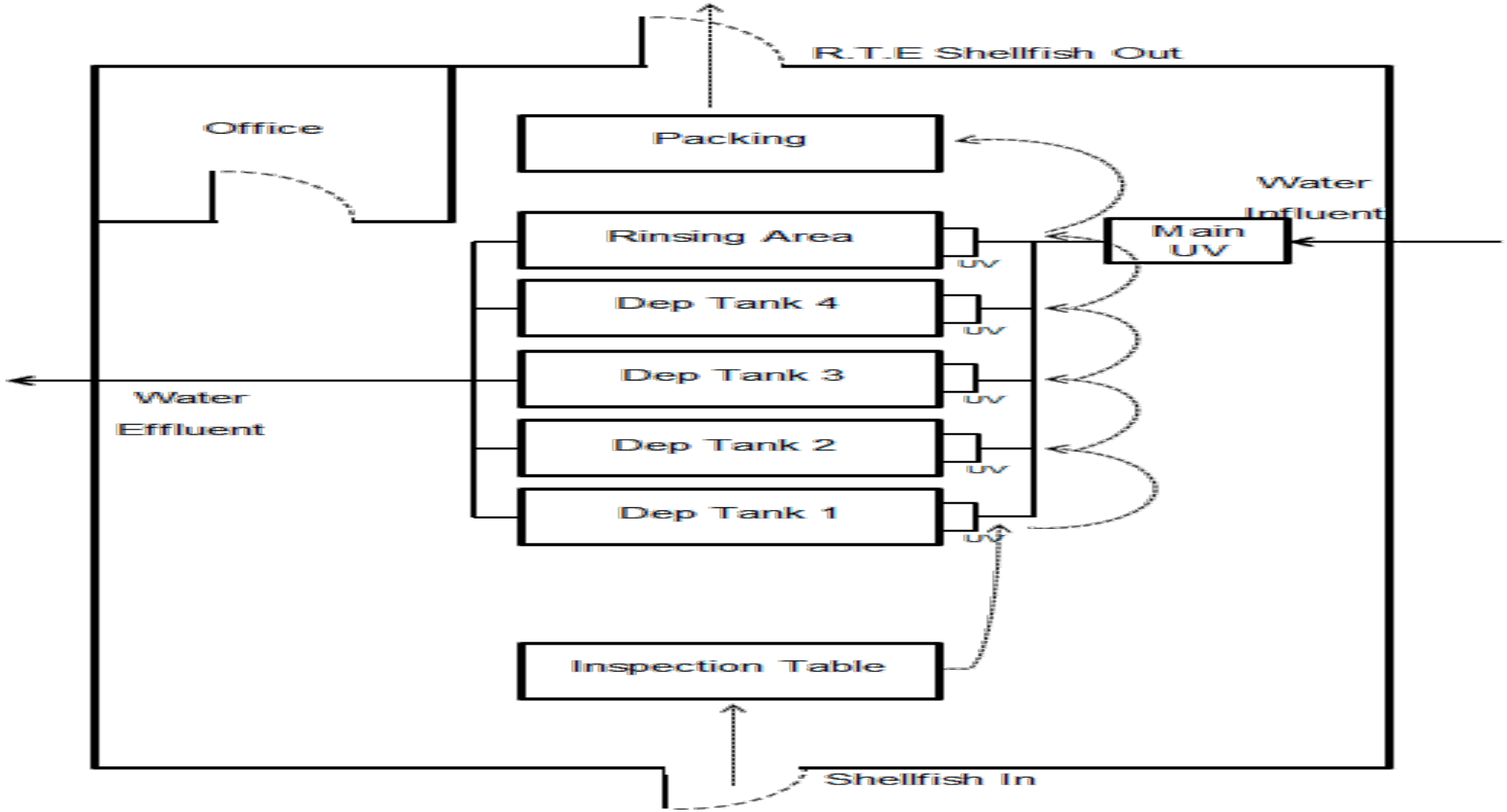
Triangulations



The Official Control FCMS study

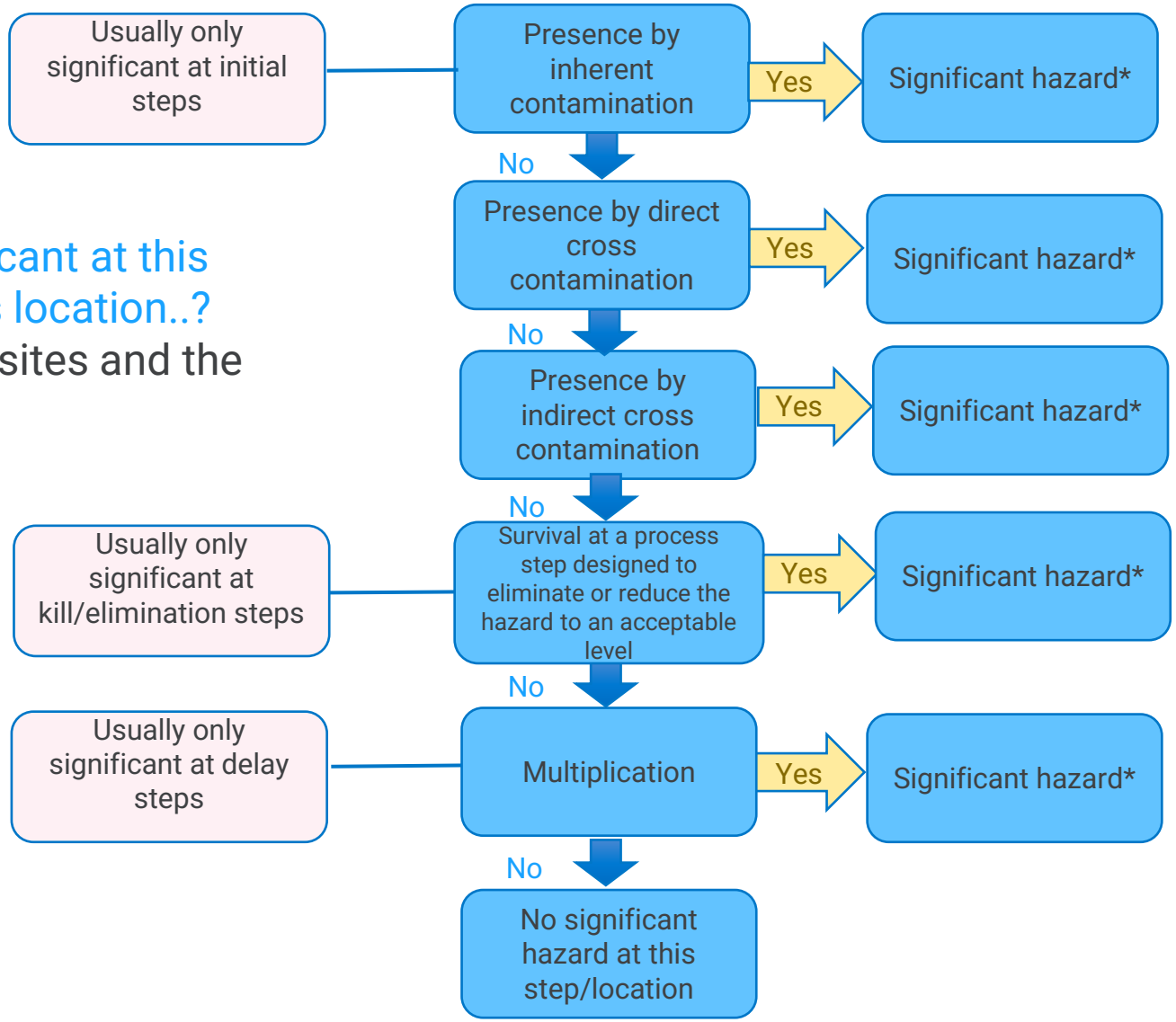


The Official Control FCMSS study - tracking the process flows and the water flows



