Summary Report

Review of approaches for establishing exclusion zones for shellfish harvesting around sewage discharge points

Desk study to inform consideration of the possible introduction of exclusion zones as a control for Norovirus in oysters

Project Code: FS513404

16 February 2015

FINAL REPORT

AQUATIC WATER SERVICES LIMITED

Working with:

Aquafish Solutions Limited

European Centre for Environment & Human Health

Intertek

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1 OVERVIEW

This Summary Report is intended to be read in conjunction with the accompanying Technical Report which also has a technical summary at the end of each section. The objective of this report is to provide an overview with signposted access into the Technical Report (marked in **Green**). No referencing will be provided in this document other than to the relevant Sections within the Technical Report where source citations and links can be found. For easy use selected Figures reproduced from the Technical Report are provided at the end of this document, followed by a basic 'Questions and Answers' Appendix.

1.1 The Need for New Controls

Technical Report 1.1, 1.2 and 1.3

Norovirus (NoV) is a relatively mild disease to most sufferers with complete recovery generally in a couple of days, although some vulnerable groups can be more severely affected. The overall cost of NoV to the economy is significant with a major impact in communal settings such as hospitals. NoV outbreaks are associated with colder temperatures giving rise to its common name – Winter Vomiting Bug.

Whilst most NoV is acquired directly from other people or via contamination from food handlers, a number of recent studies have shown that NoV can be commonly found in shellfish (**Technical Report 1.3.4**). Reported shellfish related illness outbreaks are relatively uncommon. However, when they do occur NoV is one of the most common types foodborne disease implicated (**Technical Report 1.2 and 1.3.3**). This has led to concerns about the potential route for environmental contamination through shellfish consumption and the need for more effective control measures (see Figure 1).

Current hygiene controls are based on bacterial test organisms which are generally good at indicating faecal contamination. Unfortunately, studies have shown that they do not provide complete control for infectious viruses such as NoV. Consumers can therefore still be made sick from eating legally 'safe' shellfish if contaminated by NoV. Whilst cooking can deactivate viruses, oysters are often eaten raw and therefore are considered to present an increased health risk relative to other shellfish. High profile outbreaks of NoV associated with oyster consumption have increased awareness of this problem and led to calls for improved controls and the setting of new standards.

Modern molecular biological techniques have been developed which can detect low levels of NoV contamination. These new methods are now considered appropriate for regulatory use (**Technical Report 1.3.5**). This allows authorities both within the UK and Europe to consider the use of NoV shellfish standards for 'harvest' (as fished) or 'End Product' (for consumer) shellfish (**Technical Report 7.1.1**). Alternative control measures are also under consideration and include the use of 'exclusion zones' or 'buffer' areas where shellfish harvesting could be prohibited in the vicinity of sewage discharges. This project has been commissioned by the UK Food Standards Agency (FSA) to assess the potential suitability of these alternative risk management options.

This Summary Report provides an overview of the issues reviewed and analysed in a more complex accompanying Technical Report

1.2 Project Scope

Technical Report 1.4

The Technical Report provides a comprehensive review and analysis of shellfish hygiene zoning related issues including:

Technical Report 2. ***Existing shellfish zoning*** controls (not based on NoV) included examples from Europe (see Section 2.1 or (**Technical Report 2.1**) and US/Canada (see Section 2.2 or **Technical Report 2.2 and 2.3**).

Technical Report 3. ***Evidence based zoning for NoV*** – This looks at a 'whole system' approach for all the stages between a wastewater treatment and harvesting of shellfish (see Figure 1). Stages in this environmental transmission route included: NoV loading in crude sewage (**Technical Report 3.1 and 3.2**), NoV reduction through wastewater treatment (**Technical Report 3.3**) dilution (**Technical Report 3.4**), environmental degradation (**Technical Report 3.5**) and bioaccumulation (**Technical Report 3.6**). Key points of interest are summarised within Section 3.

Technical Report 4. ***Case Studies*** are provided which show how zoning and other viral risk management tools are utilised in other countries. Examples have been drawn from US/Canada (**Technical Report 4.1**), Australia (**Technical Report 4.2**) and New Zealand

(**Technical Report 4.3**). In addition, a number of detailed studies looking at the relationship between NoV in shellfish and the distance from discharge points are also reviewed (**Technical Report 4.4**) Case study findings are summarised in context of UK application and management options (Sections 4 and 5) .

.

Technical Report 5. ***Computer modelling*** was a major topic of consideration with a review of existing relevant models and including some original work by Intertek (**Technical Report, Appendix B**) who recalibrated a couple of their existing models in shellfish water areas using NoV variables. This is summarised within Section 5.1.

Technical Report 6. The ***UK applicability*** of zoning needs to take into account the profile of the UK oyster industry and the corresponding exposure to various wastewater discharges (an oyster database was constructed to capture and link both datasets (**Technical Report, Appendix A**). Continuous Waste Water Treatment Plants (WWTPs) (**Technical Report 6.1**) and intermittent Combined Sewer Overflows (CSOs) (**Technical Report 6.2**) are the two main types of discharge handled by Water Utility companies. However, diffuse sources (**Technical Report 6.3**) of wastewater can also come from septic tank, vessels and potentially from biosolids (sewage sludge). Consideration of different zoning operations (**Technical Report 6.4**) and analysis of how these might be implemented was illustrated using a couple of catchment scenarios (**Technical Report 6.5 and 6.6**). UK applicability is summarised in this report (Section 4).

Technical Report 7. ***Management options*** included shellfish management (**Technical Report 7.1**) and Wastewater management (**Technical Report 7.2**) options. These have been reviewed and considered in a UK context. Consideration of how the various management tools might be incorporated to support possible zoning was explored through the development of generic risk scoring models (**Technical Report 7.3**). Computer modelling (Section 5.1) and Active management (Section 5.2) are summarised in this report.

Technical Report 7. ***Recommendations*** were provided for research needs to fill evidence gaps (**Technical Report 8.1**) as well as implementation needs (**Technical Report 8.2, 8.3 and 8.4**) such as an impact assessment. High level strategic issues were also considered (**Technical Report 8.5**).

2 EXISTING ZONING CONTROLS

No examples of NoV based exclusion zoning are currently used. However, exclusion zoning around wastewater discharges based on other criteria do exist. These are described in this section.

2.1 European Zone Based Controls

Proximity - zoning based on geographical proximity. Examples include Italy and Netherlands (**Technical Report 2.1**) where regional and national regulations have set zones ranging from 50m-1500m around wastewater discharges, marinas, ports and freshwater inputs. Iceland and Denmark also have some specific exclusion zones around marina and port settings. UK implications for this type of approach are considered in Section 4.2.

2.2 US Affiliated Shellfish Zone Based Controls

Dilution based zones. Examples include buffer zones for waters adjacent to marinas in US affiliated NSSP (National Shellfish Sanitation Program) countries such as US, Canada, Australia and New Zealand (**Technical Report 2.2**). These zones are designed to protect bacteriological water quality standards for shellfish. Regulations for marinas set out dilution calculation criteria to support modelling (from simple box models to computer models) to determine potential prohibition zone size.

Continuous WWTP discharges also have prescribed dilution prohibition zone criteria (**Technical Report 2.3.1, 4.1.3**) with 100,000:1 dilution required for a Prohibition : Approved boundary (see Figure 2, Scenario 1) and 1000:1 dilution required for a Prohibition : Conditional boundary (see Figure 2, Scenario 2). UK implications for this type of approach are considered in Section 4.2.

Dilution/Time – A time component is also required for NSSP Prohibited : Conditional zone boundaries (**Technical Report 2.3.1**). This is on the basis that in the event of a WWTP malfunction, or a spill, there is sufficient response time for reactive management. A number of prescribed system requirements with post-event monitoring and actions are also required. UK implications for this type of approach are considered in Section 5.2.

2.3 Existing Use of Viral Sampling to Support Shellfish Management

Although not used for the setting of zoning viral testing is used in some countries to support shellfish management. In the US (and within the NSSP Model Ordinance) there is now allowance for using Male Specific Coliphage (MSC) sampling to provide an early re-opening criteria following an 'event' (21 day closure unless <50 pfu/100ml detected (**Technical Report 2.3.2**). Similarly in France the 'Winter Norovirus Protocol' allows for early re-opening for 28 day closure where 'negative' NoV in shellfish samples are obtained (**Technical Report 7.1.5**). In New Zealand an outbreak closure requires a 'negative' all clear viral samples after a minimum 28 day closure period (**Technical Report 4.3.2**). US/Canada are currently in the process of undertaking a comprehensive risk assessment of NoV impact upon shellfish (**Technical Report 2.3.3**) (Figure 3). As part of this program the US FDA has been assessing NoV and bacteriophage shellfish quality in relation to wastewater discharge proximity in parallel with dilution dye studies (Section 4.2).

3 FACTORS INFLUENCING POTENTIAL NOV ZONING

3.1 Pathogen: Indicator Differences

Food and environmental regulatory microbiological monitoring is based upon the use of Faecal Indicator Organisms (FIOs) such as faecal coliforms or *E. coli* (**Technical Report 6.7.2**). NoV as a pathogen has very different features and risk factors to those of *E. coli* as a FIO. This has a major bearing on what requirements might be needed for zoning (e.g. what dilution level), and how we might use shellfish testing to help regulate zoning.

Shellfish NoV Testing (**Technical Report 7.1.1**).

There are two key testing issues:

- *How do results relate to human faecal contamination? E. coli* originates at fairly constant levels within the guts of warm blooded animals. NoV originates at highly rates within the guts of ill humans suffering from NoV. This means that testing of *E. coli* from samples of water, shellfish flesh or food products can provide a valuable indication of potential broad faecal contamination. However, the level of NoV in a wastewater or shellfish sample corresponds to the specific risk of NoV illness through the environmental transmission pathway.
- *How do results relate to risk of illness? E. coli* is measured using culture techniques and as such only living or viable bacteria are measured. NoV is analysed using a Real Time Polymerase Chain Reaction (RT-PCR) molecular technique which measures a small part (~1%) (see **Technical Report 3.3.3**) of the NoV genome (viral nucleic acid). This means NoV testing results may overestimate the risk of infection which requires the whole genome and the outer viral capsid to be intact. (**Technical Report 3.1.3**).

Whole System Considerations for Dilution Factors

EU Food Hygiene Regulations (which provides for official monitoring of *E. coli* in shellfish) and the Water Framework Directive are the two parallel regulatory processes protecting food and environmental quality (**Technical Report 6.7.2**). Under guidelines developed in England for the Shellfish Waters Directive a $5.25\log_{10}$ reduction in *E. coli* levels was required between crude sewage and the shellfish waters. This was achieved through a combination of wastewater treatment, dilution and environmental degradation – with the vast majority of reduction through wastewater treatment. A similar 'whole system' approach is not yet available for NoV (**Technical Report 3.7**). .

Considering a 'whole system' approach from wastewater treatment to shellfish flesh (Figures 1 and 4) allows a comparison between *E. coli* and NoV through the environmental transmission pathway:

- *Wastewater Loading ('Catchment Health').* (**Technical Report 3.1, 3.2**). *E. coli* concentration in crude sewage is relatively constant at ~10^7/100ml. In contrast, for NoV during the summer contamination levels may not be detectable, whilst in the winter levels may be >10^8/100ml (although more generally 10^4/100ml-10^6/100ml). This high level of variability makes assessment of reduction requirements through subsequent stages challenging.

- *Wastewater treatment.* (**Technical Report 3.3**). For *E. coli,* secondary treatment generally provides $2\text{-}3\log_{10}$ reductions with a further ~$2\text{-}3\log_{10}$ (**Technical Report Figure 3.5**) through UV disinfection. In contrast, for NoV, secondary treatment generally provides $1\text{-}2\log_{10}$ reductions. UV disinfection probably provides $2\log_{10}$ deactivation, although testing using the RT-PCR method (see above) cannot directly demonstrate this. In essence, this means the detectable NoV discharged from a UV WWTP may be assumed to be ~1% viable.

- *Environmental Degradation.* (**Technical Report 3.5**). Viral survival in the environment has been well documented. Decay rates are reported in terms of T_{90} (time for 90%, or $1\log_{10}$, to die, or degrade). T_{90} values for bacteria are short (~8hr) relative to viruses (~4-6 days). Decay behaviour is complex and influenced by dark and light reactions and exact knowledge for NoV is limited by the inability to test viability. However, this issue is potentially problematic as environmental survival of NoV may extend the range of plume impact and persistence. It also extends the potential sphere of influence from 'up river' of discharge points with a potential for adverse impact (see Figure 8).

- *Bioaccumulation*. (**Technical Report 3.6**). Viral studies have shown the potential for hyper-accumulation in the winter when Bioaccumulation Factors of ~100 have been obtained relative to *E. coli* rates of <10. Research has shown selective biochemical binding of NoV within oysters which highlights a different mechanism for behaviour for viruses within shellfish relative to that of *E. coli*. This process has also been implicated in the reduced NoV depuration rates relative to that of *E. coli* (**Technical Report 7.1.3**).

In summary, NoV is potentially more difficult to remove, or inactive, than *E. coli* at every stage of the transmission pathway.

3.2 Variables Influencing Evidence Based Zoning

Dilution Requirements and a Precautionary Approach

Considering all stages in the environmental transmission pathway (Section 3.1), NoV is less effectively removed from the 'whole system' than *E. coli* (Figure 4). From a zoning perspective this is likely to have a bearing on the level of dilution factor which might be required to attain any future NoV water quality standard (**Technical Report 3.4, 3.7**). .

As wastewater treatment performance is so effective for *E.coli* even minimal 10:1 Initial Dilution (for a UV WWTP) is sufficient to attain the required 100 counts/100ml water quality standard. For NoV even a 1000:1 dilution (see Section 2.2) may be insufficient if all worst case wastewater loading and bioaccumulation factors were applied for precautionary zoning. Using a holistic approach it may be possible to set meaningful guideline design standards (Figures 11 and 12). However, considerations for a potential NoV water quality standard would need to be based on a strong science evidence base. A number of related current evidence gaps are reflected in the research recommendations (Section 7).

