



Libraries and Learning Services

# University of Auckland Research Repository, ResearchSpace

## Copyright Statement

The digital copy of this thesis is protected by the Copyright Act 1994 (New Zealand).

This thesis may be consulted by you, provided you comply with the provisions of the Act and the following conditions of use:

- Any use you make of these documents or images must be for research or private study purposes only, and you may not make them available to any other person.
- Authors control the copyright of their thesis. You will recognize the author's right to be identified as the author of this thesis, and due acknowledgement will be made to the author where appropriate.
- You will obtain the author's permission before publishing any material from their thesis.

## General copyright and disclaimer

In addition to the above conditions, authors give their consent for the digital copy of their work to be used subject to the conditions specified on the [Library Thesis Consent Form](#) and [Deposit Licence](#).

# Rethinking Science in Oyster Food Safety Regimes: Vibriosis and the Interstate Shellfish Sanitation Conference as an Actor Network

Dorothy-Jean McCoubrey

A thesis submitted in fulfilment of the requirements for the degree of Doctor of  
Philosophy in Environmental Science, The University of Auckland, 2019.

## ABSTRACT

Providing the world with a safe and secure food supply is an on-going challenge. National and international food safety agencies have long attempted to conquer this challenge by using a variety of regimes. This thesis considers the role that science has played and continues to play in such food safety regimes. The case of foodborne vibriosis amongst raw oyster eaters is used to explore the role science and identify the multiple relationships that exist in any food safety situation. Further, this thesis takes a 'double-dip' novel approach by using the Actor-Network Theory (ANT) framework to consider the United States of America's Interstate Shellfish Sanitation Conference (ISSC) as an assemblage. The ISSC is the governance agency tasked to deal with foodborne vibriosis caused by *Vibrio parahaemolyticus* and *Vibrio vulnificus*. A mixed-method approach was used to gather the research data which included semi-structured interviews, a review of published and grey literature and observation of key relationships during a two-year placement in the United States Food and Drug Administration's Office of Seafood. Much of the resulting data rich material was exposed during the 73 interviews, which included every scientist reporting to the ISSC and all the voting members empowered to determine the USA oyster food safety regulations.

In using ANT to explore how the ISSC members use science and food safety policy to deal with vibriosis it becomes apparent that many of the wider assumptions about science are not what they seem. Moreover, our complex world requires that science's matters of fact are considered with societies' matters of concern. If a binary division is made between scientific facts and other matters of fact, then food safety solutions are unlikely to be robust or acceptable.

The research makes four contributions to the literature and to the food safety policy realm. First, it provides the first study of the ISSC as a unique assemblage. Second it provides the first account of the ISSC and food safety as seen through the opinions of its own members. Third, it suggests that the food safety science most frequently posed to science, namely "Why has science not solved the problem?", is the wrong question. Finally, through each of these points there is a contribution to food safety policy. The findings identify that we need to rethink how science can and should be used within the food safety risk paradigm.

## ACKNOWLEDGEMENTS

Many, many years ago I had the desire to write a PhD thesis; I thought it was a simple matter of writing another report. Fortunately, a great professional team emerged to support my ambition - not only with the thesis content, but through debate and encouragement ensuring I gained a new and deeper understanding of my topic area, and a full appreciation of the effort required.

Associate Professor William Smith (Willie) who supervised my MSc thesis and started me on the PhD science-policy trail. Willie, you have been a piece of Scottish granite, weathering all my storms since 2004, while maintaining your kind, patient assistance well into your retirement.

Associate Professor Nick Lewis offered a new and colourful world when introducing me to the scallops of St Brieuc Bay. Nick, having taken on principle supervision duties, never missed an appointment, patiently showing me the exciting possibilities offered by Science Technology Studies and Actor-Network Theory - thank you for changing my way of thinking. Meanwhile Dr Susan Owen used her specialist skills, providing wisdom when presenting me with new concepts, ensuring focus on the goalposts, and keeping my work firmly on track.