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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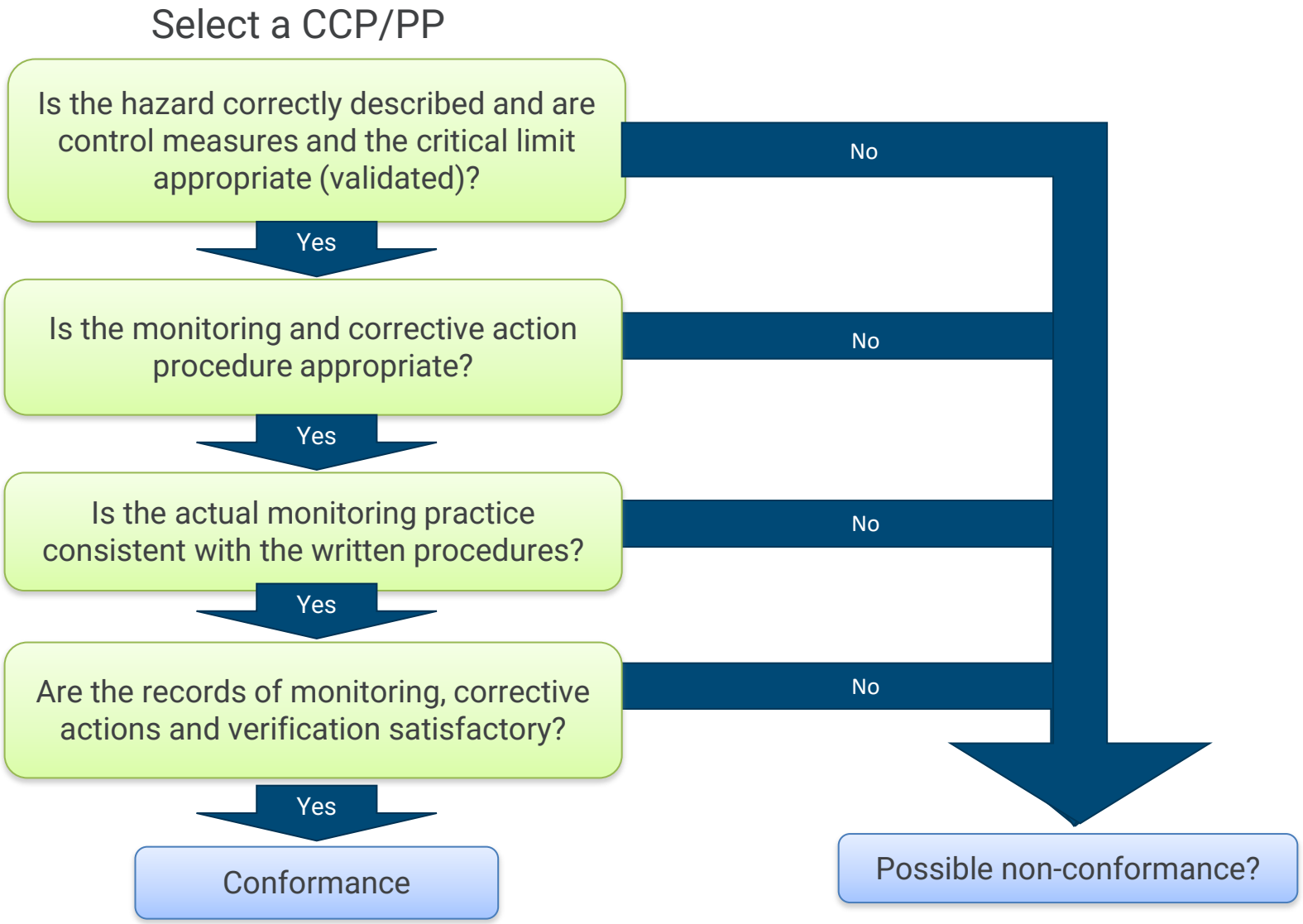
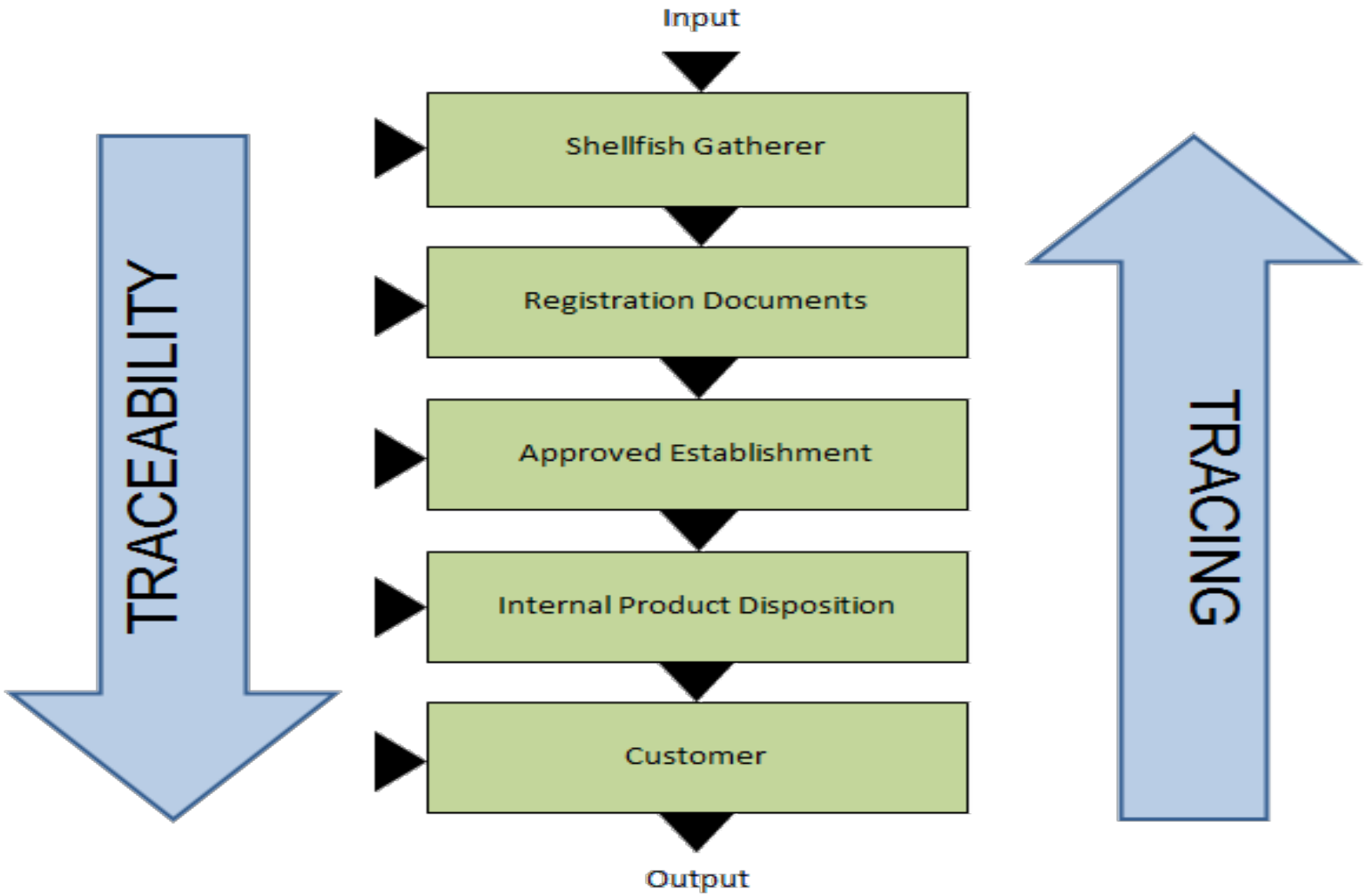
Example - verifying CCP's and PP's