Receiving Water Dilution and Environmental Degradation Characteristics

It is apparent from the reduced whole system removal of NoV relative to *E. coli* that a greater reliance is likely to be placed upon dilution and environmental degradation to achieve a potential water quality guideline design standard (**Technical Report 3.7**). These are therefore key variables in the setting of any future zoning requirement.

Field measurements of NoV in shellfish using molecular RT-PCR techniques indicate a high level of persistence within the environment leading to potential contamination at an extended distance from a wastewater discharge source (**Technical Report 4.4**). Unlike *E. coli* indicators there is evidence that NoV impact may extend for significant distances. NoV shellfish wastewater proximity studies undertaken to date indicate a wide range of concentration gradients in the vicinity of wastewater discharges.

- ~0.6 $\log_{10}$ in 10km from the UK South Coast study (**Technical Report 4.4.4**).
- ~1.25 $\log_{10}$ in 10km from the New Zealand Dunedin study (**Technical Report 4.3.3**).
- ~2.5 $\log_{10}$ in 5km from the US Mobile Bay study (**Technical Report 4.1.3**).

Although the marine settings for these three studies were each quite different, ranging from an enclosed estuary to an open coast environment, there is clearly a need for a much greater level of understanding of this wastewater discharge proximity relationship. In particular it is also important to measure the underlying variables which influence both NoV degradation and shellfish uptake (e.g. sunlight deactivation, type and level of suspended solids). This data could then be used to ground-truth computer modelling to refine future predictions.

4 UK APPLICABILITY (**Technical Report 6**).

When considering whether exclusion zoning will work in the UK it is important to review where the oyster production site are in relation to the wastewater discharges in these areas. Using the UK oyster/discharge database constructed in this study (**Technical Report, Appendix A**) risk profile maps have been provided for all UK oyster production areas. Figure 6 shows the magnitude of WWTP discharges, whilst Figure 7 shows the number of identified CSOs considered to potentially impact the oyster shellfish water. The regional contrast between Scotland and the other UK regions corresponds with the NoV data shown in Figure 5. The types of discharge, how they can impact shellfish waters and the applicability of zoning are considered below and summarised in Table 1.

4.1 NoV Wastewater Sources

There are many different types of wastewater discharge which can release NoV into the environment and contaminate shellfish (see summary in Table 1). Main types include:

- *Continuous discharges from WWTPs* (Waste Water Treatment Plants). (**Technical Report 6.1**). All major urbanised areas (and most smaller settlements) are served by secondary biological treatment processes. These will generally remove ~99% (~2$\log_{10}$ reductions) of NoV by Activated Sludge processes although there may be lower performance in older types of process. Some WWTP (particularly those which might have a major impact on shellfish waters) also provide tertiary treatment with UV disinfection (**Technical Report 7.2.1**). Current understanding (see Section 3.1) is that this may provide a further ~2$\log_{10}$ reductions of NoV in terms of viability (**Technical Report 3.3.3**). (see Application zoning Scenarios **Technical Report 6.5.2**).

- *Intermittent Discharges e.g. CSOs (Combined Sewer Overflows*). (**Technical Report 6.2**). Many of the older urban sewerage systems in the UK allow input of surface waters (e.g. from roads and roofs) which can overwhelm sewers, pumping stations or WWTP capacity following intense rainfall periods. This leads to a crude wastewater spill with potentially very high concentrations of NoV when 'catchment health' (**Technical Report 7.2.2**) is poor. There is considerable data to demonstrate that CSO spills can contribute more NoV to shellfish waters than adjacent WWTP discharges (**Technical Report 4.4.1 and 4.4.4**). The number of CSOs in coastal and catchment areas which may contribute NoV load to a shellfish water can be very large (see Figures 7, 8 and 10 and application zoning Scenarios **Technical Report 6.5.3**) and may have a sphere of influence beyond that previously determined for shellfish waters.

- *Septic Tanks and other catchment sources.* (**Technical Report 6.3.1**). Many small rural settlements or individual houses are not connected via sewerage systems to a public utility WWTP. Some will be served by small private WWTPs, whilst many will have their own septic tank which may discharge to a soakaway. NoV removal from these types of systems is highly variable and difficult to regulate and control. There have been many examples where septic tanks have impacted upon oyster NoV outbreaks even though they are small in volume (**Technical Report 4.2.3 and 4.4.2**). (see Application zoning Scenarios **Technical Report 6.5.4**).

- *Vessel Discharges*. (**Technical Report 6.3.2**). As highlighted in Section 3.1 a small quantity of NoV contaminated wastewater can impact shellfish over a large area. Previous studies have demonstrated vessel impact on water and shellfish quality and been implicated in NoV outbreaks (**Technical Report 6.3.2**). Utilisation of pump ashore wastewater facilities is also limited leading to concerns about pleasure craft impact in coastal areas with high vessel use. (see Application zoning Scenarios **Technical Report 6.5.5**).

It should be noted that scenario application examples have indicated CSOs, septic tanks and vessels all have potential to contribute loads comparable (or greater) to those of the treated WWTPs (**Technical Report 6.5**). This means that for some complex catchments with multiple wastewater sources the potential for successful zoning around individual discharge may be limited (see Figure 10).

4.2 Zoning Options (Technical Report 6.4).

Proximity - zoning based on geographical proximity. Section 2.1 considers examples of European proximity zoning. This type of zoning has been favoured as the easiest to adopt (**Technical Report 2.1**). However, from a NoV perspective the sizing of a zone might be somewhat arbitrary with limited grounding upon scientific evidence (**Technical Report 6.4**). This means if zones are sized on a precautionary basis the exclusion area could be very large – far beyond the level of actual risk (Section 3.2). This could lead to a legal challenge by shellfishermen who might be negatively impacted through loss of their production areas.

Dilution based zones. Section 2.3 considers examples of NSSP dilution zoning. From a NoV perspective dilution zoning would require a target water quality standard which is problematic. At present there is no consensus on an appropriate shellfish flesh NoV standard and limited bioaccumulation data to relate this to a corresponding water quality (Section 3.1).

Dilution/Time – Section 2.2 considers examples of NSSP dilution/time zoning. From a UK perspective this time reactive element to zoning would face implementation problems as all of the potential tools and data to deliver this approach are owned by the Water Utilities and are not readily available. Preliminary CSO Event Duration Monitoring (EDM) text alert trials have recently been conducted in two Water Utility regions (**Technical Report 7.2.2**). Although technically possible the number of potentially contributing assets which might require inclusion would be prohibitive if conducted for all areas (**Technical Report 6.5.3**).

Viral Shellfish Sampling – (**Technical Report 7.1.1**). No examples can be found of countries which base wastewater zoning criteria purely on viral sampling and testing, although Section 2.2 considers overseas examples where viral testing of shellfish are used within regulatory measures.

From a UK perspective, since the RT-PCR method for detection of NoV in shellfish is considered by EFSA to be appropriate for use in a legislative context, it could be used to provide an indirect indication of risk. However, the viability issue (see Section 3.1) has, at present, undermined the degree to which its use can be directly linked to consumer illness. Furthermore, there is also a wider issue as to the relative significance of shellfish contamination (at the levels under discussion) to foodborne infection and ultimately to general population health (**Technical Report 3.1.2**). .

It is suggested that the US FDA style dilution studies with corresponding viral bio-sentinel monitoring are a good way to link environmental processes with NoV impact (**Technical Report 4.1.3**). The current Cefas work will certainly further inform this understanding and provide guidance on dilution zone requirements. However, wider use of NoV shellfish monitoring as an indication of point source discharge impact should be approached with caution. For complex estuarine settings where multiple NoV sources may contribute to load (Figure 10) there is no guarantee that the resultant NoV quality can be matched to a specific outfall. Higher resolution sampling (temporal and spatial) may give a 'sense check' to data (e.g. bio-sentinel monitoring adjacent to CSOs) but will not help avoid this issue. In consequence, zone considerations around the obvious wastewater sources based purely on NoV shellfish data may not necessarily deliver improved shellfish NoV quality.

5 MANAGEMENT TOOLS

Technical Report, Section 7 considers a range of alternative shellfish and wastewater management tools which could help reduce NoV contamination impact upon shellfish quality. In many cases these management tools may be complimentary to exclusion zoning. The risk exposure (Figure 5) and options for both shellfish and water industry management vary on a regional basis (**Technical Report, 6.7.1**) and could include computer modelling and/or Active Management.

5.1 Computer Modelling (Technical Report 5).

The marine environment is complex with multiple variables which can influence NoV concentration and viability. Computer modelling has the capacity to readily alter a number of environmental parameters enabling NoV water quality or dilution predictions for a range of wastewater discharge conditions. In consequence, modelling has the potential to provide a valuable risk assessment tool (**Technical Report 5.3.3**) (Figure 11).

The ability to superimpose the impact of various contributory sources could be very powerful in the prioritisation of any future wastewater zoning or management measures. Models can theoretically differentiate between a UV treated discharge (with high levels of non-viable NoV) from a smaller volume CSO spill (with high viability). Model output could be a useful tool in guiding judgement calls when high shellfish RT-PCR results are produced with no means to assess potential viability risk.

It is concluded that this sort of computer model output could provide valuable tools to both regulators and shellfish operators when evaluating risk (**Technical Report 7.2.4**). Future optimisation of the spill 'tool' user interface (e.g. the EXCEL variable input fields) might need to be adjusted to the target audience. For example a less interactive 'traffic light' type of risk management tool might be suitable for a shellfish operator, whereas a regulator user may prefer access to a wider range of inputs and more complex output.

5.2 Early Warning Systems and Active Management (**Technical Report 7.1.4**)

With an increased understanding of site specific risk factors there may then be scope for a dynamic risk assessment approach. Active management enabled by monitoring a range of wastewater and environmental variables to provide early warning systems could allow responsive actions to be taken. Potential risk assessment parameters could include wastewater load (health of catchment), CSO and emergency spill status, rain gauging and in some cases *in situ* water quality surrogates (e.g. sea temperature and salinity) (Figure 12).

CSO monitoring is a key potential contaminant source and a priority for future Active Management would be to capture CSO EDM output (**Technical Report 7.2.2**).

5.3 Risk Scoring Schemes and Enhanced Management Zones (**Technical Report 7.3**)

Two risk scoring schemes have been considered:

- *E. coli NoV Proxy risk scoring* – (**Technical Report 7.3.2**) This is based on work done by Cefas on behalf of the FSA using the oyster NoV baseline survey. This study encapsulated both temperature based seasonal component with a wastewater proximity component using *E. coli* as a proxy for NoV. The suitability of this scheme will be somewhat determined by the degree to which the non-human *E. coli* can be discounted to improve the relationship between these two parameters. Another limitation to the scheme is its inability to provide a responsive score to 'events'. The advantage of this approach is that it can be applied relatively quickly, easily and cost effectively. This makes it suitable as a tool within the impact assessment process (**Technical Report 8.4**) (see Section 7).

- *'Whole System' risk scoring approach* – (**Technical Report 7.3.1**) Using an evidence based HACCP style applied to the environmental transmission pathway provides a direct gauge of NoV risk. The transmission pathway from wastewater to shellfish flesh includes: crude wastewater NoV load (catchment health), wastewater treatment level, dilution, environmental degradation and bioaccumulation (see Figures 1 and 13). A risk scoring scheme has been scaled, at various risk levels, for each stage with the relative magnitude factored to the significance of each stage. The key disadvantage of the scheme is that the scoring cannot easily be linked to existing criteria and therefore must be developed from new. Where data is not available this could be challenging. Trial survey data and further research may also be needed to 'calibrate' the scoring scheme (**Technical Report 8.1, 8.2, 8.3**). The advantage of the scheme is that it can be responsive to 'events' (e.g. CSO spills) and improved as the science database is developed. There should also be scope to build in a NoV outbreak influence to risk scoring. This could give rise to a potential closure regime similar to the French Winter NoV Protocol. The 'whole system' scheme is currently under consideration by a UK Industry working group. A whole system perspective on NoV risk is also apparent from the current US/Canadian risk assessment group (see Figure 3).

- *'Enhanced management'* approach (**Technical Report 7.3.3**) would allow zoning to be adjusted according to risk levels (i.e. whole system risk score) and draws on experience from the US. The NSSP system (see Section 2.2), although based on bacterial water quality standards, has scope for 'Conditional' areas which can be subject to periodic, but predictable, drop in quality following an 'event' such as a storm. This rationale allows a change in management practice (e.g. harvest closure) under certain pre-determined criteria such as rainfall intensity, which are known to compromise quality in the specific production area. An example of how this might work in a 'Conditional restricted' type of area is illustrated in Figure 15.

Figure 9 and Figure 10 are drawn from two catchment Scenarios developed from real UK shellfish waters using actual wastewater discharge positional and load (for WWTP) data (**Technical Report 6.5**). In Scenario 1 default proximity zoning is applied for summer and winter conditions around the few small WWTPs. A further layer of responsive 'Conditional' style of zone is applied around affected CSOs following a spill event. From experience in this catchment CSO spill impact is limited to only a couple of sites (with only small volumes discharged). In consequence, this type of 'enhanced management' can probably be accommodated by industry. For Scenario 2 the same type of approach is used but the number and magnitude of discharges are much greater. In consequence, a storm event may impact multiple discharges and could have a significant adverse impact to industry.

This raises the question as to whether this approach would be the most appropriate for this type of catchment.

It is apparent that the type of zoning and management measures adopted will need to vary according to risk profile and that a combination of approaches may be needed.

6 RECOMMENDATIONS

A number of science evidence gaps require additional research if an evidence based approach is to be adopted to support exclusion zoning (**Technical Report 8.1**). Key study areas include:

- *Viability.* (**Technical Report 3.1.3**) Although there is no current definitive test for NoV viability a number of supporting test methods are available. These in combination can give an indication of capsid integrity (potential for viral to 'infect' a host cell) and genomic RNA integrity (potential for replication inside a host cell). These approaches should be considered to ascertain UV efficacy and environmental degradation to inform meaningful risk assessments.