This thesis would not have been possible without the Oak Ridge Institute for Science and Education Scholarship offered by the USA Food and Drug Administration to deal with a specific shellfish food safety matter. This original matter was resolved, But Dr Angelo DePaola then threw me the added vibriosis food safety challenge and has valiantly championed this thesis ever since.

Add into the mix many shellfish colleagues, ISSC members and others who graciously answered questions and shared their wisdom. Marc Glatzer is specifically remembered, unselfishly sharing Vibrio information since 1994, but sadly dying in October 2017, before this story was complete.

Lastly, but by no means least, John McCoubrey is thanked for always supporting my endeavours and for putting up with the vagaries of a study household. But be warned, John, I am now itchy for a new challenge.

# TABLE OF CONTENTS

ABSTRACT .....	iii
ACKNOWLEDGEMENTS .....	iv
LIST OF TABLES .....	viii
LIST OF FIGURES .....	viii
GLOSSARY .....	ix
CHAPTER 1: INTRODUCTION .....	1
1.1 The Complex Problem of Food Safety .....	1
1.2 Food Safety and Science .....	2
1.3 The Limits of Science .....	3
1.4 The Oyster .....	5
1.5 An Opportunity to Explore Further .....	8
1.6 Thesis Structure .....	11
CHAPTER 2: REVIEWING FOOD SAFETY, SCIENCE, PUBLIC POLICY AND SCIENCE TECHNOLOGY STUDIES .....	12
2.1 Food Safety in Changing Times .....	12
2.2 Science and the Making of the Food Safety Problem .....	15
2.3 Regimes of Food Safety Governance .....	17
2.3.1 A History of Food Safety Regimes .....	19
2.3.2 Arrival of the Contemporary Risk Based Regime .....	21
2.3.3 Hazard Analysis Critical Control Point as Risk Control Technology .....	22
2.3.4 Risk Regimes in Practice: International, National and Local Food Safety Governance .....	22
2.3.5 Science and the Food Safety Risk Analysis Regime .....	24
2.3.6 Messiness of Universal Food Safety Regimes .....	28
2.4 Science and Public Policy – a History of Entanglement .....	29
2.4.1 Science, Nature-culture and the Scientific Method .....	30
2.4.2 Public Science: Objectivity, Neutrality and Public Good .....	31
2.4.3 An Inherently Compromised Enterprise .....	32
2.4.4 Science Based Solutionism .....	34
2.4.5 Science-Policy Relations; A Troubled Space .....	36
2.5 Science and Technology Studies .....	38
2.5.1 Actor-Network Theory .....	40
2.5.2 Actors .....	41
2.5.3 Actor-Networks .....	41

2.5.4 Translation .....	43
2.6 Mobilising ANT Concepts to Theorise the Food Safety Regimes .....	44
2.6.1 Assemblage .....	44
2.6.2 The Politics of Metrology and Qualculation .....	46
2.6.3 Matters of Fact Versus Matters of Concern .....	49
2.6.4 Social Life of Things.....	50
2.7 Science and Food Safety: An ANT Inspired Rethink.....	52
CHAPTER 3: METHODOLOGY .....	55
3.1 An STS Inspired Approach Anchored in Ethnography .....	55
3.2 The ISSC as the Object of Research.....	56
3.3 Positionality .....	57
3.3.1 The Insider-Outsider Conundrum.....	59
3.4 Mixed-Method Qualitative Approach.....	60
3.4.1 Semi-structured Interviews.....	61
3.4.2 Documents.....	63
3.4.3 Observation and Participation .....	63
3.5 Data Analysis .....	65
3.6 Research Integrity .....	66
3.7 Conclusion.....	66
CHAPTER 4: SCIENTISING VIBRIOSIS .....	68
4.1 Biology of the Vibrio genus .....	68
4.1.1 Introducing Vp and Vv.....	69
4.1.2 Vibrios and Oysters.....	71
4.1.3 Vibrios and Humans.....	72
4.2 Science Calculates the Vibrios .....	74
4.2.1 Laboratory Analytical Assays for Vp and Vv .....	75
4.2.2 Epidemiology .....	76
4.2.3 Risk Assessments and Scientific Modelling Tools.....	77
4.2.4 Pathogenesis Remains an Unknown.....	78
4.2.5 Reducing and Eliminating Vibrios in the Oyster.....	79
4.2.6 Looking to the Future - Climate Forecasting.....	80
4.3 Synopsis of the Vibriosis story.....	81
CHAPTER 5: THE INTERSTATE SHELLFISH SANITATION CONFERENCE FRAMES THE 'PROBLEM'.....	83
5.1 Oyster Economies in the USA .....	83
5.2 The Interstate Shellfish Sanitation Conference .....	84
5.2.1 The ISSC Participants.....	85