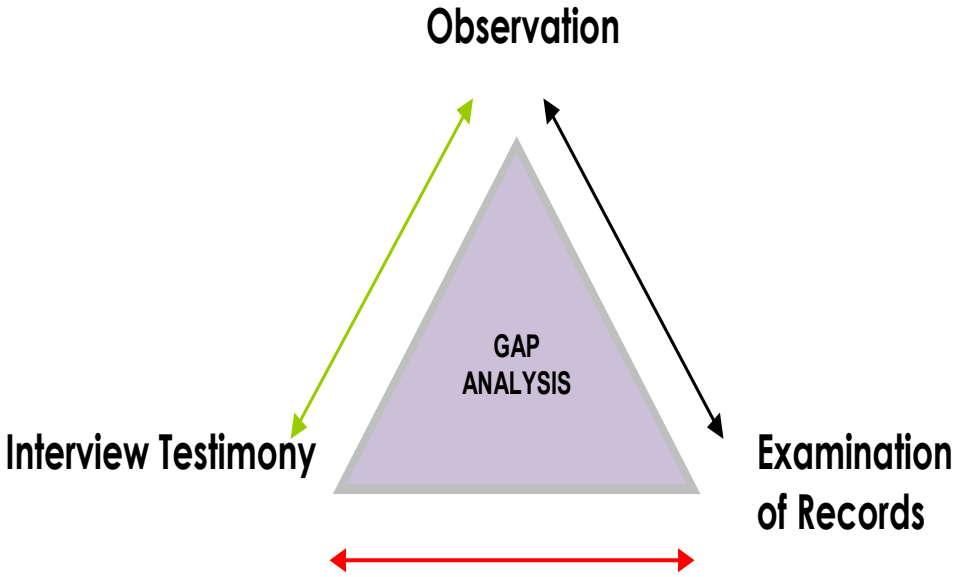


Shellfish mass balance

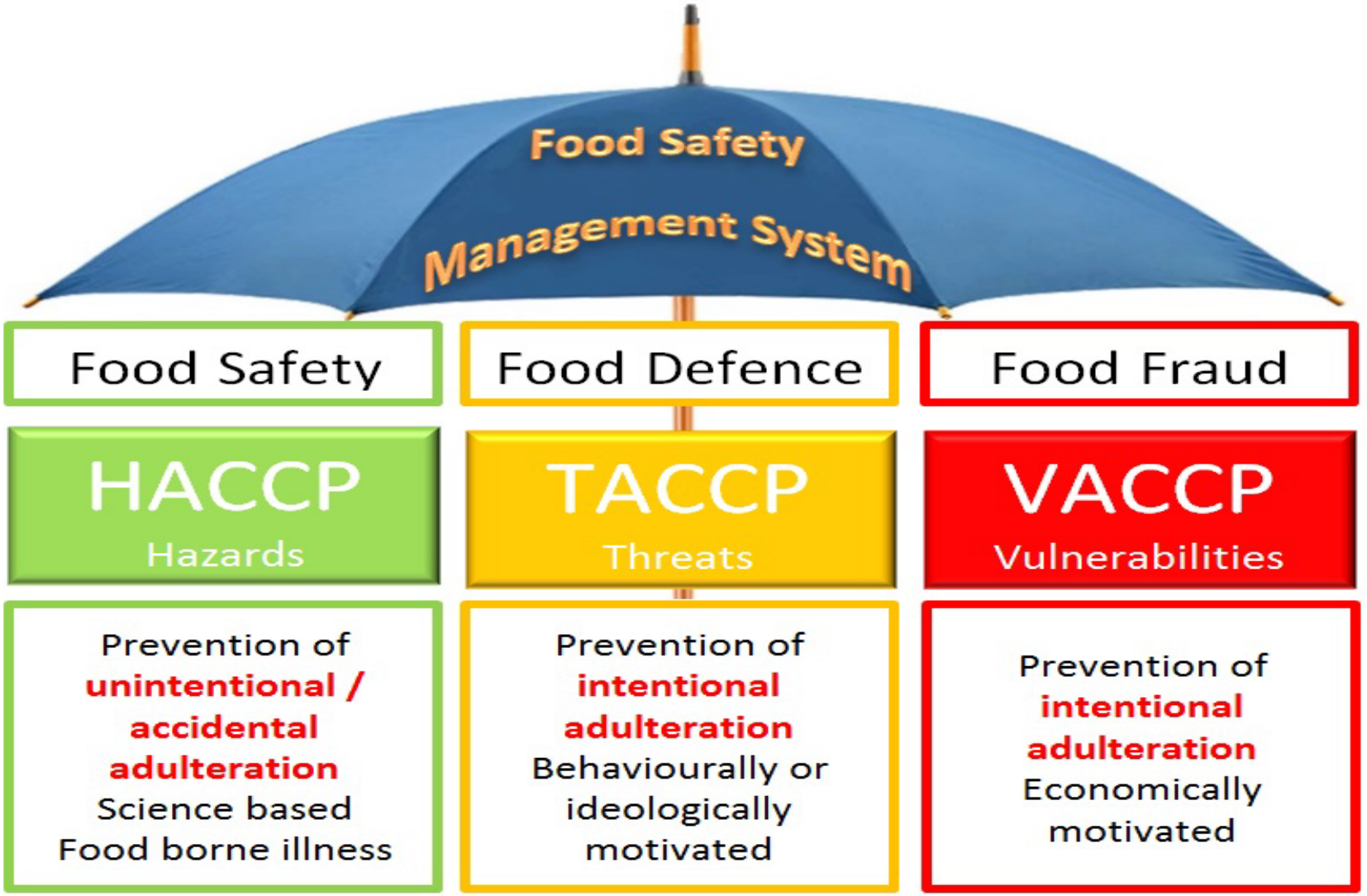


Triangulation of evidence

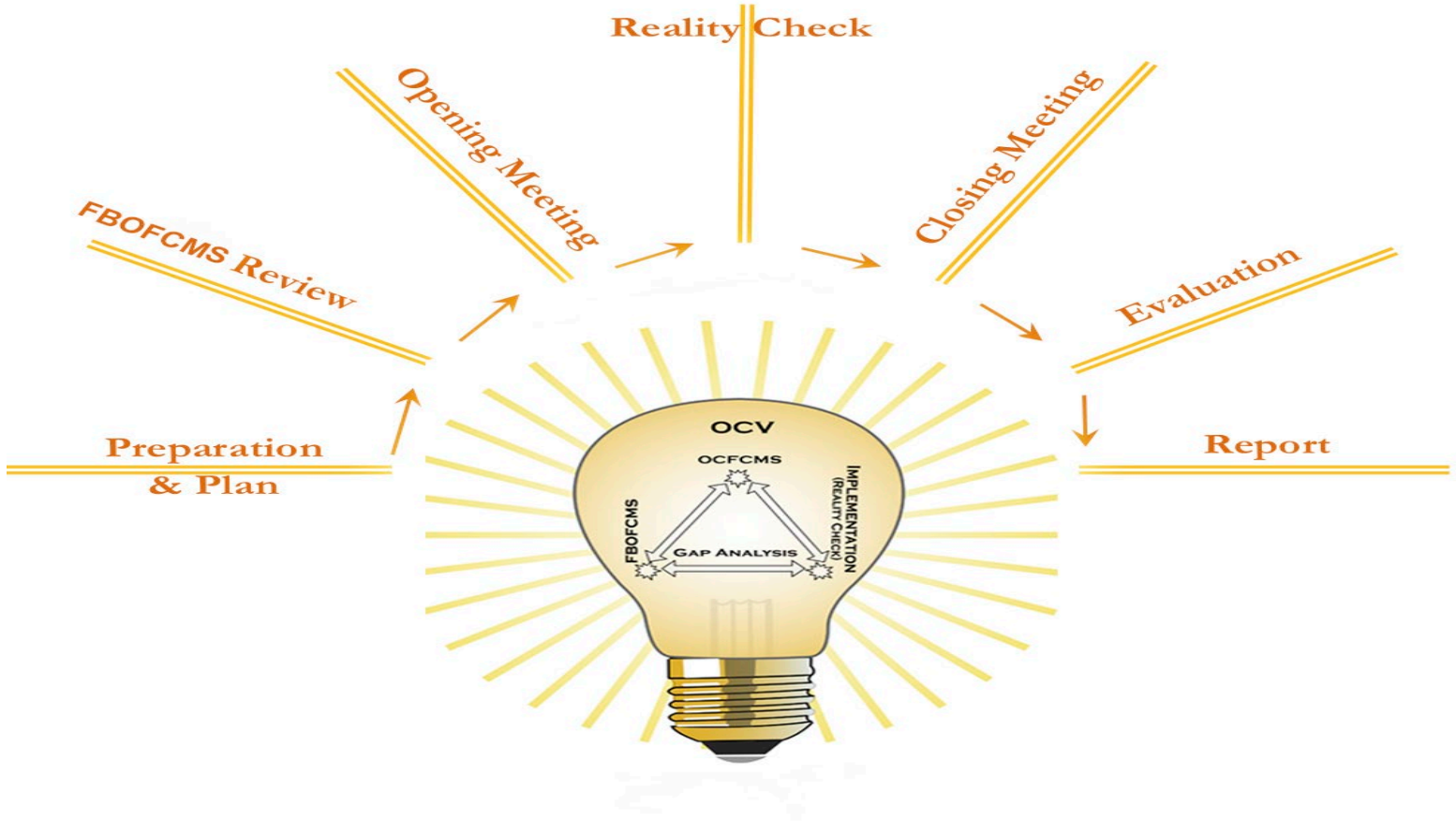
- Triangulation seeks to enhance certainty in enforcement decisions
- Essentially three discreet sources of evidence are cross referenced
- Corroboration is being sought
- Research has confirmed the utility of this technique



Food safety management system



Structure of the inspection



Presentation summary

- Regulation 2017/625 & the Food Law COP – ‘Official Control Verification’
- ‘A more educated scientific approach’
- Scope of the inspection
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General Control Measures

Scenarios re training and fraudulent records:
Considering depuration general control measures in terms of all of the contributory factors
('*warm-up*')

Purification centre staff not adequately trained

- Legislation- 852 / 2004, Annex II Chapter XI
- GMPG - step 16
- Business unable to effectively manage operations if staff not competent
- Lack of training and/or qualifications does not always mean incompetent staff

Staff training – possible and practicable?

- **What is possible?**
  - Seafish approved courses exist for operatives and managers
  - National Shellfish Training Centre established by Seafish.
- **What is practicable?**
  - It takes time to organise courses
  - Remote delivery now the norm

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Staff training – reasonable?

- Discuss

- Consider:
  - What are the risks?
  - Size of business
  - Availability of specialist training
  - Business capability
  - Evidence of competence, or lack of competence
  - Impact of action / inaction

- Recommendations?

Discuss

Suggested recommendation

- That the operator be given a reasonable time period within which to receive training from an approved trainer
- **Note:** should 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 a formal qualification.
- Is enforcement required?

Suggested recommendation

- Staff may require additional:
    - training
    - instruction
    - supervision
- What else?

Illegal harvesting - false records - food fraud/crime

- Legislation – 852/2004 annex I, part b 2 (j)
- GMPG – appendix 4
- Science – the monitoring and control of provenance, loading and environmental parameters is essential to effective management of purification:
    - Provenance and category of seawater harvested
        - NB validation of depuration is by reference to an upper limit of contamination
    - Loading of tanks
    - Temperature
    - Salinity
    - Dissolved Oxygen
    - Turbidity
    - Flow rates
    - Water quality
    - Etc.