- *Bioaccumulation.* (**Technical Report 3.6**) There is very limited data regarding the relationship between NoV in water and resultant levels in shellfish flesh at environmentally relevant concentrations and conditions. It is known that shellfish uptake behaviour (and likely retention within flesh) is influenced by the type of particles filtered from water. Feeding behaviour and NoV association with suspended solids is complex and likely to vary on a seasonal basis. Until we have a better understanding of these underlying processes which determine bioaccumulation factor we cannot derive a NoV water quality standard. (N.B This assumes acceptance of a target shellfish flesh NoV quality standard.). A NoV water quality standard is vital to provide a meaningful target for dilution zones (e.g. 1000:1 dilution). Once a NoV water quality standard exists it may be then possible to consider appropriate levels of wastewater treatment to attain this quality.

- *NoV Loading ('Catchment Health').* (**Technical Report 3.1**) Existing datasets have yielded wastewater NoV concentrations which have been orders of magnitude different. It is hard to know to what degree this has been as a result of real differences in crude NoV loading and what has been methodology (as there is no standard method). It is important to understand this more fully as a risk factor within a 'whole system' approach. Otherwise any requirements for a dilution factor to attain a target water quality standard could be un-attainable.

Generic models (Section 6.3) of risk scoring schemes require further work to make them fit for purpose:

- Whole System approach requires application to a series of real world trial (**Technical Report 8.2**) shellfisheries to calibrate scoring regime (addressing science based evidence gaps).

- *E. coli* NoV Proxy risk scoring needs to be adjusted to try and overcome mismatches between *E. coli* and NoV. Use of an improved scoring scheme within a UK impact assessment (**Technical Report 8.4**) could allow consideration of the shellfisheries to which this scheme could be applied.

Management tools (**Technical Report 8.2**) are likely to be required in combination with zoning:

- *Computer modelling* (Section 6.1) could be applied and verified in a couple of trial catchments where harmonised sampling of background water quality and shellfish NoV can be conducted. There is scope to model both continuous and CSO discharges (depending on particular area and model availability). Future development of the CSO spill impact tool (**Technical Report 5.3.3**) would need to shape the interface appropriately for regulatory and/or industry use.

- *Active Management* (Section 6.2) utilising a range of input monitoring tools (e.g. rainfall, EDM CSO spill data, sea temperature, salinity) could be assessed against NoV shellfish flesh quality. This would help develop variable 'enhanced management' zoning where scaling is reactive to 'events.'

A potential route-map for implementation is illustrated in Figure 16. Implementation of potential zoning (**Technical Report 8.4**) would require a phased approach:

- *Stage 1 - Microbial Contamination Inventory* - Working with environmental agencies compile a catchment specific database of loading sources with a more quantitative NoV perspective than current Sanitary Surveys.

- *Stage 2 - Impact Assessment* – use Cefas *E. coli* NoV proxy risk scoring scheme applied to historical classification and temperature data to score all oyster areas. A proximity assessment to the contamination inventory can then help provide a 'sense check' to *E. coli*: NoV relationship for each catchment. GIS work to link wastewater and oyster data.

- *Stage 3 - Review and Consultation of Default Zoning* - Scaling a default proximity zone relative to the Cefas risk score will require an iterative consultative process.
- *Stage 4 – Develop Option for Evidence Based Zoning* - Consideration of whether 'enhanced management' approach is a possibility for a better targeted zoning approach.

There are high level strategic issues relating to policy and cross-sector integration which need resolution (**Technical Report 8.5**). Only then can appropriate regulations and drivers be developed to deliver required quality objectives. The interplay between the need for cross-section guidelines is illustrated in Figure 14.

7 SUMMARY

There are no easy options for establishing future evidence based exclusion zones to manage NoV risk. Experience from around the world shows that there are a range of zone types, currently based on other criteria, each with different strengths and weaknesses. Possible options for exclusion zones could include:

- *Geographical proximity* – easy to apply but poorly targeted,
- *Dilution* – stronger science rationale but more difficult/expensive to apply
- *Time* (with dilution) – scope for 'event' based criteria but difficult/expensive to apply
- *NoV in shellfish* – potentially a good risk factor link but there are technical concerns (viability) and variable degradation and uptake influences.

The UK is subject to wastewater inputs from a range of sources each with different characteristics and regional risk profiles:

- *Continuous WWTP* treated wastewater for larger population settlements. Generally good quality effluent which is often disinfected for shellfish waters. Fixed zoning (perhaps on a seasonal basis) could be applied.
- *Intermittent CSOs* crude wastewater is likely to generate significant storm 'event' contamination to many oyster areas adjacent to urban settlements. Variable responsive zoning could be applied using modelled or Active management tools.
- *Septic tanks* and small WWTP have reduced treatment levels with potentially significant NoV loads for some catchments. Very hard to effectively remove contaminant risks and precautionary zoning is likely to have an adverse impact.
- *Vessel* discharges crude wastewater with a theoretical potential to impact shellfish waters on a site specific basis. However, discharge potential is largely seasonal and therefore reduces winter risk. Zoning of marinas possible, otherwise difficult.

Generic risk scoring could help scale both fixed and variable zone approaches. A science evidence based approach would ideally use 'enhanced management' where actions are dynamically adjusted to a changing NoV risk profile. An impact assessment is needed to consider zoning implications. Preliminary risk profile in this study shows that oyster areas in Scotland have a markedly lower risk exposure to both continuous WWTPs and CSOs than the rest of the UK – also indicated by baseline NoV in shellfish data.

Recommendations for future research, trials and implementation have been provided (Section 6 and **Technical Report 8.**).

Table 1: Summary of Wastewater discharge types, NoV impacts and zoning issues

(see **Technical Report 6.**).

Type of Wastewater discharge	**Potential NoV Impact**	**Zoning Issues**
Continuous WWTPs *(see* **Technical Report 6.1 and 6.5.2**). -Secondary (~$2\log_{10}$ removal of NoV) -UV tertiary (probable further ~$2\log_{10}$ deactivation) -Serve major and minor population settlements -NoV loading seasonal (catchment health)	Possible but generally controlled. -Long sea outfall studies have shown extensive plume impact with shellfish uptake of NoV over large distance. -Theoretical viable load may be lower than other contributing sources -'Malfunction' conditions have been associated with reported NoV outbreaks. -Most UK oyster areas, although much fewer and smaller in Scotland	Good potential for zoning. -Discharges often via sea outfall with modelled dilution and known plume behaviour. -Magnitude of NoV loading varies seasonally so zone scaling might need to be variable -UV discharges will make shellfish NoV testing risk verification difficult (viability)
Intermittent CSOs *(see* **Technical Report 6.2 and 6.5.3**). -Crude sewage with potentially high NoV levels (in the winter) -Serve primarily urban areas with sewerage networks -NoV loading seasonal (catchment health) -NoV loading 'event' related (storms)	High probability for periodic contamination with high viability NoV -Studies have shown significant NoV loading and impact following storm spills -Most UK oyster areas although fewer and smaller in Scotland. Number of potential CSOs from wider catchment can be large	Some potential for reactive zoning in some areas. -EDM trials have shown that responsive alerts can be generated following spills -Spill significance has not been determined -Number of discharges to have zoning could be problematic in larger complex catchments and urbanised areas by shellfishwaters.

Septic tank and small private WWTPs *(see* **Technical Report 6.3.1 and 6.5.4**). -Variable treatment levels which are hard to regulate, control and improve -Serve generally rural populations with small settlements or houses -NoV loading seasonal (catchment health) -Some storm impact possible	High potential for diffuse contamination with high viability NoV -NoV outbreaks and studies have demonstrated significant impact. -Many UK oyster areas although fewer and smaller in Scotland. Rural catchments can have many small widespread sources.	Difficult in coastal areas. Possible for catchment sources but only if whole river zoned as a 'discharge'. River zoning may be hard to have solid science evidence base and scale. Precautionary zoning has high potential for adverse commercial impact in estuarine oyster production areas
Vessel discharges *(see* **Technical Report 6.3.2 and 6.5.5**). (harvest boats, pleasure craft, larger vessels) -Crude sewage for small vessels -Larger vessels may have holding tanks (or advanced WWTPs in the case of cruise ships) -NoV loading seasonal (catchment health)	Possible although limited seasonal risk Outbreaks associated with harvest boats recorded. Harvest vessel impact mainly relevant to native oyster areas. Reduced pleasure craft impact risk over winter. Pleasure craft intensity generally lower in Scottish areas and risk site specific (access to shore-side facilities, pump ashore utilisation, level of live-aboard users etc.)	Possible for marinas. Difficult in open waters unless whole area may be excluded. Precautionary zoning has high potential for adverse commercial impact in estuarine oyster production areas.

Figure 1: NoV Environmental Transmission Pathway

(Source: Technical Report Section 3, Figure 3.1)

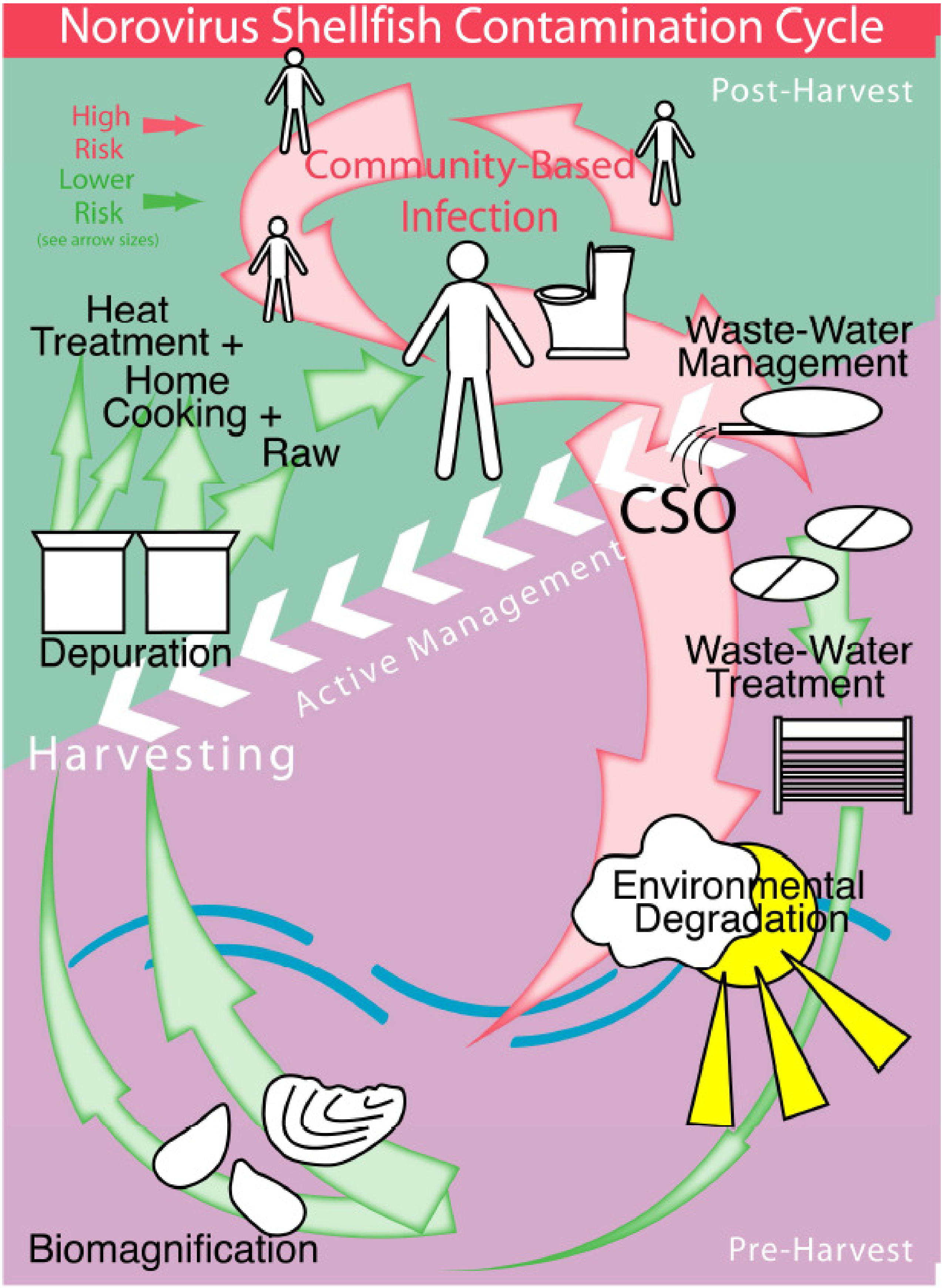
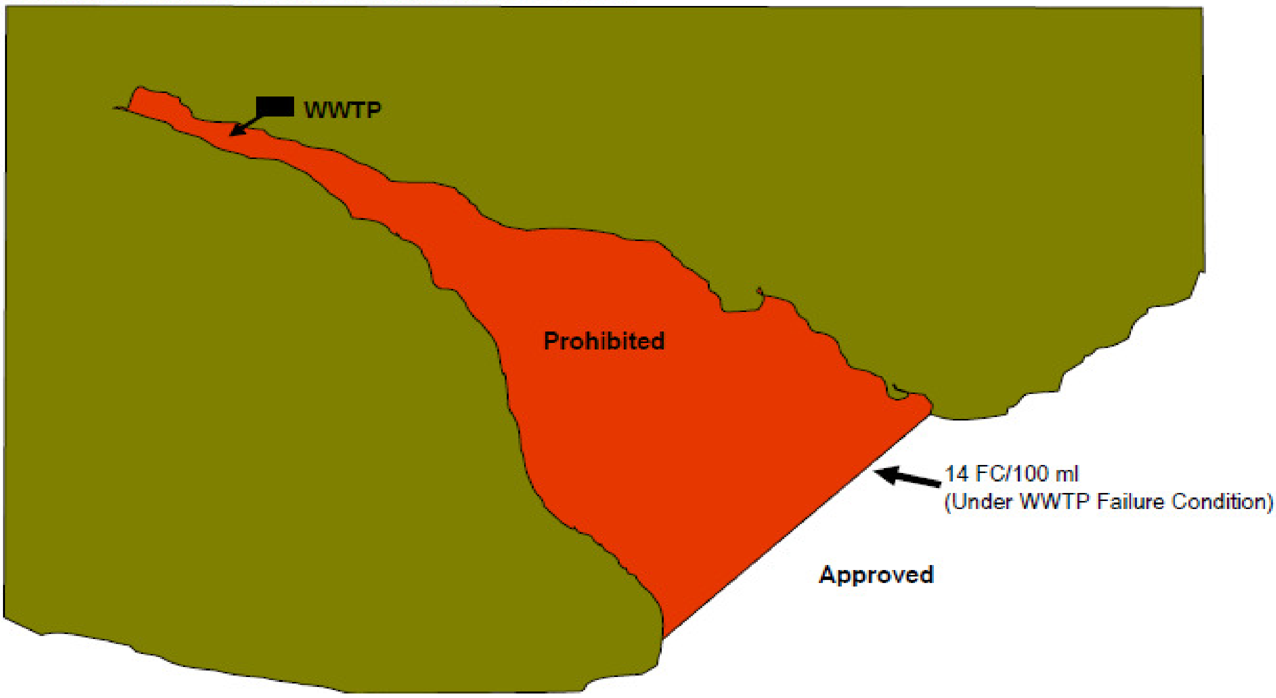