5.2.2 How the ISSC Co-operates.....	87
5.2.3 The ISSC's Vibriosis Food Safety Work.....	87
5.2.4 Opening the Lid on the Black Box of Vibriosis.....	89
5.2.5 An Alternative Way to Expose the Black Box's Contents.....	91
5.3 The Making of the 'Vibriosis Problem'.....	92
5.4 Confronting 'The Problem'.....	95
5.5 Accounting for Vibriosis.....	96
5.5.1 Science in Practice.....	97
5.5.2 Metrics at Work.....	100
5.5.3 Cultures of Oyster Eating.....	103
5.5.4 Oyster Economies in Practice.....	106
5.5.5 Public Policy and Politics in Practice.....	109
5.5.6 Natural Biophysical Environment.....	118
5.6 The Continuous Cycle and How to Break Away.....	120
CHAPTER 6: REFRAMING THE PROBLEM.....	124
6.1 Will the Real Actors Please Stand Up?.....	124
6.2 The ISSC as Assemblage.....	127
6.3 The Conference Agenda: Holding the ISSC Assemblage Together in a Dynamic Stability.....	130
6.4 Reflections on Translation.....	132
6.4.1 Problematization: Houston, do we have a Problem?.....	133
6.4.2 Interessement: Science a Compromised Lead Actor.....	134
6.4.3 Enrolment.....	134
6.4.4 Mobilizing Allies.....	136
6.5 What Does the Reframe Identify?.....	136
CHAPTER 7: RESEARCH CONCLUSIONS AND CONTRIBUTIONS.....	138
7.1 The ISSC as Assemblage.....	138
7.2 A Multiple and Complex ISSC.....	139
7.3 Expecting Too Much of Science.....	141
7.3.1 Nature-Culture and the Work of Science.....	141
7.3.2 Beyond Solutionism.....	142
7.3.3 Beyond Universalism.....	143
7.3.4 Beyond Political Neutrality.....	145
7.4 From 'Matters of Fact' to 'Matters of Concern': What We Should Expect of Science.....	147
7.5 What We Now Know.....	149
7.6 Applying ANT Outputs.....	151
APPENDIX I: UAHPEC's rationale for Research Ethics Approval.....	152

APPENDIX II: History of FDA’s Principle Actions re Vp and Vv.....	153
APPENDIX III: History of ISSC Actions Taken in the Attempt to Reduce Vp and Vv Illness Amongst Oyster Eaters.....	154
APPENDIX IV: Examples of specific national dynamics in countries dealing with vibriosis.	156
REFERENCES .....	157

## LIST OF TABLES

Table 1: Agendas of FDA/ISSC Vibrio workshops .....	88
Table 2: Responses to Vp and Vv being a significant food safety problem .....	92
Table 3: Summary of responses regarding appropriate vibriosis risk management steps .....	95
Table 4: Reasons provided by interviewees for persistent vibriosis amongst raw oyster eaters .....	97
Table 5: Interviewees expressed common themes blocking scientific solutions.....	98
Table 6: Interviewee quotes about the weakness of institutional science .....	99
Table 7: Metrics which explain the increased incidence of vibriosis .....	101
Table 8: Interviewees reasoning on the oyster industrial reasons for persistent vibriosis .....	107
Table 9: Stakeholder comments on relationship issues with the FDA .....	112