Provenance and traceability

HEALTHMARK
LIVE SHELLFISH

Country of dispatch	Approval number of dispatch centre
Species consigned (scientific name)	Species consigned (common name)

Day and month of wrapping

[EITHER 'WARNING: THESE ANIMALS MUST BE ALIVE WHEN SOLD'
OR DATE OF DURABILITY]

HARVESTER SEAFOOD & SHELLFISH INC.
25 Perry Ave., Buzzard's Bay, Bourne, MA 02532
CERT. NO. **MA7474SS** ID No. 065437
Tel. (508) 759-7295

ORIGINAL SHIPPER (If other than MA7474SS) _____ (Cert No.)
HARVEST DATE: _____
HARVEST LOCATION: _____

TYPE:			
	( ) STEAMERS	( ) QUAHOG	( ) MUSSELS
	( ) COUNTNECK	( ) MIXED QUAHOGS	( ) SURF CLAM
	( ) LITTLENECK	( ) OYSTER	( ) OCEAN QUAHOG
	( ) TOPNECK	( ) BAY SCALLOP	( ) RAZOR CLAM
	( ) CHERRYSTONE	( ) SEA SCALLOP	( )

QUANTITY: _____

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL THE CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.

SHIP TO: _____ SHIP DATE: _____

- Legislation Regs (EC) 853/2004, Annex 3 S7, Chapter 7 (EC)178/2002, Article 18. (EU) 93/2011, Article 3
- Provenance can be critical to food safety:
  - **N.B** upper limit to the validation of depuration re contamination –harvest classification sites
- High value of shellfish/limit on approved loading rates potential incentives to falsify these documents

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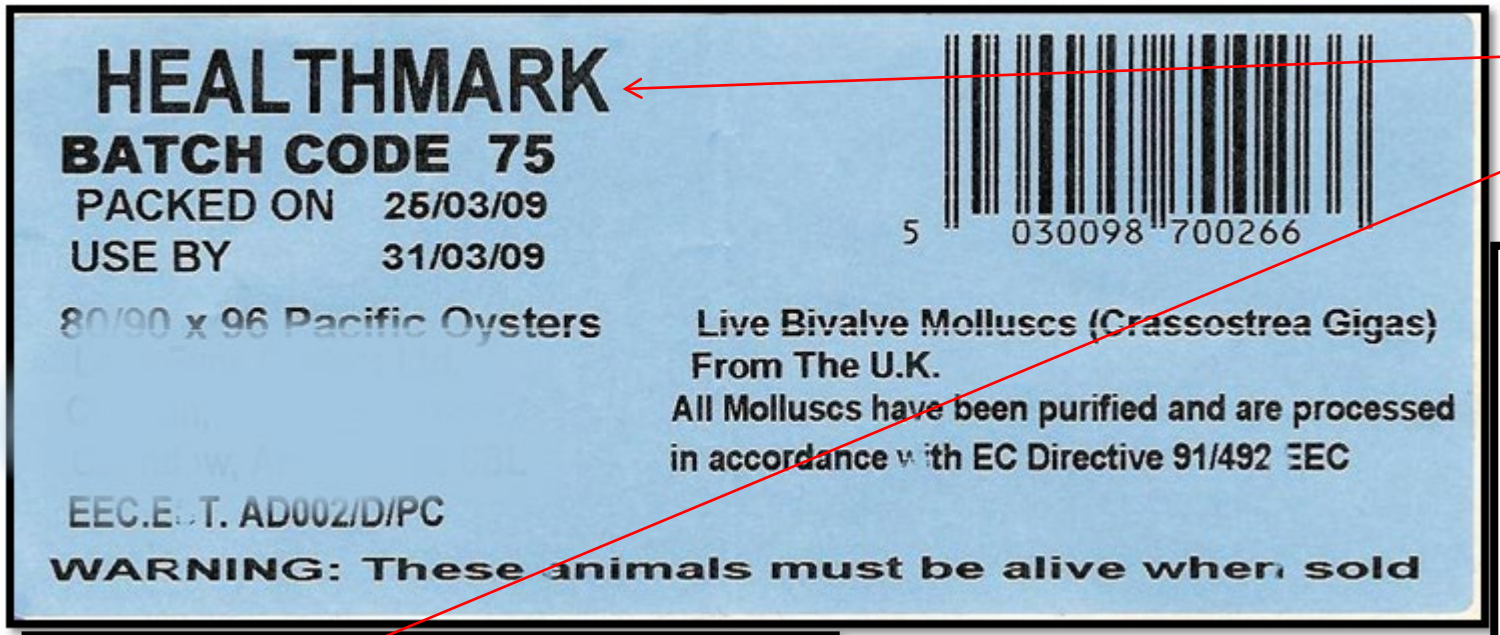
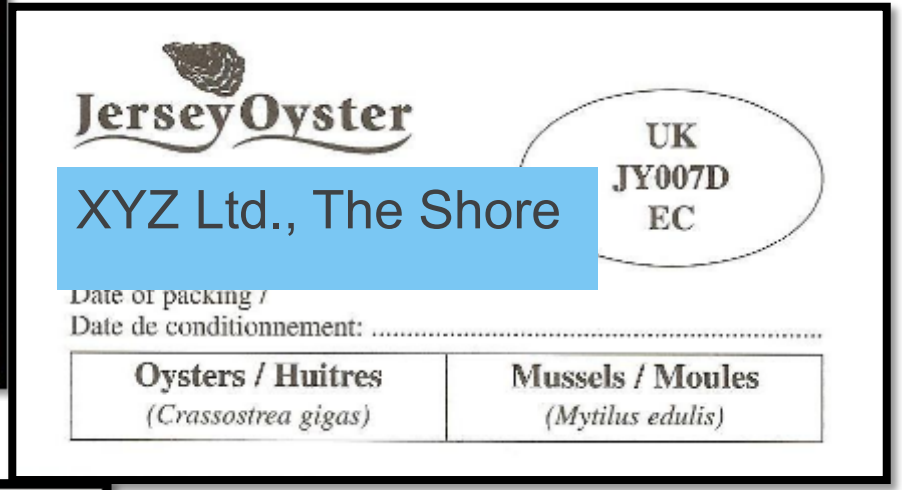
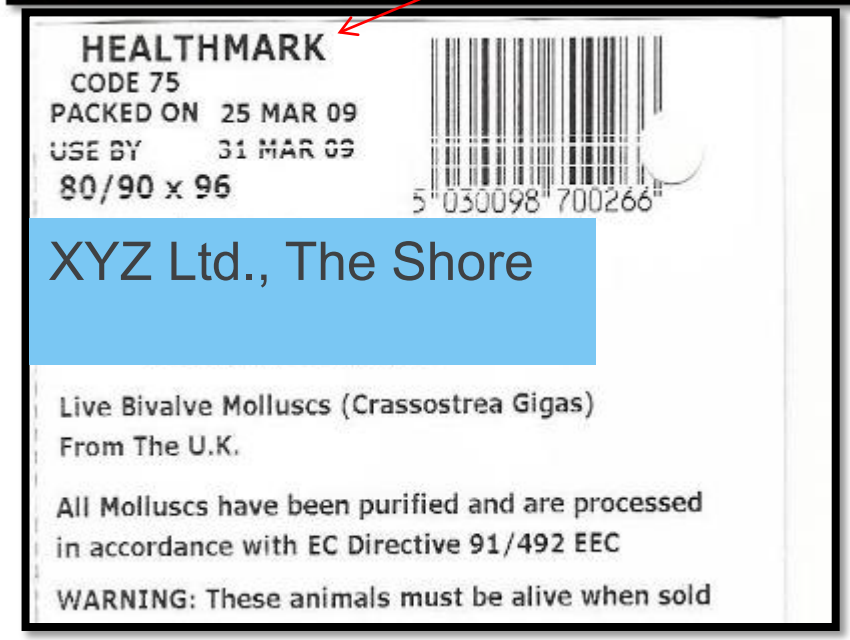


Now known as Identification Marks





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The real problem!

Provenance and traceability – possible and practicable

- Provenance/locus of capture clearly specified:
    - GPS reference
    - Handheld GPS inexpensive
    - Date and time reference
    - Photograph with a date and location reference
- Traceability - LA registration documents to specify provenance and destination
- The law - Legislation Regs (EC) 853/2004, Annex 3 S7, Chapter 7 (EC)178/2002, Article 18. (EU) 93/2011, Article 3

Discuss

False records – possible and practicable

- Means of provenance verification – available, locus of capture.
- Fit & proper persons – due diligence
- EHCs issued on basis of FBO reg doc? – LA due diligence! Does this render illegal harvesting and FBO reg docs uneconomic for FBO?

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:
    - conditions of approval
    - Seafish guidance
    - training courses

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False records – reasonable?

- Discussion

- Consider:
  - Operator error?
  - Management failings?
  - Malicious intent?
  - Risk to public health?

- Recommendations.

P – Presence of inherent contamination

Scenarios considering depuration control measures in terms of the contributory factor of the presence of inherent hazards

Using contaminated water in purification operations

- Legislation - 853 / 2004, Annex III, Section VII, Chap IV a3 and b, and 178/2002. Article 18. and 852/2004, Chap II Article 5
- GMPG - step 13
- Science - existing purification systems are validated to treat water supplies contaminated with low levels of microbiological contamination

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Using contaminated water in purification operations – possible and practicable

- Reduction in flow rate on filling tanks will increase residence time in UV bank

- Mechanical filtration of particulate matter will reduce associated microbiological contamination

Using contaminated water in purification operations – possible and practicable - continued

- Sophisticated water treatment plant is available
- Recirculation systems – seawater can be reused
- Artificial seawater is used and can be used to address temporary problems

Using contaminated water in purification operations – reasonable?