Figure 2: Scenarios for sizing prohibition buffer zones

(Source: Technical Report Section 2.1, Figure 2.1

Scenario 1: Prohibited / Approved Area Classification



Scenario 2: Prohibited / Conditionally Approved / Approved Area Classification

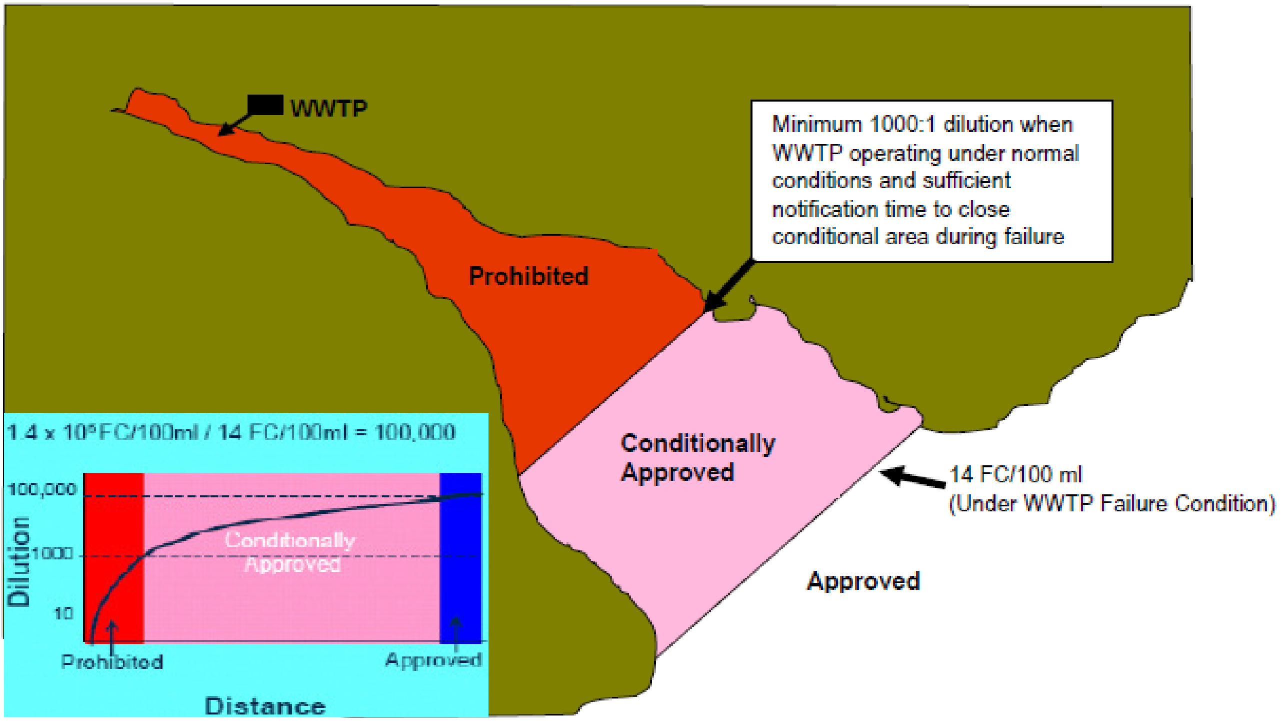
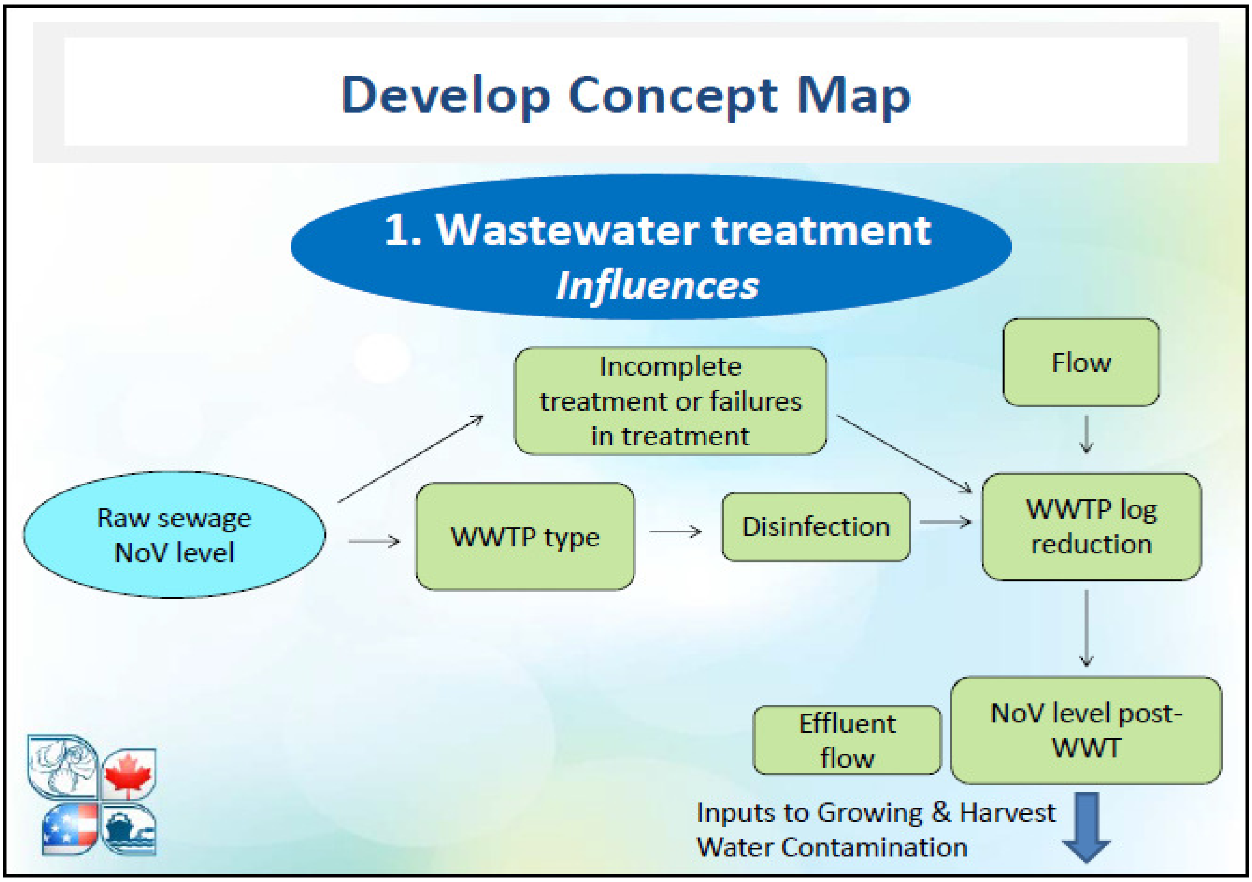
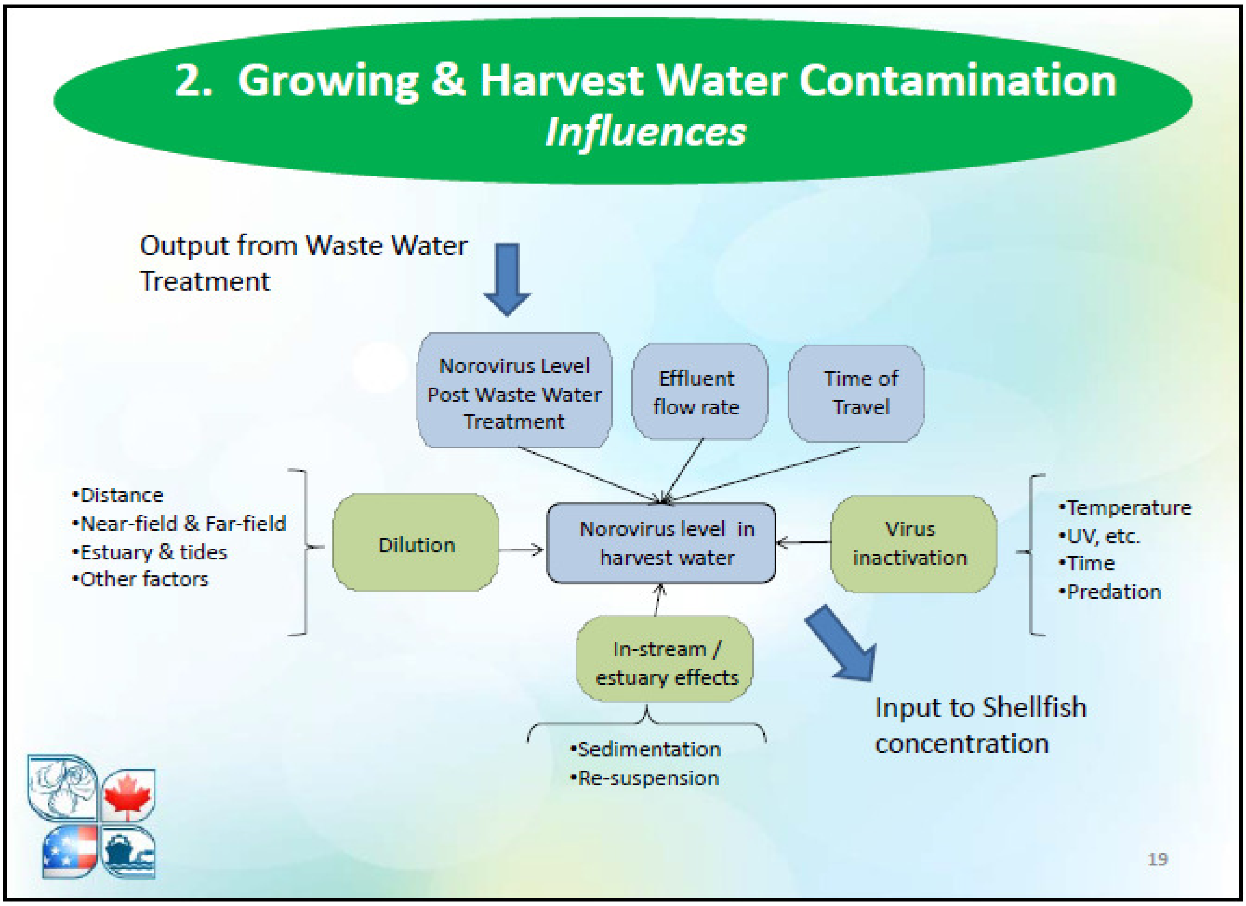


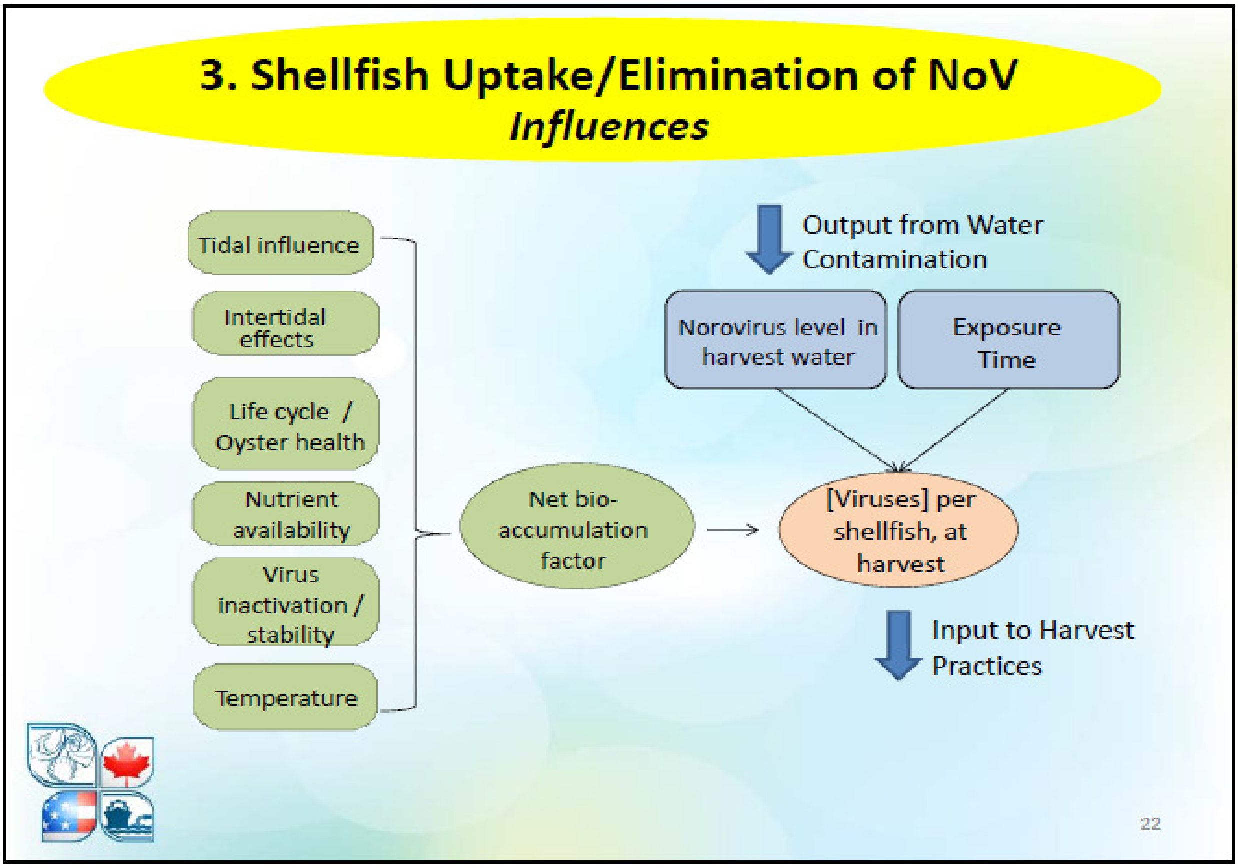
Figure 3: US/Canadian Risk Assessment - NoV Influence Mapping