## LIST OF FIGURES

Figure 1: Pacific oyster with right valve removed. ....	5
Figure 2: Incidence of Vibrio foodborne illness compared with other foodborne pathogens for the period 2006-2014. ....	89
Figure 3: ISSC’s scientised decision-making framework. ....	90
Figure 4: Reasons provided by interviewees for persistence of vibriosis.....	97
Figure 5: Modelled factors which ensure raw oysters are safe to eat .....	125
Figure 6: List of actors identified during the semi-structured interviews .....	141

## GLOSSARY

ANT	Actor-Network Theory
BC	Before Christ
BSE	<i>Bovine Spongiform Encephalopathy</i>
C	Celsius
CDC	Communicable Disease Center
CFU	Colony forming unit
Codex	Codex Alimentarius Commission
CI	Confidence Interval
CSPI	Centre for Science and Public Interest
DNA	Deoxyribonucleic acid
EU	European Union
EFSA	European Food Safety Authority
F	Fahrenheit
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FedReg	Federal Regulator
g	gram
HACCP	Hazard Analysis Critical Control Point
HHP	High Hydrostatic Pressure
ICMSS	International Conference of Molluscan Shellfish Safety
Ind	Industry
ISSC	Interstate Shellfish Sanitation Conference
kGy	Kilogray
MPN	Most Probable Number
NASA	National Aeronautics and Space Administration
NOAA	National Oceanographic and Atmospheric Administration
NZ	New Zealand
OPP	Obligatory Passage Point
OR	Odds Ratio
ORISE	Oak Ridge Institute for Science and Education
PCR	Polymerase Chain Reaction
PHP	Post Harvest Processing
psi	pounds per square inch
Sc	Scientist

StateReg	State Regulator
SPS	Agreement on the Application of Sanitary and Phytosanitary
STS	Science Technology Studies
RT-PCR	Real Time Polymerase Chain Reaction
UAHPEC	University of Auckland Human Participants Ethics Committee
UN	United Nations
U.S.	United States
USA	United States of America
Vp	<i>Vibrio parahaemolyticus</i>
Vv	<i>Vibrio vulnificus</i>
WHO	World Health Organization
WTO	World Trade Organization

# CHAPTER 1: INTRODUCTION

When Fonterra, New Zealand's largest dairy co-operative, admitted in 2013 that scientists had found the potentially lethal *Clostridium botulinum* in infant milk powder it caused a global media frenzy and widespread public concern (Lewis, Le Heron & Campbell, 2017). Several nations intervened to block imports and serious costs were incurred by exporters. Had this milk powder batch been contaminated with botulinum, which causes death and paralysis, it could have been one of the worst food disasters for decades. There would have been infant deaths, long-term illness for others and emotional toll for everyone involved. The actual event costs included product recall and disposal, compensation claims from customers, loss of reputation and in some cases the imposition of new food safety market access conditions. The total financial cost remains unclear, but Fonterra alone lost NZ\$60 million dollars within days of the announcement (Hussain & Dawson, 2013). In December 2017 Fonterra was ordered to pay 105 million euros (NZ\$183 million) in damages to the French food giant Danone because of the 2013 food safety failure (Fraser, 2017). Some countries, such as Russia, continue to ban the importation of New Zealand (NZ) milk powder (MPI, 2017). Such events point not only to the immediate health and economic concerns at stake in questions of food safety, but also to the complexity that underlies relationships between science and food safety governance. It is these relationships that I explore in this thesis.

## **1.1 The Complex Problem of Food Safety**

Food is essential for survival. Access to safe and nutritious food is a common global goal and is recognised by the United Nation's 'Rome Declaration' as a basic human right (FAO, 1996). However, food is much more than just a basic commodity or a configuration of nutrients and biochemical compounds. Eating is a social and cultural practice. People come together to eat, while foods commonly have cultural meanings as well as material properties. These meanings may be imparted by flavours and textures, their provenance and their roles in social practices or judgements about health qualities. Raw oysters, for example, are often believed to be an aphrodisiac (Prasad, *et al.*, 1996); broccoli, blueberries and salmon are currently understood to enhance both our physical and mental wellbeing (Pratt & Matthews, 2006; Ramesh & Jamuna, 2012); and too much red meat, sugar and dairy products are deemed bad for our health and longevity (Kushi, Lenart & Willet, 1995; Pan, Sun & Bernstein, *et al.*, 2012). Different peoples in different parts of the world have diverse dietary habits. Food is a way of life as much as a means to life.