- Discussions

- Consider:
  - Type and degree of contamination
  - Availability of effective technical solution
  - Competence of business to implement solution
  - Investigation of alternatives to treatment

- Recommendations

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Discuss

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Suggested recommendation

- Abstraction should be allowed where the treatment of the seawater can be demonstrated to meet the definition of clean seawater:
    - Treatment with ozone is being investigated
- Alternative solutions can be considered:
    - Tankering clean seawater
    - Artificial seawater
    - Re-siting abstraction point
    - Tide dependent abstraction
- Report pollution events

I – Introduction by direct contamination

Scenarios considering depuration Control Measures in Terms of the Contributory Factor of Introduction of Hazards by Direct Contamination.

Obstructed seawater feed in purification systems

- Legislation – 852/2004, Chap II, article 5
- GMPG – Step 18
- Science:
  - Reduced flow rate and oxygen levels of water
  - Potential additional contamination

Obstructed seawater feed – 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

Obstructed seawater feed in purification systems – reasonable?

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

- Recommendations

Discuss

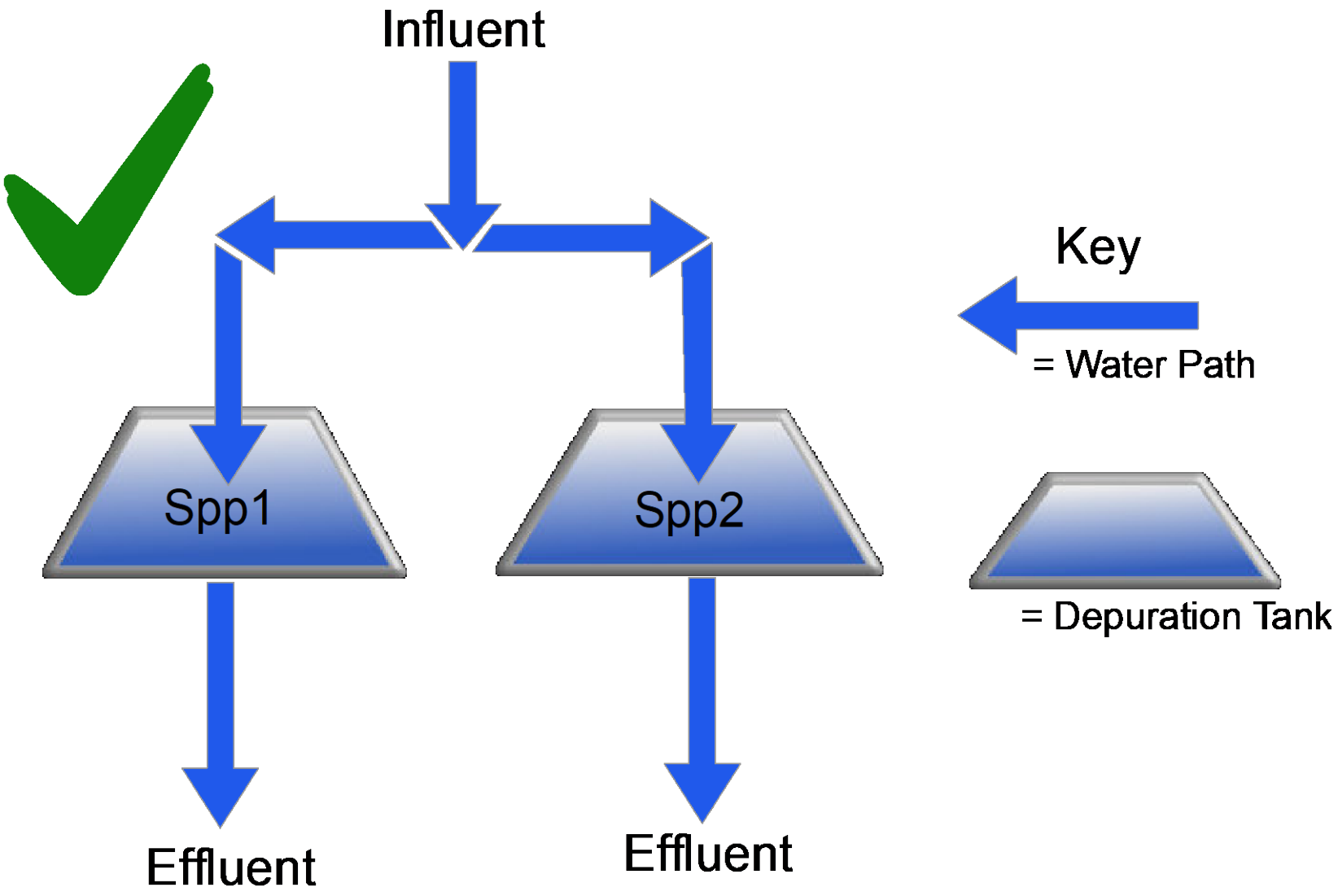
Suggested recommendation

- It may be reasonable to allow the cycle to continue provided there is evidence that operating conditions are within acceptable limits:
    - Specific end product testing may be necessary
    - The problem should be corrected ASAP and steps taken to avoid a recurrence
    - May require positive release following investigation of impact of cause
- Other actions may include:
    - Closer examination of UV effectiveness
    - Damaged
    - Occluded

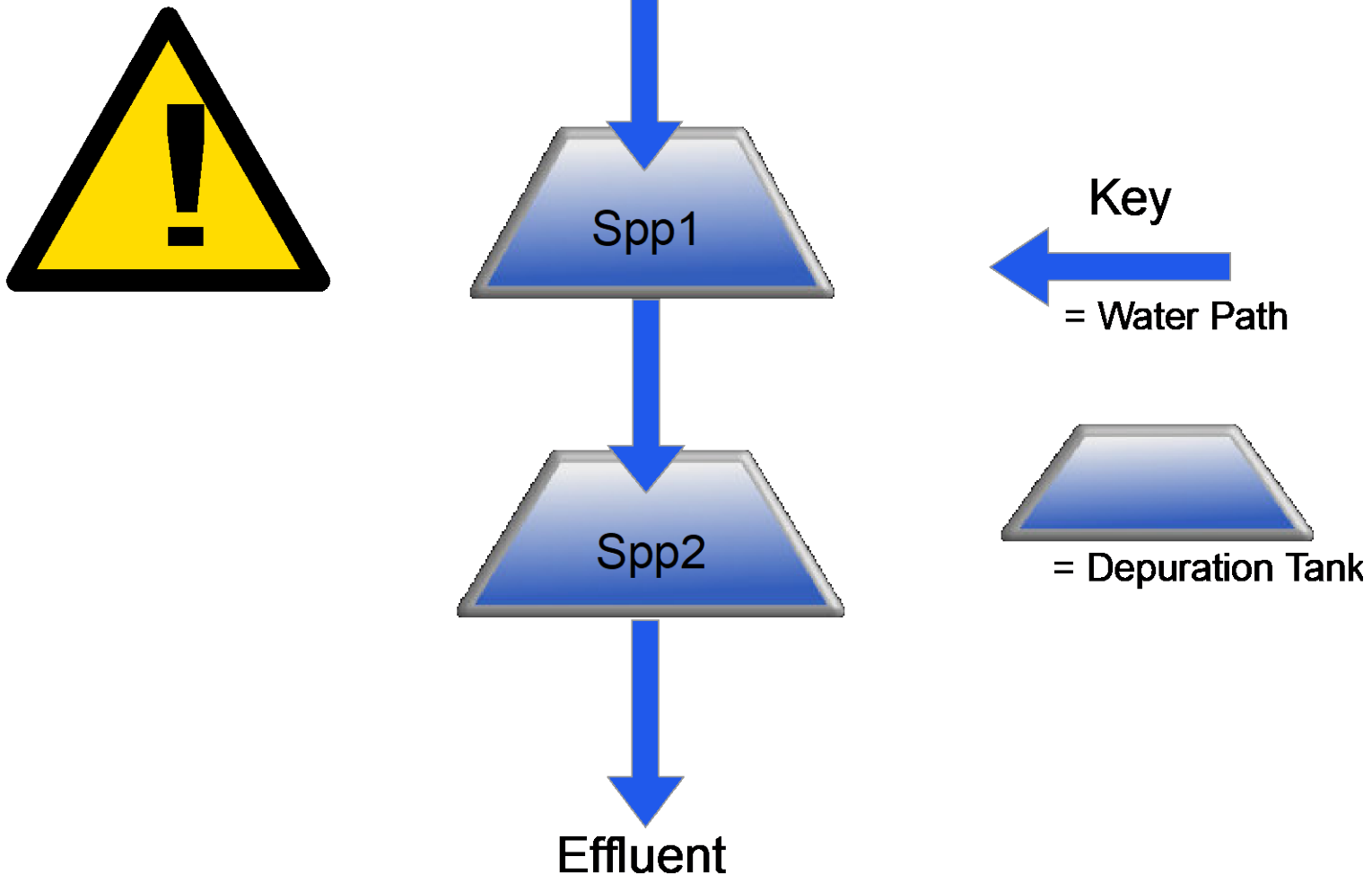
I – Introduction by cross contamination

Scenarios considering depuration control measures in terms of the contributory factor of introduction of hazards by cross contamination

Process design dual species depuration



Process design dual species depuration



Placing two bivalve species within the same system

- Legislation - 853 / 2004, Annex III, Section VII, Chap IV a4 & a6
- GMPG - step 14
- Science - Different bivalve species have different environmental and physiological needs
- Cross contamination is a risk

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

Two species within the same system – reasonable?