(Source: Technical Report Section 2.3, Figure 2.2)

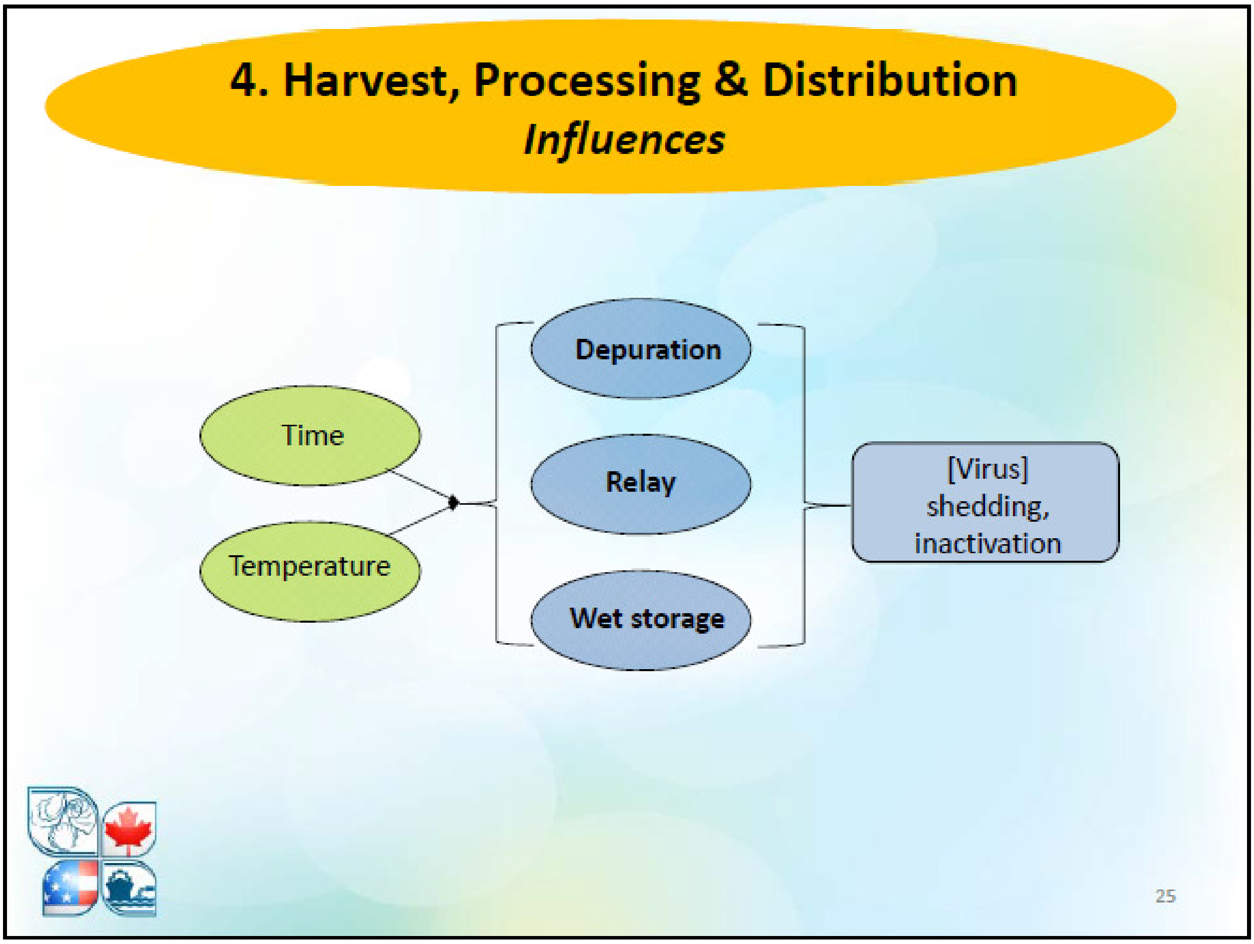




(continued)



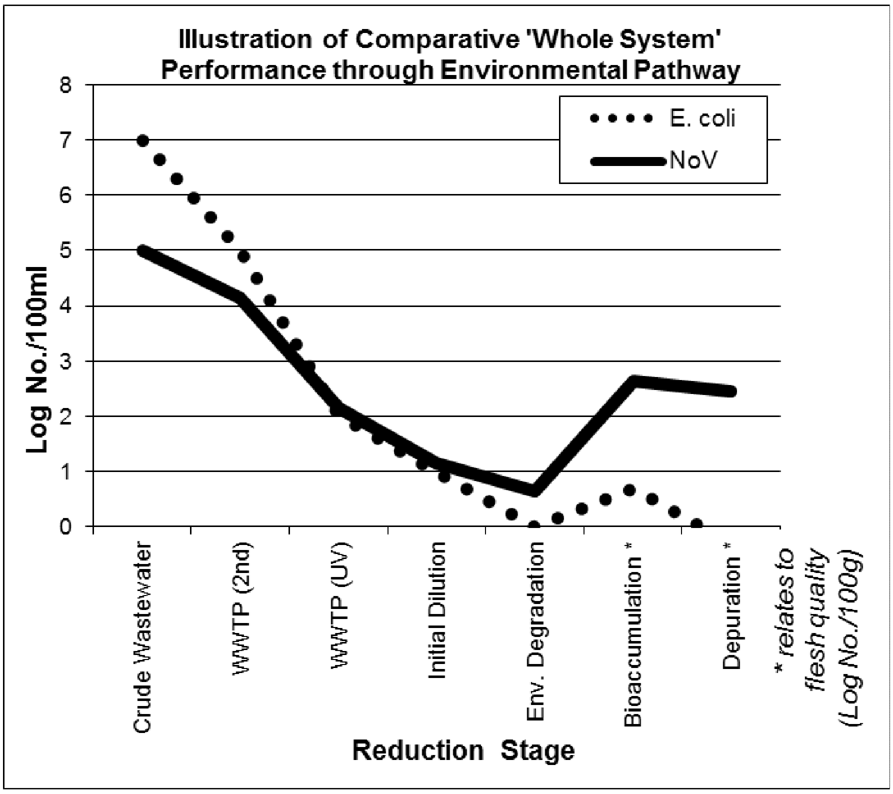
3. Shellfish Uptake/Elimination of NoV
Influences
Tidal influence
Intertidal effects
Life cycle / Oyster health
Nutrient availability
Virus inactivation / stability
Temperature
Output from Water Contamination
Norovirus level in harvest water
Exposure Time
Net bio-accumulation factor
[Viruses] per shellfish, at harvest
Input to Harvest Practices
22



4. Harvest, Processing & Distribution
Influences
Time
Temperature
Depuration
Relay
Wet storage
[Virus] shedding, inactivation
25

Figure 4: Illustration of *E. coli* and NoV 'Whole System' performance

(Source: Technical Report Section 3.7, Figure 3.11)



Note: Reductions using 'mean' values (see text)

Figure 5: Monthly Geometric Mean NoV Levels in Shellfish for Different UK Regions

(Source: Technical Report Section 1.5, Figure 1.4)

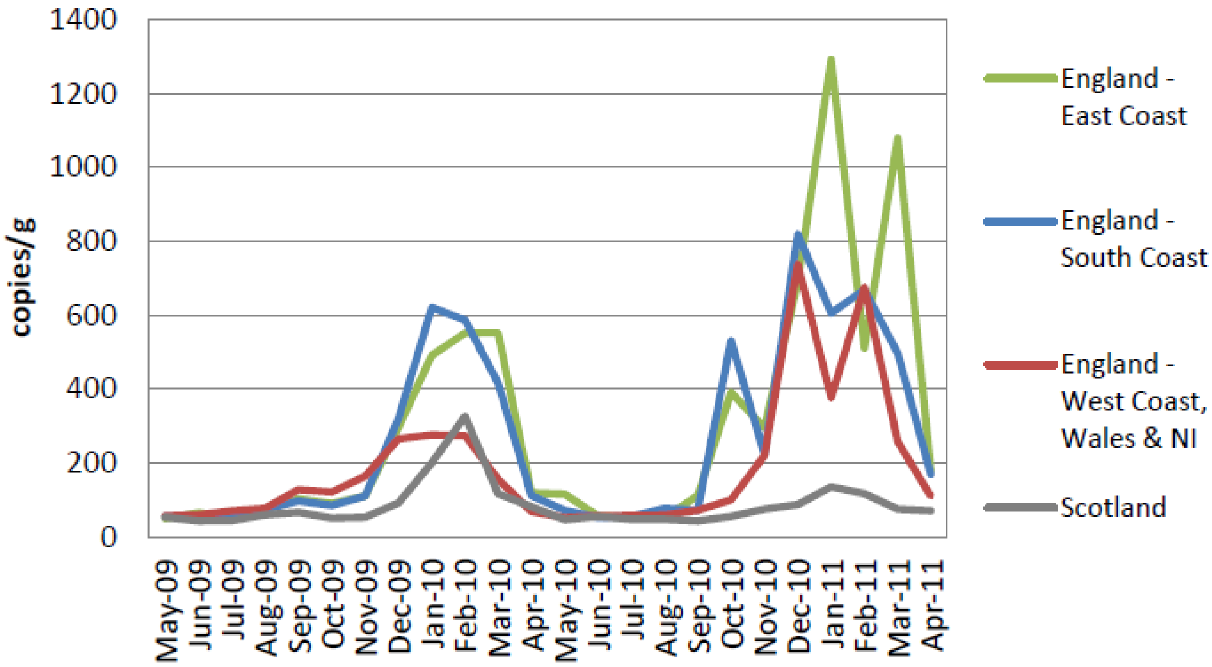


Figure 6: UK Oyster Production Areas – Population Wastewater Loading

(Source: Technical Report Section 6.1, Figure 6.1)

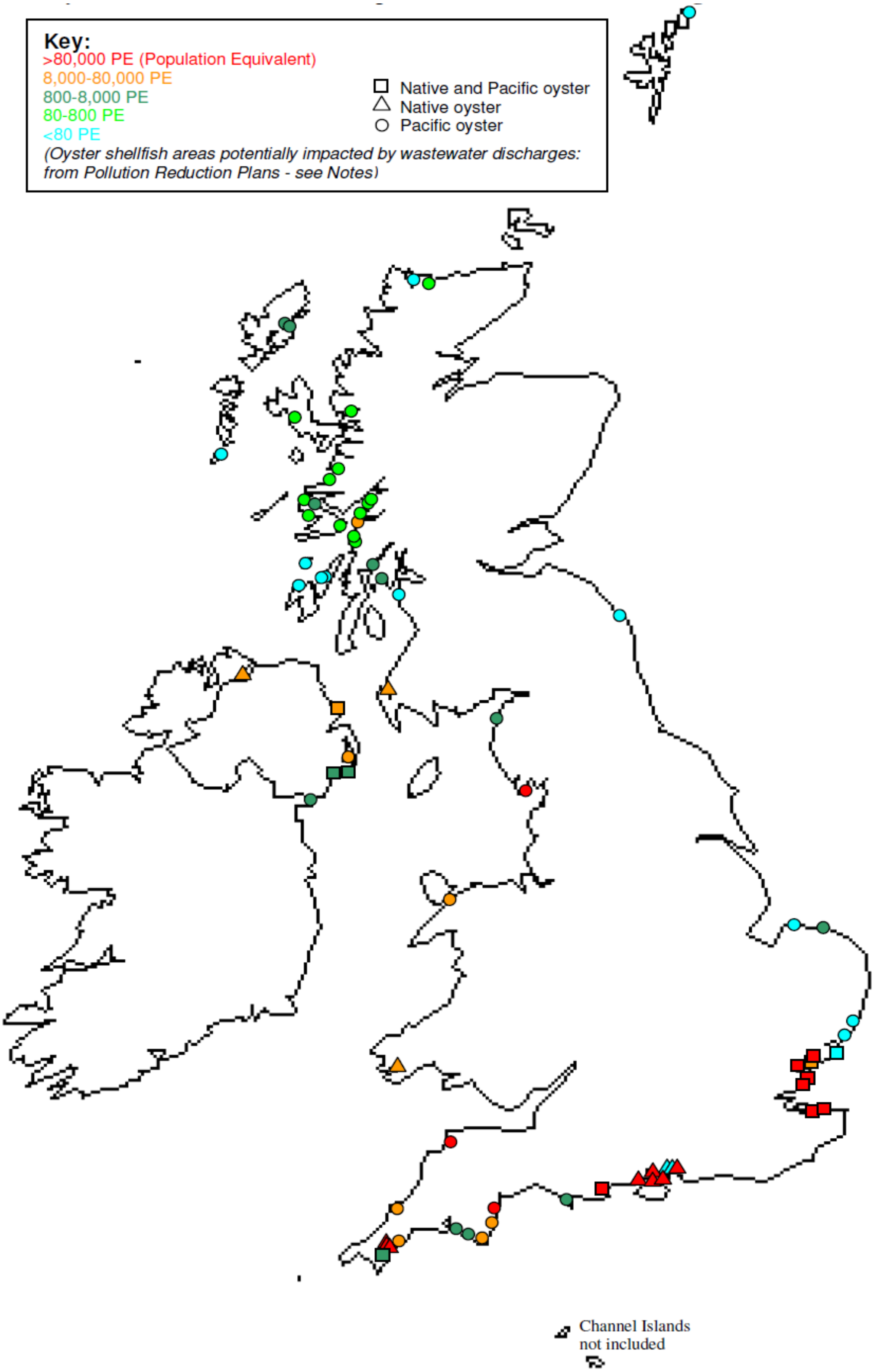


Figure 7: UK Oyster Production Areas – Number of CSO Intermittent Discharges to Shellfish Area *(Source: Technical Report Section 6.2, Figure 6.2)*

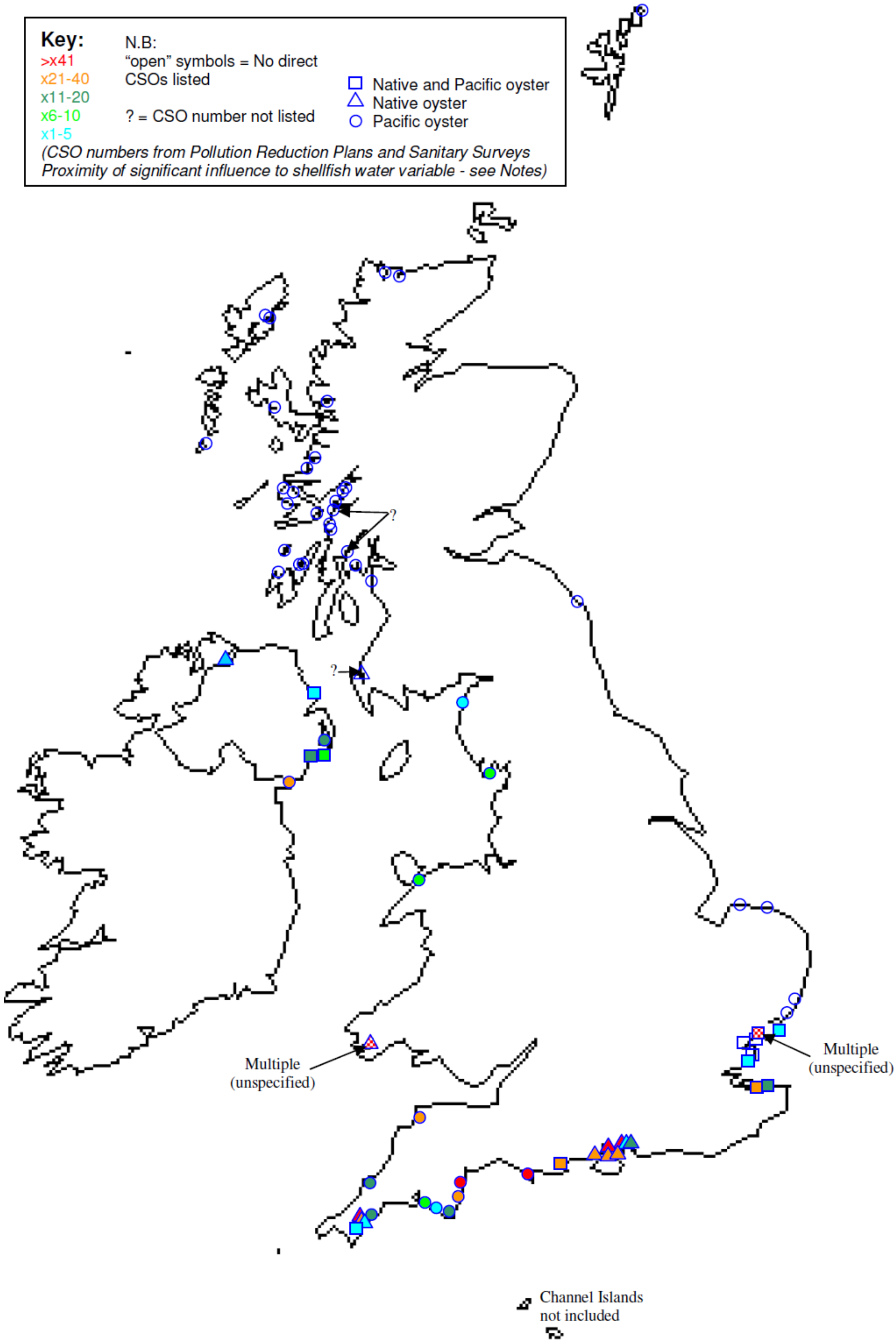
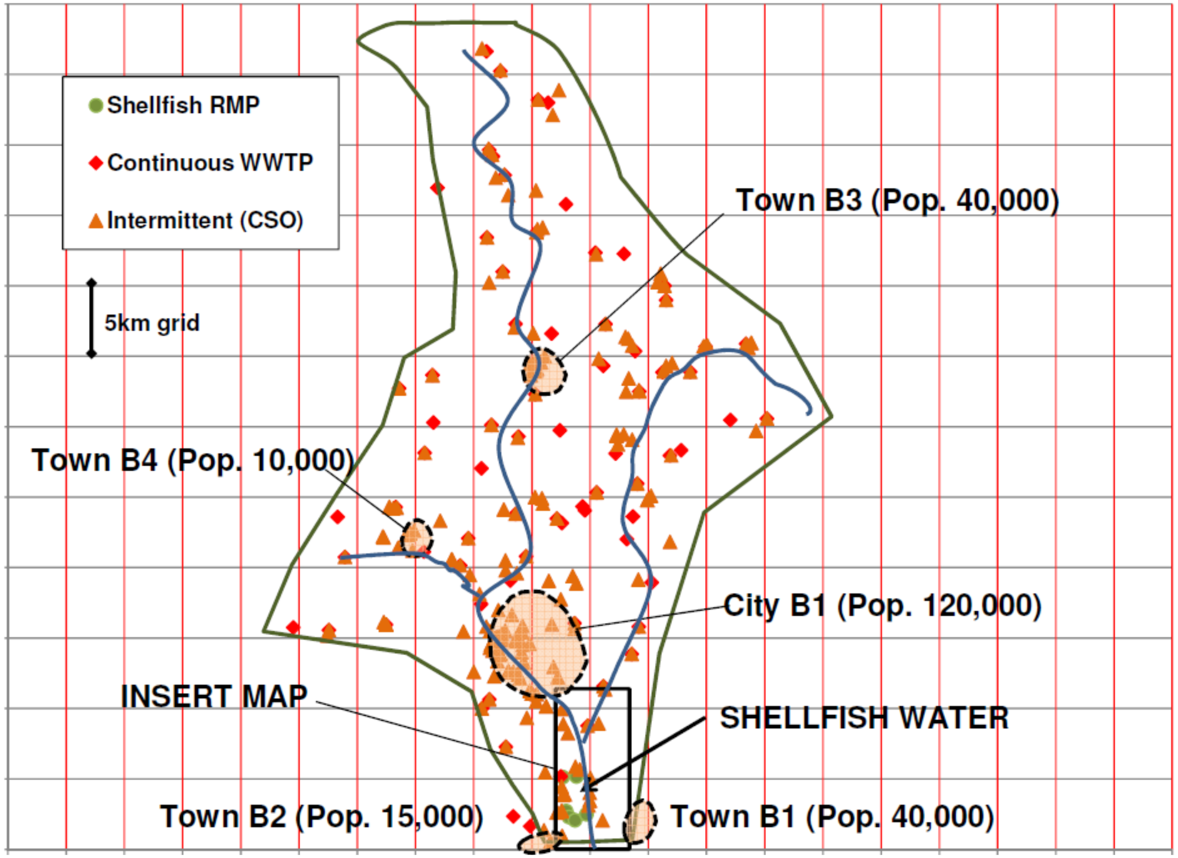


Figure 8: Proximity Relationship between Discharges and RMP Positions in Catchment Scenario B

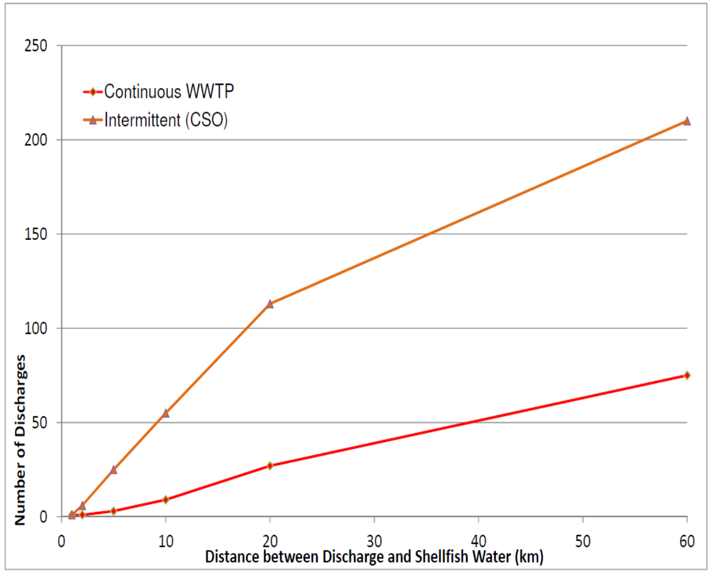
(Source: Technical Report Section 6.5, Figure 6.4)

Catchment B – Scatterplot of Discharge and Shellfish RMP Locations *(Note 1)*



(Note 1: Town, river positions and catchment boundary illustrative)

Catchment B – Discharge Proximity *(Note 2)*

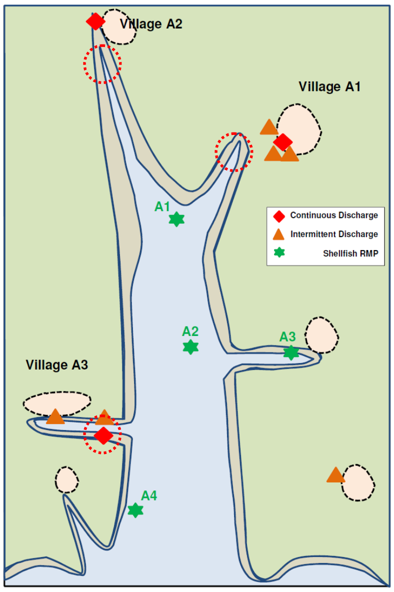
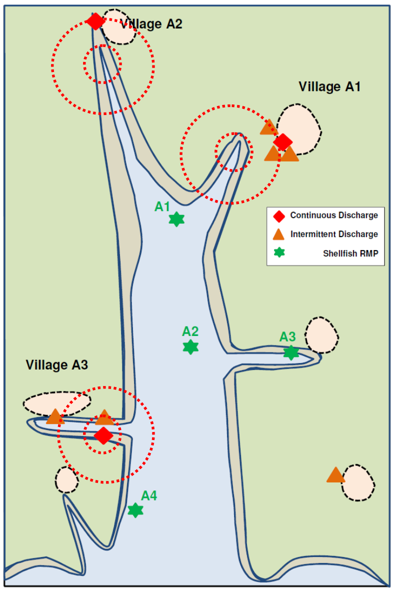
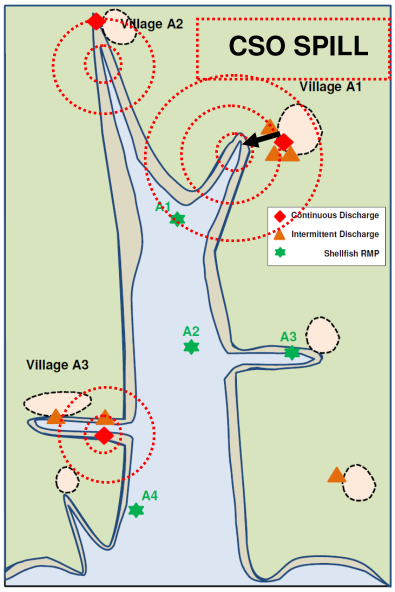


Distance (km) Discharge to SW	Continuous Discharges	Intermittent Discharges
<1	0	1
<2	1	6
<5	3	25
<10	9	55
<20	27	113
<60	75	210

(Note 2: Distances relative to most inland Representative Monitoring Point (=RMP))

Figure 9: Scenario A - Illustration of Potential Composite Zoning

(Source: Technical Report Section 6.6, Figure 6.6)

a) Default zoning (based on low risk WWTP summer load)	b) Seasonal zoning (based on higher risk WWTP winter load)	a) Spill zoning (based on EDM data e.g. from Village A1)
		

Could this approach work here?

Possible Issues:

a) Zone range shown is diagrammatic and would need to be scaled on evidence base. (i.e. Unknown: dilution effects, environmental removal and degradation, uptake rates. Possible to proceed using NoV flesh testing and surrogate measurements) ,

b) Diffuse NoV load from catchment or vessels could undermine zoning

(background NoV shellfish flesh biosentinal monitoring?)