- Discussion
- Consider:
  - Water path – is it the same system?
  - Species specific temperature and salinity needs
  - Oysters and mussels not similar
  - Old Regs allowed this (pre 2006)
- Recommendations

Discuss

Suggested recommendation

- No mitigating factors (but old reg's allowed this)
- Stop purification
- Separate species
- Re-purify for full cycle
- Exceptions may include:
    - *Mytilus edulis and Mytilus trossulus*
    - *Tapes decussatus and Tapes philippinarum*

Holding crustaceans and bivalve shellfish in same water system

- Legislation - 853 / 2004, Annex III, Section VII, Chapter IV a4 & a6
- GMPG - step 14
- Science - Crustaceans excrete Vibrio spp:
  - Represent a serious human health risk in ready to eat products.

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Holding crustaceans and bivalve shellfish – possible, practicable and reasonable?

- No mitigating factors for LBM/crustacea mixing
- Don’t allow it
- However, storing crustaceans in display or wet holding systems is permissible
- Recommendations?

Discuss

Suggested recommendation

- Bivalves must not be used for human consumption and should:
    - Be disposed of, or
    - Be purified, or
    - Be relayed
- Crustaceans can continue to market and sale

Holding crustaceans and bivalve shellfish in adjacent systems

- Legislation - 853 / 2004, Annex III, Section VII, Chapter IV a4 & a6
- GMPG - step 14
- Science:
  - Crustaceans excrete Vibrio
  - **Spray** could carry cross contamination into bivalve tanks and packing area
  - The mechanism for cross contamination is not fully understood

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Adjacent systems – possible and practicable?

- Temporary physical barriers may be effective at separating crustaceans and bivalve holding areas
- It would seem practicable to separate crustacean and bivalve processing areas as required
- Water systems **MUST** be separate
- Cross contamination must be avoided

Adjacent systems –reasonable?

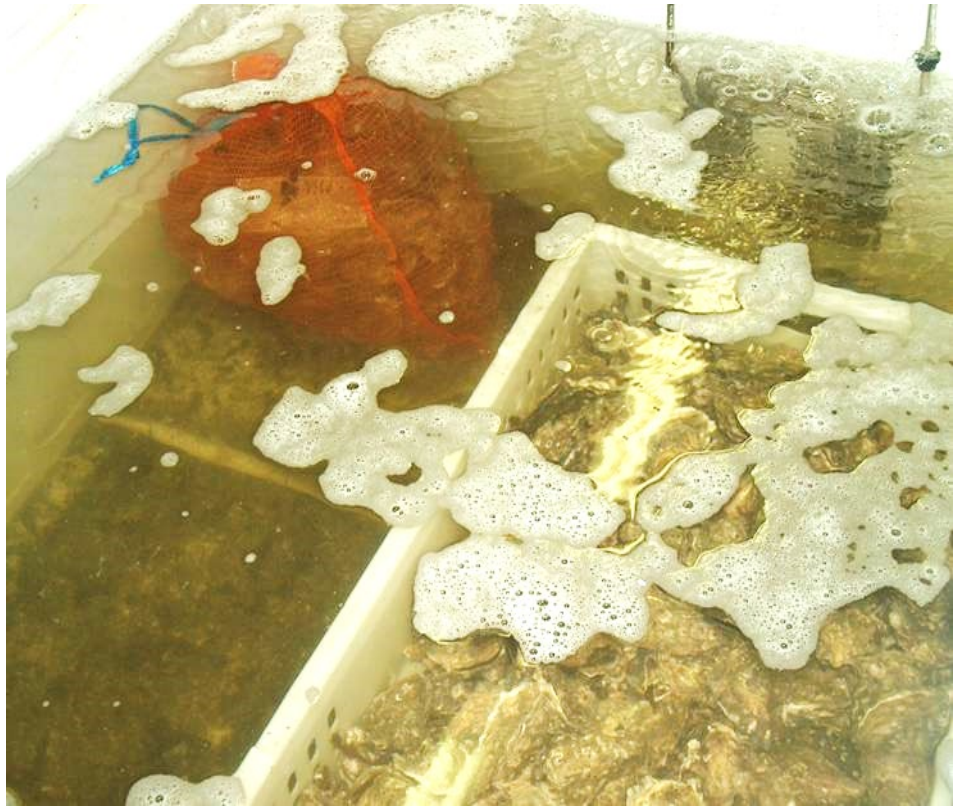
- Discussion
- Consider:
  - Risk assessment?
  - Proximity of tanks?
  - Why is it happening?
  - Frequency?
  - Management capability
- Recommendations

Discuss

Suggested recommendation

- Separate by:
    - Time
    - Space
    - Barriers
- Cross contamination must be avoided:
    - Place onus on the operator to demonstrate adequate safety

Placing purified bivalves back into active purification tanks



- Legislation - 853 / 2004, Annex III, Section VII, Chapter IV a4
- GMPG - step 15
- 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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Placing purified bivalves back – reasonable?

- Discussion
- Consider:
  - Purifying bivalves:
    - What is the risk?
    - What is the cost of restarting the clock?
    - How long have they been purifying
      - 1 hour into the cycle?
      - 1 hour from the end of the cycle
- Recommendations?

Discuss

Suggested recommendation

- The bagged bivalves are contaminated and must be:
    - debagged
    - washed
    - purified

- The bivalves in the tank must be risk assessed:
    - restart the ‘42hr clock’

Dead bivalves and mud balls in tanks

- Legislation - 852/2004, Chap II Article 5
- GMPG - step 14
- Science – dead bivalves contaminate batch
- Mud balls contaminate batch

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 – 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

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Discuss

Suggested recommendation

- Just a few dead bivalve shellfish
    - where the bivalve flesh has started to putrefy:
        - drain down tank and inspect all trays
        - remove dead / duds.
        - restart the clock and re-purify

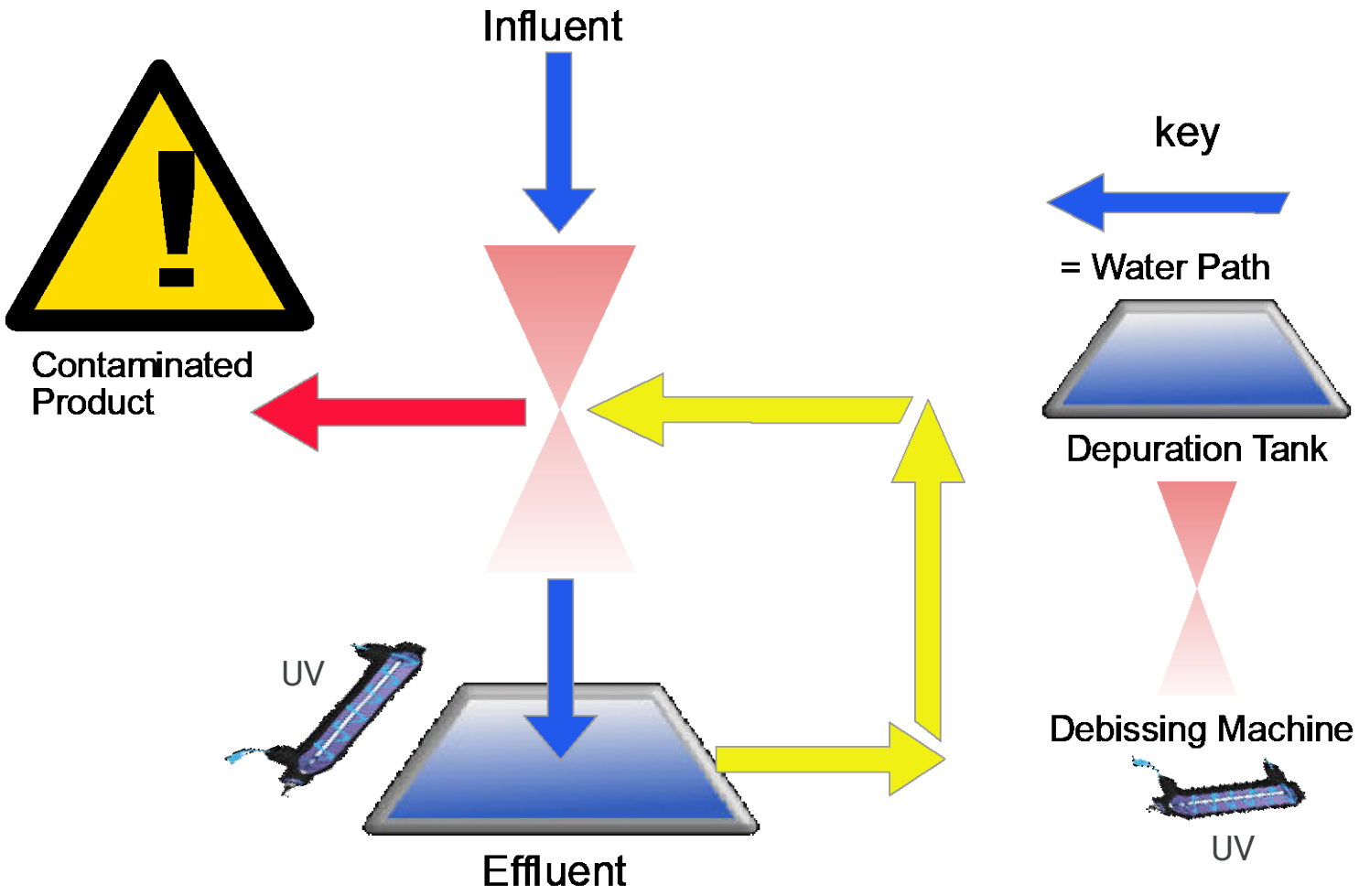
- Significant numbers of dead bivalve shellfish:
    - this suggests a failure in procedures, or
    - problems with pre purification handling or,
    - issues concerning the supply of LBM
    - LBMs possibly over-stressed and unsuitable for further treatment

- Duds which are clean empty shells are not a significant food safety risk

Cross contamination during post purification handling

- Legislation - 852/2004, Chap II Article 5.
- GMPG - step 19 and FSA cross contamination guidance
- Science - cross contamination between un-depurated and depurated batches.