Possible other management components:

a) NoV shellfish flesh testing

b) EDM monitoring of CSO performance

c) Receiving water monitoring of in-situ temperature and salinity

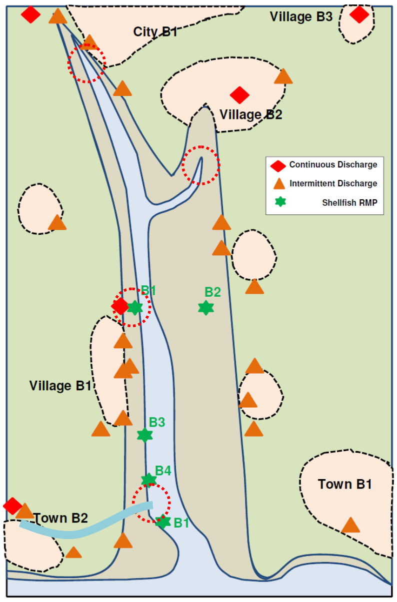
Composite zoning with Active Management (Enhanced Management) – Could work

Figure 10: Scenario B - Illustration of Potential Composite Zoning

(Source: Technical Report Section 6.6, Figure 6.7)

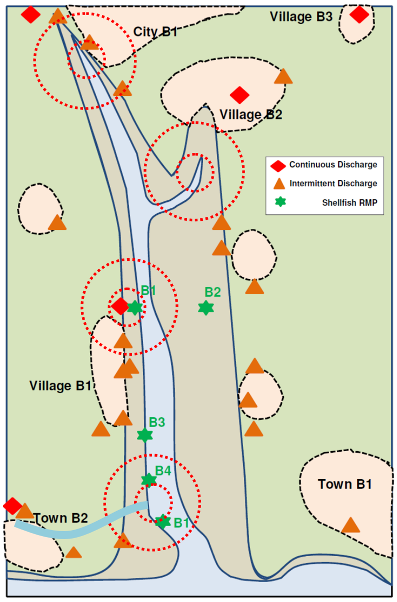
a) Default zoning

(based on low risk WWTP summer load)



b) Seasonal zoning

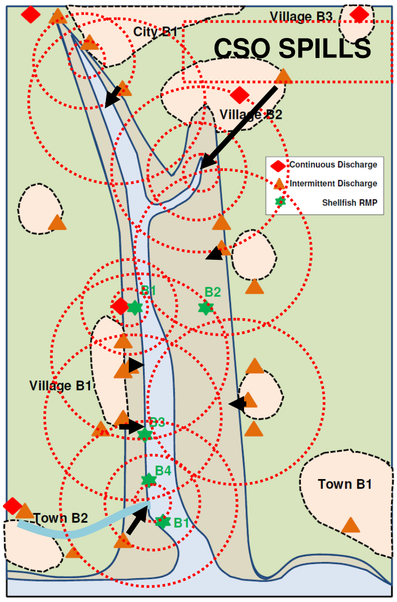
(based on higher risk WWTP winter load)



a) Spill zoning

(based on EDM data)

e.g. from multiple sources)



Could this approach work here?

Possible Issues:

a) Zone range shown is diagrammatic and would need to be scaled on evidence base.

Multiple WWTP discharges make risk from winter seasonal B zones challenging

Multiple CSO discharges make risk from CSO spill unmanageable

b) Potential for significant diffuse NoV load from catchment and vessels

Potential for extensive impact on shellfishery. Unlikely to be effective

Figure 11: Example computer model NoV chart and timerseries output

(Source: Technical Report Appendix A)

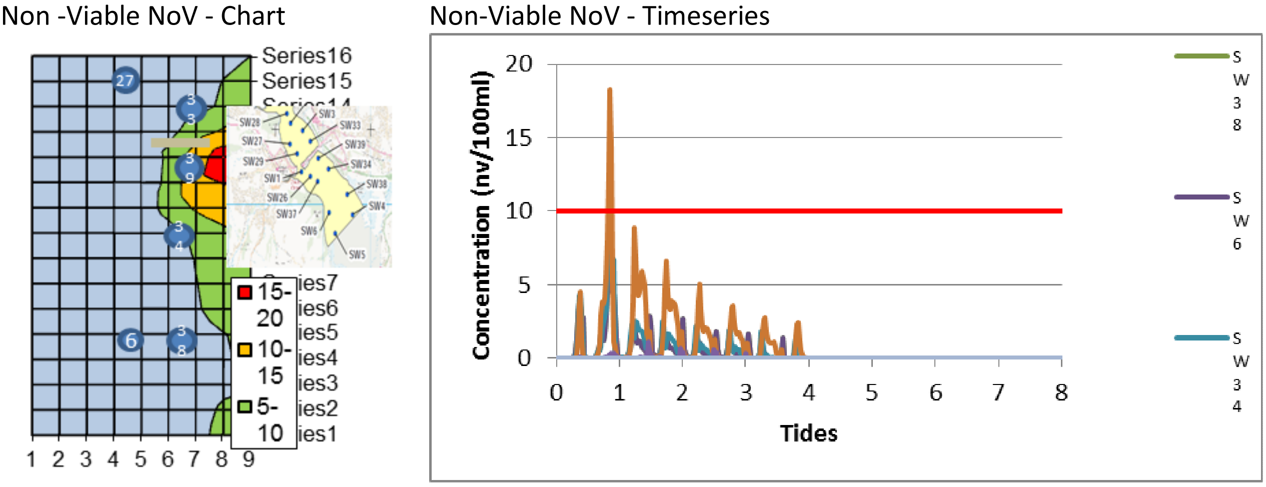


Figure 12: Active management network strategies to limit shellfish viral contamination

(Source: Technical Report Section 7.1.4, Figure 7.2)

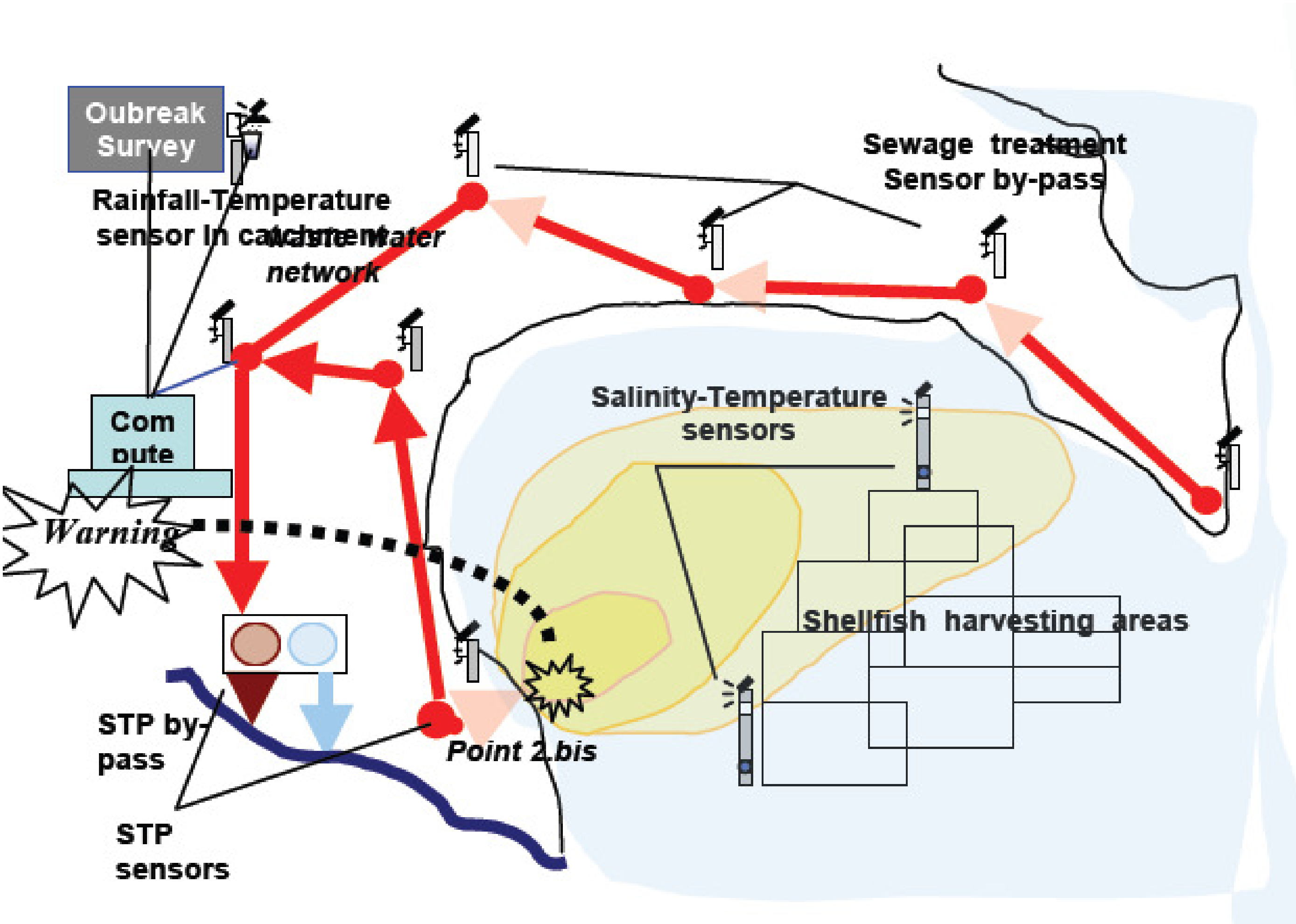


Figure 13: Relationship between food hygiene and environmental process affecting shellfish ***(Source: Technical Report Section 1.5, Figure 1.6)***

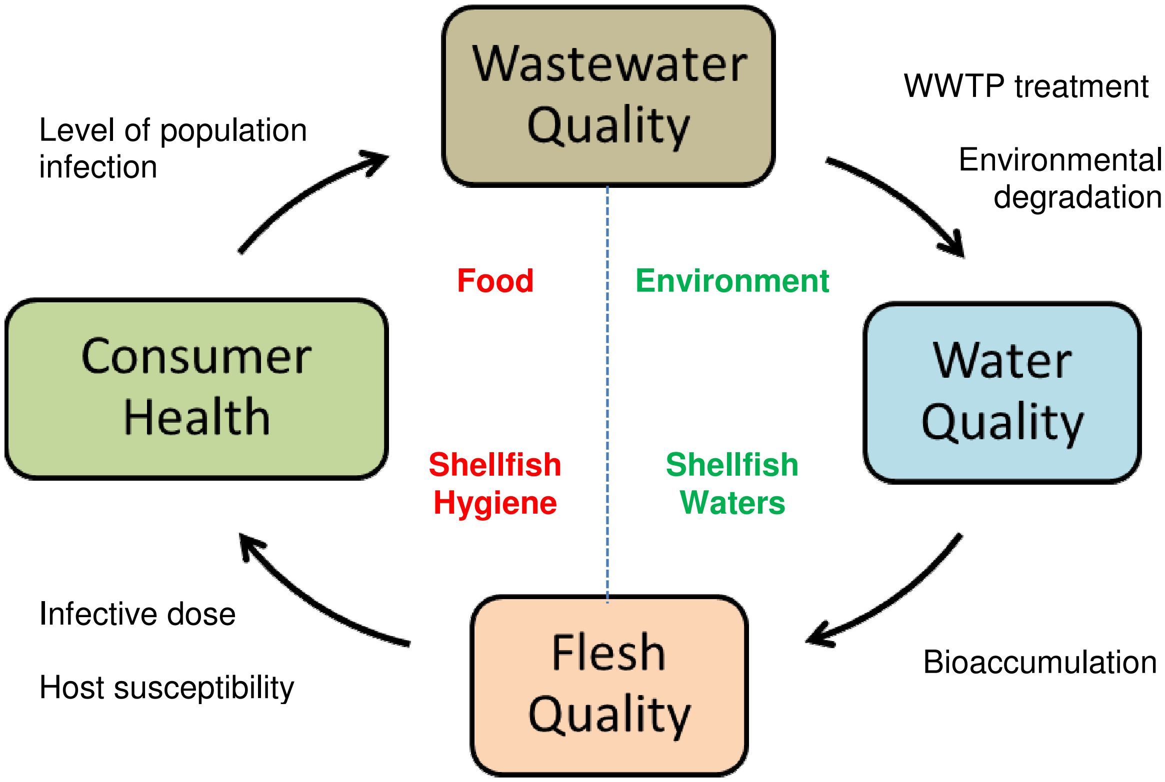


Figure 14: Link between stages in NoV transmission and guideline requirements

Environmental Tranmission Pathway		
Stage 1: Catchment Health NoV in wastewater	**Stage 2:** Environmental Quality NoV in seawater	**Stage 3:** Food Quality NoV in shellfish
Guideline Requirements		
Stage 1: Population Health Significant impact level	**Stage 2:** Food Quality Shellfish flesh standards	**Stage 3:** Environmental Quality Water quality standard

Figure 15: Illustrative application of risk scoring to conditionally restricted zone area

(Source: Technical Report Section 1.5, Figure 1.4)

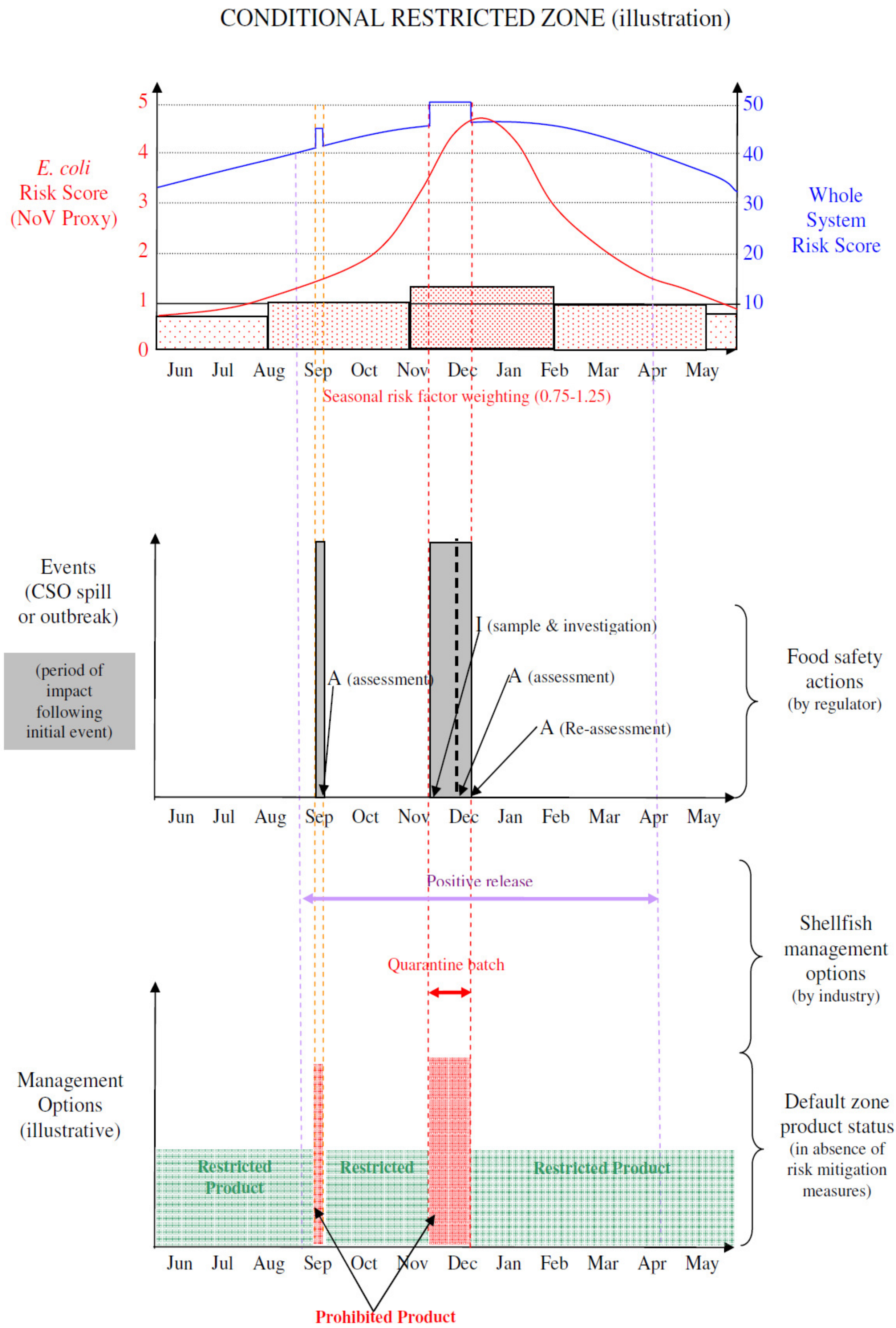
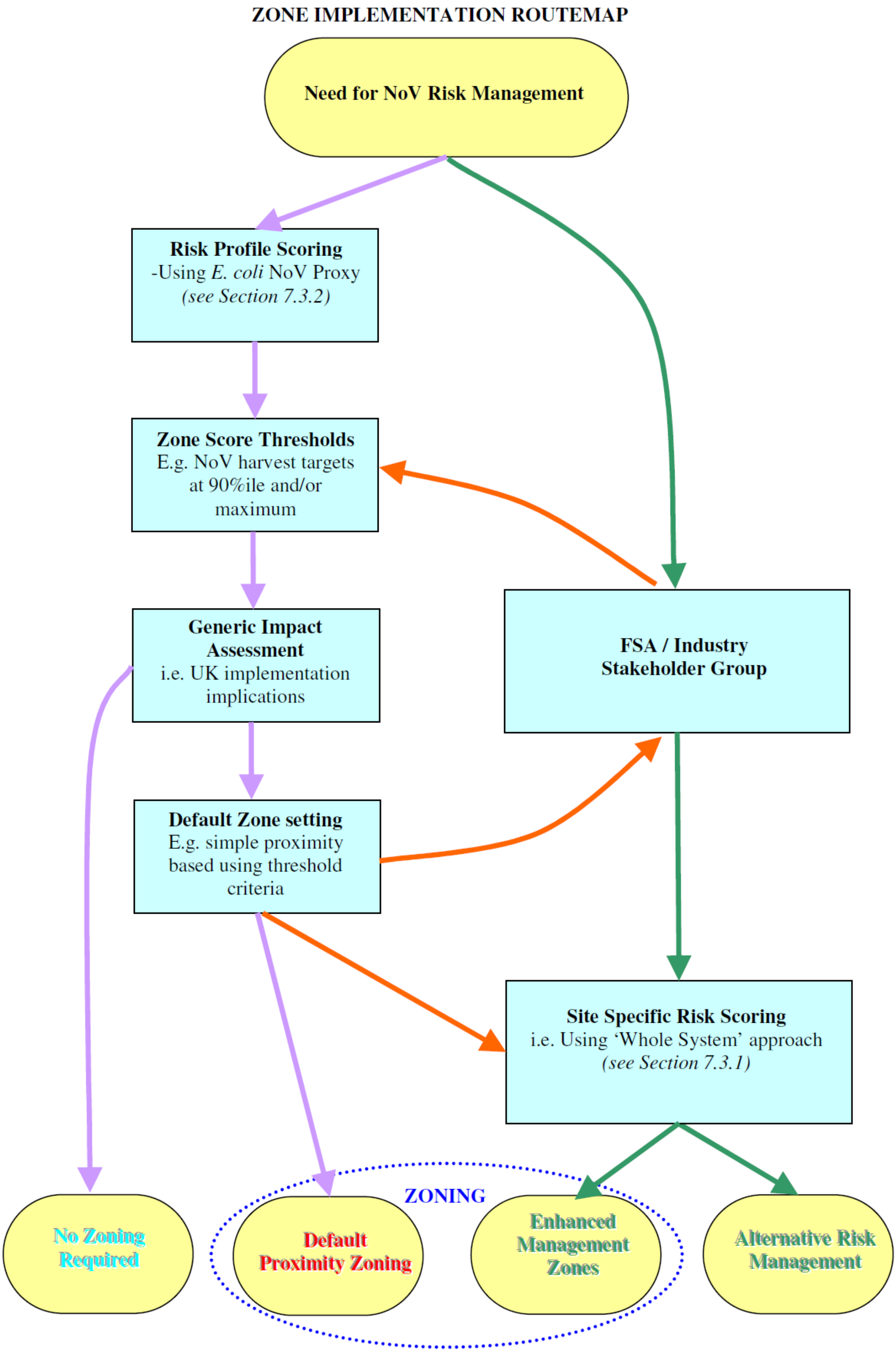


Figure 16: Illustrative zone implementation routemap

(Source: Technical Report Section 7.3.4, Figure 7.10)



Appendix A – Questions and Answers

Why do we need zoning?

Zoning is an option to limit the risk of shellfish foodborne NoV illness resulting from wastewater impact upon shellfisheries. Alternative management options exist, or could be used with zoning.

Do all shellfish need zoning?

Oysters are the main concern as they are often eaten raw. NoV is deactivated by cooking.

What shellfish activities might require zoning control?

Differing zoning could be applied to shellfish for activities based on risk:

Harvest for market size removal where microbial quality of food product is critical.

Production for grow-out stages where pre-harvest microbial quality is less critical.

What wastewater discharges might require zoning?

NoV can be derived from any human wastewater sources. As crude sewage can occasionally contain high NoV concentrations even small discharges can have a big impact. Wastewater sources could include:

Continuous treated discharges (municipal and private Waste Water Treatment Plants – WWTPs). These are relatively few in number and generally well controlled.

Intermittent untreated discharges (Combined Sewer Overflows - CSOs and Emergency Overflows - EOs). These are common in catchments with larger urban populations with limited control and understanding of impact 'significance'. Viable NoV load from CSOs following storm events may exceed that from WWTPs

Septic tanks maybe numerous and difficult to regulate in some catchments with dispersed rural populations and potential for significant impact.

Vessels/marinas have potential for significant contamination in close proximity to shellfish areas but are poorly regulated and difficult to control. Potential for discharges in winter may be reduced.

Riverine from catchment (e.g diffuse sources from unconnected discharges, septic tanks, sewage sludge). Increasing recognition that much of faecal coliform indicator contamination (particularly after storm run-off) may be derived from agriculture. It is difficult to assess catchment risk from NoV. Many shellfisheries are situated in, or by estuaries, with uncertainty over how any potential riverine zoning would be applied to a non-fixed point source.

What would be basis of zoning?

Distance – some European examples of geographical proximity to fixed point (e.g outfall) or potential contamination source (e.g. river mouth). Distance would be an undefined proxy for a combination of dilution and time.

Dilution – US affiliated countries have set dilution rates for zone boundaries (i.e 1000:1 for prohibited zones and 100,000:1 for approved zones) to achieve bacteriological water quality standards.

Time - US affiliated countries have time requirements to allow for early warning responsive measures with set Management Plans in areas subject to potential intermittent contamination events (i.e. Conditional zones).

Shellfish Flesh Quality - Current US studies of dilution requirements for zoning has included the use of shellfish testing for NoV and viral surrogates. The timing of 'open' or 'closed' status in Conditional zones following an event can be influenced shellfish flesh viral surrogate sampling.

Combination of factors – US affiliated countries may use both dilution and time for Conditional zones supported by shellfish flesh testing.

To what degree can NoV shellfish testing be used to support zone determination and management?

Shellfish testing for NoV has been part of Due Diligence Good Practice by some shellfish operators for many years. NoV shellfish flesh harvest and End Product standards for regulatory purposes is under consideration within EU but are likely to be controversial as it has both good and bad features:

The RT-PCR detection method for NoV in shellfish is considered by EFSA to be suitable for use in a legislative context and has been shown to provide a better indication of NoV pathogenic risk than the current regulatory faecal indicator *E. coli*,

Viability is not measured by this molecular method leading to concerns that the method is not fully fit for purpose as it will not reflect inactivation by wastewater disinfection (e.g. UV) and within the environment.

What should zoning regulate?

Exclusion or prohibition of shellfish activities (i.e. harvest or production).

Enhanced management with extra management measures at times of increased risk.

It is possible that some areas could have a combination of both.

Should zoning be precautionary?

It is uncertain at this stage what is 'burden of proof' for setting zone thresholds if evidence based scaling for zoning were to be adopted:

Beyond reasonable doubt would aim to give assurance that product is safe. Scaling is based on worst case conditions to give high confidence that shellfish products are consistently safe.

Balance of probabilities that product is safe. Scaling based on best available knowledge with likelihood that shellfish are generally safe without significant impact on consumers.

Hybrid approach with differing zoning requirements at set levels of assurance. Differing thresholds might be sought for differing purposes on a site specific basis. Product could be tailored to range from Good Production Guide levels for US Trade, 'assured' product for raw consumption, product with advisory labelling.

Should zoning be fixed or variable according to risk?

Fixed zoning (constant and based on proximity) would be relatively easy and cheap to implement and regulate. However, it is hard to know what NoV risk profile to apply. If precautionary then many shellfisheries could be commercially impacted. If limited to major continuous WWTP discharges (with disinfection) then open to legal challenge from Food Business Operators that zoning has no risk based evidence.

Variable zoning based on evidence/science is likely to be complex to establish with a need for a site specific assessment to guide enhanced management and appropriate monitoring. Risk profile can vary with:

- Seasonality (worse in winter) when level of ill people in the population increases and loading in crude sewage increases
- Events (such as storms or failures) when the level of loading to environment may be intermittently increased.

Combination approach a default fixed zone could initially be implemented until a more appropriate risk based variable zone can be established on the basis of site specific knowledge, data and systems – perhaps using risk scoring.

What is risk scoring?

Risk scoring is a numerical scheme based using a combination of parameters with known relationships to NoV risk. Options include:

- *E. coli* NoVsurrogate based approach taking to account catchment specific data relationship with weighting from NoV influencing factors (e.g. temperature and season). Relatively simple to implement but a rather 'blunt tool' for some settings.
- 'Whole system' approach looking at NoV loading, treatment, decay, bioaccumulation and post-harvest treatments to determine a science evidence based approach. The scheme is well suited to reactive approach to encompass 'events' but potentially complex.

Could evidence based risk scoring be used to set enhanced management zoning?

Evidence based risk profiles - Using principles of the US system for Conditional Zones, areas subject to intermittent but predictable contamination events can vary their 'Open' or 'Closed' status. Harvest restriction criteria are developed and set within a Management Plan where Active Management monitoring of wastewater discharges and WWTP system performance is used to inform shellfish operators and regulators.

Enhanced zone management - Dynamic risk matrix scoring could be flexible to seasonal changes in profile and responsive to contamination 'events' allowing an escalation of shellfish management measures beyond just 'Open' or 'Closed' status.

Can a secure commercial route to market be balanced against provision of safe shellfish products?

Enhanced management zoning in all shellfish catchments is likely to have significant resource implications. A 'carrot and stick' pragmatic approach may be needed to balance needs of shellfish industry with protection of public health. Some related UK and EU issues and projects which may help with zone development include:

US Trade Harmonisation – Many of the prohibition zone requirements of the NSSP system could be useful in the development of appropriate UK measures (e.g. use of Active Management to support risk scoring system). Resource from schemes devised in these more pristine sites could be used to help develop enhanced management zoning.

Harvesters Own Sample Protocol provides scope for a more reactive risk management whilst improving classification scheme. Creative mitigation measures by Water Utilities for Class C sites could help resource enhanced management zoning.

Relay area access – FSA has recently revised guidance on access to relay areas to ensure that product from Class C areas can also be relayed in Class B areas. A similar approach for any NoV zoning could help maintain ongrowing in areas not always suitable for harvesting. Development of cost effective intermediate culture systems is likely to be required, perhaps with assistance for access to regional shared resource.

Enhanced Depuration – FSA is currently funding research into improving depuration efficacy for NoV removal. Access to regional shared resource (coupled with ‘chill banks’) could support zone requirements.

Product Differentiation and Marketing – ACMSF have reiterated the need for FSA to reinforce its advice on the risk of consuming raw oysters and that cooking reduces this risk. Suggestions are also made to provide more targeted advice for various shellfish products. It is possible that zoning could provide differentiation for an ‘assured’ product more suited for raw consumption, whilst market development is supported for standard shellfish products with appropriate labelling.

What are potential next steps?

It is likely that any zoning scheme would need to be evidence based and would require gradual implementation following a consultation process. There are a range of issues to resolve:

Research for science evidence gaps A number of important aspects are still poorly understood and require both laboratory and trial work.

Implementation A UK impact assessment will be required based upon a more comprehensive inventory of potential wastewater sources. Site trial work in real shellfisheries will also help develop generic risk scoring schemes. The potential for various levels of proximity zones using existing simple risk scoring schemes could be considered within the impact assessment study.

Strategic Issues Holistic policy approach to regulations and appropriate cross-sector drivers are required before resourcing problems can be resolved.