Cross contamination during post purification handling - schematic



Cross contamination – possible and practicable

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

Cross contamination – reasonable?

- Discussions
- Consider:
    - cost of duplicating equipment
    - footprint of building
    - ease of cleaning – what is effective?
    - management capability
    - post purification bivalve shellfish are effectively contamination free
- Recommendations

Discuss

Suggested recommendations

- The use of the same equipment is acceptable provided batch separation and clean down are effective
- This can be as simple as removing bivalve shellfish and rinsing equipment
- A deep clean may not be needed
- It would not be reasonable to insist on such a thorough clean down process when unpurified bivalves are following purified bivalves with a minimal time delay

Algal matt growth in purification systems and water holding tanks

- Legislation - 852/2004 and 853/2004
- GMPG – step 16
- Science:
  - no control on 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

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Algal matt growth – possible and practicable

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

Algal matt growth – reasonable?

- Discussion

- Consider:
    - what specific legislation applies?
    - what are the risks?
    - are there other failures?
    - how long has this been going on?
    - does this suggest a systemic management failure?
    - how can we know the seawater is clean?

- Recommendations

Discuss

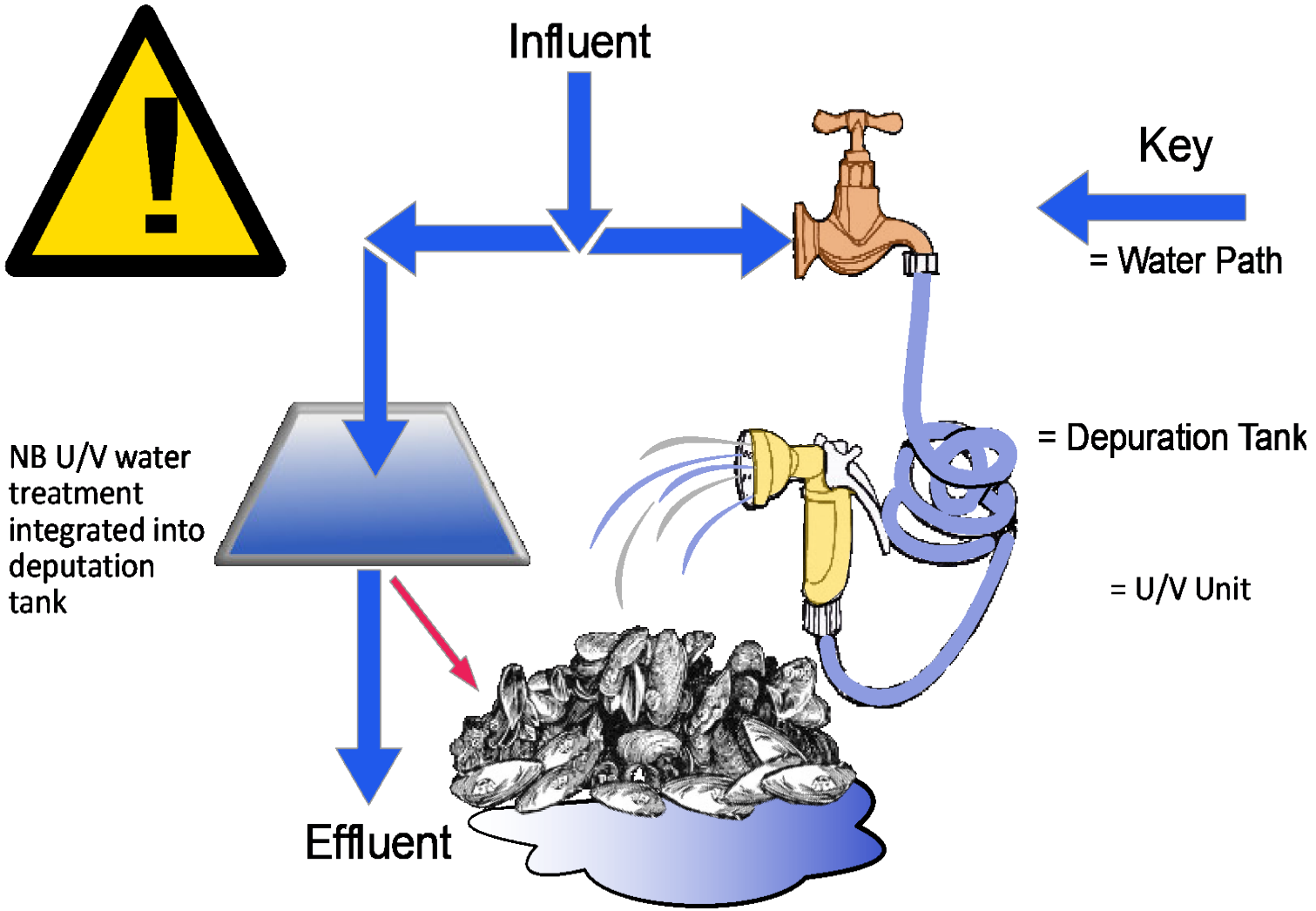
Suggested recommendation

- 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 more thorough examination of procedures and practices may be warranted

Washing purified batches with contaminated seawater

- Legislation - 853/2004, Annex III Section VII Chapter IV Article 5
- GMPG - step 19
- Science - contaminates bivalve shellfish.

Washing purified batches with contaminated water - schematic



Washing purified batches– possible and practicable

- Can use potable water provided bivalve shellfish are not immersed
- Can use **treated** category B seawater
- Can use artificial seawater
- Can use category A water untreated

Washing purified batches – reasonable?

- Discussion
- Consider:
  - why might this have happened / what went wrong?
  - who was responsible?
  - how should it be avoided?
- Recommendations

Discuss

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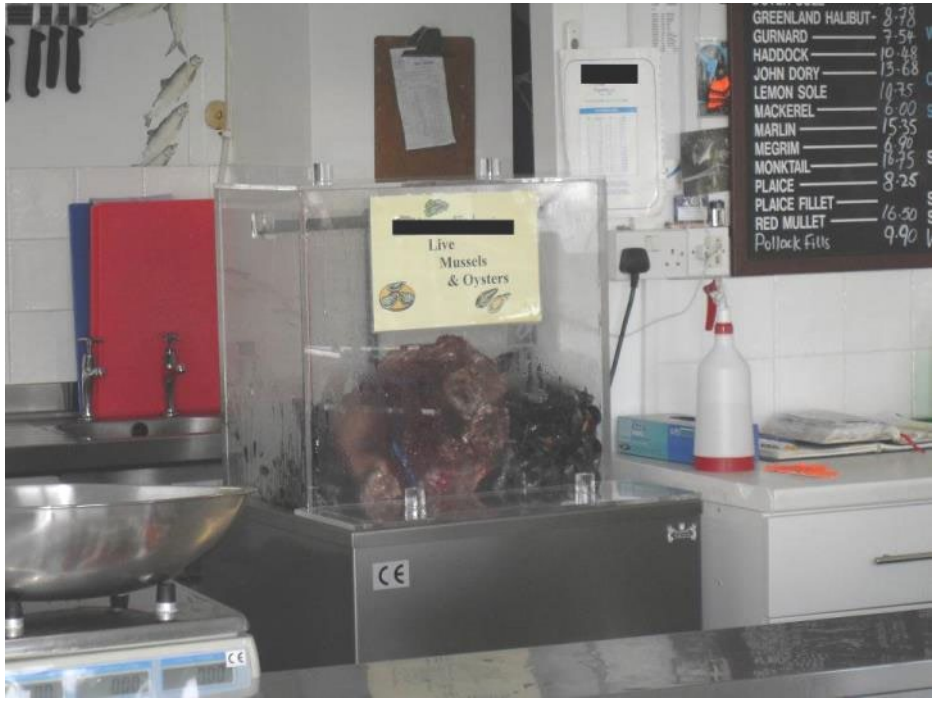
Suggested recommendation

- 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

Re-immersion in display cabinets, post purification



- Legislation - 853 / 2004, Annex III, Section VII, Chapter VIII 2
- GMPG - step 20
- Science - poor controls can lead to stressed and cross-contaminated bivalves

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Re-immersion in display - possible, 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
- Recommendations

Discuss

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Suggested recommendation

- Display cabinet immersion is not permissible:
    - withdraw cabinet from use
    - dispose of contents
        - not for human consumption without purification

M – Multiplication of hazards

Scenarios considering depuration control measures in terms of the contributory factor of the multiplication (persistence) of hazards

Temperature and time control

HARVESTER TAG

Cooling option (circle one): Traditional Rapid Cool On-Board Cool

HARVESTER SPL # or AQ # _____

DATE OF HARVEST _____ TIME OF HARVEST _____

Time of Refrigeration, if applicable _____

Legal Harvest Area Name or # _____

Specific Harvest Location Name or # _____

Type of Shellfish _____ Quantity of Shellfish _____

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY
OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS

- Legislation - 853/2004, Annex III Section VII Chapter IV Article 5
- GMPG - step 19
- Science - Multiplication of contaminating hazards due to loss of temperature and time control. Can occur at any point in the process.
  - ‘just-in-time-process’
  - eliminate ‘**delay-steps**’
  - an aspect of broader ‘process-control’
    - ❖ master manufacturing instructions/traceability/lot-marking

Discuss

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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 within the ambit of 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

S – Survival of hazards

Scenarios considering depuration control measures in terms of the contributory factor of the survival (persistence) of hazards

Incorrect biomass to water ratio

- Legislation - 853/2004, Annex iii, Section VII, Chapter a3. Chapter III.2 (a-c)
- GMPG - step 14
- Science:
    - oxygen depletion and degraded environmental conditions
    - result in reduced shelf life and increased mortality
    - species and purification system dependent

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

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Biomass to water ratio – reasonable?

- Discuss
- Consider:
    - approval conditions
    - degree of risk
    - species
    - seasonal water temperature
    - frequency and duration of the issue
    - business capability
    - impact of action / inaction
- Recommendations?

Discuss

Suggested recommendations

- In order not to undermine the group discussions which provide an opportunity for participants to explore each issue in detail, we have withheld the slides that detail our recommendations, and which could have biased the discussions if revealed too soon.

- Summaries of our recommendations will be tabled during the course delivery, in four batches

Suggested recommendations – continued

- Overstocking of tanks should not be allowed
- 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

Bivalves not submerged during purification operation

- Legislation - 852/2004, Chapter II Article 5
- GMPG - step 15
- Science:
    - bivalves cannot depurate when not immersed

Bivalves not submerged – possible and practicable?

- Bivalve 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
- Bivalves will still depurate with reduced headspace of water provided oxygen and flow rates are sufficient
- Mussels do wander
- Waste material in bottom of some types of tank

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Bivalves not submerged – reasonable?

- Discuss

- Consider:
  - why is it happening?
  - what should be the appropriate operator action?
  - impact of action / inaction
  - shallow tray vs bulk bin

- Recommendations?

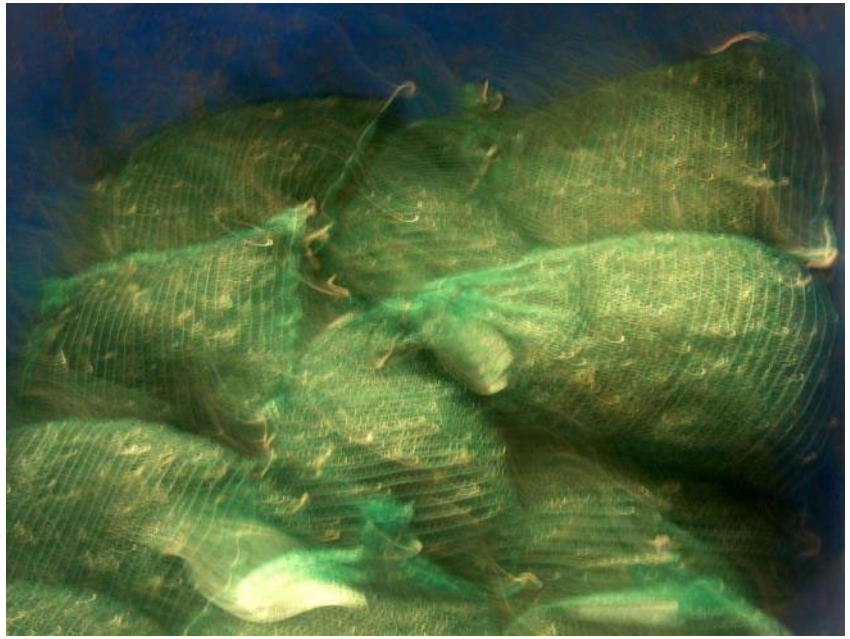
Discuss

Suggested recommendation

- 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 head space this may be allowed 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

Animals bagged during purification process

- Legislation - 852/2004, Chap II Article 5
- GMPG - step 18
- Science - Animals unable to open and respire and cannot effectively depurate



Animals bagged – possible, practicable?

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

Animals bagged – reasonable?

- Discussion

- Consider:
    - 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

- Recommendations

Discuss

Suggested recommendations

- **NOT** allowable in any way during purification operations - operator must restart purification with un-bagged bivalves

- **However,**
    - conditioning of purified bivalves is allowable provided:
        - bivalves can respirate
        - there is sufficient head room in the bags
    - batches of the same species can be mixed provided:
        - they are from the same category of water
        - individual bags are traceable

This is only allowable in a licensed dispatch centre.

Poorly maintained UV system - quartz tubes fouled

- Legislation - 852/2004, Chapter II Article 5
- GMPG - step 18
- Science - fouled quartz tube reduces UV transmission
- Can result in an unsafe system and an invalid process

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 – minutes
    - high intensity – hours
  - risk assessment
  - cleaning schedule
  - records
  - have they a system that they have failed to manage?
  - Have they failed to have a system?

- Recommendations

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Discuss

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Suggested recommendation

- 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'
- They must have, and must use a system to manage UV tube planned maintenance for:
    - inspection
    - cleaning
    - replacement

Discuss

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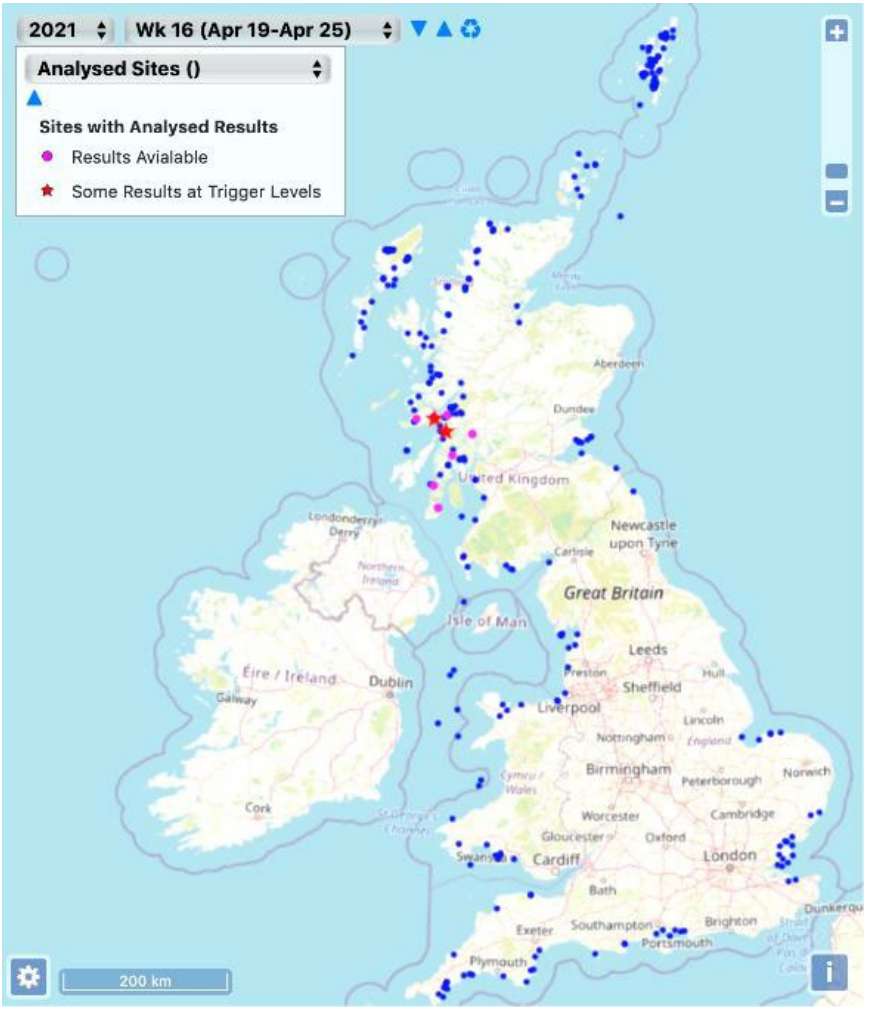
The limitations of depuration

- Algal toxins
- Viruses

Algal toxins

- **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

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



Thank you for your contributions

- Review and discussion
- A link for post course resources will be emailed to you
- Online feedback will be requested – via an emailed link

Seafish update

- Training opportunities for industry:
    - Bivalve Purification Operations training course
    - Bivalve Purification Management training course
    - Official Control Sampling training course
- Contact Seafish Onshore Training team for more information – onshore@seafish.co.uk

Thank you

Optional contact details

Optional contact details

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