Populations have long expected their leaders to ensure a secure and safe food supply. Today's consumers in most parts of the world expect the government to take the necessary steps to protect them from modern food safety hazards (McKechnie 1999; Friends of the Earth, 2003; NZFSA *Food Focus*, 2005; [www.fao.org/worldfoodsummit/sideevents/papers](http://www.fao.org/worldfoodsummit/sideevents/papers); Tirado, 2010).

Consumers in industrialized countries increasingly demand food and food products of high and consistent quality throughout the year. They express new concerns about the negative effects of bio-industrial production (McKechnie, 1999; Friends of the Earth, 2003; NZFSA *Food Focus*, 2005; Trienekens & Zuurbier, 2008), and have rising expectations with respect to its ethical production (Lupton, 2005; Devaney, 2013). All this is further complicated by the globalisation of food supply relations that imply ever more complex arrangements for regulating and securing food safety. As a result, food safety is now entangled in a complex economy that links biological actors, science, and a large variety of economic practices and regulations.

## **1.2 Food Safety and Science**

The need for a safe food supply is not a modern concept. Indeed, history provides many examples where traditional wisdom and cultural food safety protocols provided consumers with advice on foods to avoid, methods of preparation and the importance of food hygiene. When Moses wrote the book of Leviticus between 1440 and 1400 BC, he introduced laws to protect his people from food related disease, including a ban on eating shellfish. The Jewish kosher food laws stipulate only animals that chew the cud and have a cloven hoof, birds with wings, and aquatic organisms with both fins and scales are fit for human consumption (Meyer-Rochow, 2009). The Egyptians, Greeks and Romans articulated similar concerns (Mossel, *et al.*, 1995), while Māori developed their own understandings and practices to promote seafood safety. Of course, there is a science to these cultural codes: empirically derived understandings of how filter-feeding shellfish can accumulate pathogens (disease-causing bacteria) and toxins. There is also a regulatory order. In the case of Māori food safety, a mixture of quasi-religious/quasi-legal mechanisms such as *tapu*, *mana* and *rahui*, directed human interactions with the environment while defining where and when food should be gathered (Kawharu, 2000).

Traditional food safety rules were usually linked to an understanding of nature and the local environment. When the Scientific Revolution emerged, as part of the Age of Enlightenment in the 16<sup>th</sup> and 17<sup>th</sup> centuries, it promoted new ways of looking at the natural world. The Revolution also provided new ways of gathering information by using methods of observation and induction (Bowler, 1992). In turn, these new ways offered a potentially uniform and apolitical system for building knowledge and promoted the modernist conceit that humans can contain or control biophysical processes. No longer was nature seen as an organic whole, a source of mysterious and constructive powers, but instead perceived as a gigantic piece of clockwork with which humankind could tinker at will (Bowler, 1992).

Modern science was born; with it emerged new disciplines such as astronomy, biology, chemistry, mathematics and physics (Bowler, 1992). Several of these newly emerging science disciplines, particularly chemistry and biology, provided exciting new findings that could be applied to food safety and public health problems. For example, around 1630 chemists synthesized chlorine gas, which later led scientists to develop the chlorination process and in turn sanitize drinking water supplies. Other sciences were brought to bear on the problems of food storage and safety. Food safety problems also initiated scientific disciplines; *epidemiology* (the study of diseases) was born in the mid-19<sup>th</sup> century

when John Snow's methodical record-keeping and scientific deduction led him to determine that the Broad Street water pump was the source of the 1854 London cholera outbreak (CDC, 2006).

Snow's discovery about the nature of disease transfer occurred just as the "golden age of microbiology" was emerging. From 1860 to 1920, the germ theory of disease was espoused by Louis Pasteur and scientists actively competed to identify the causative agents of infectious diseases. Along with these advances came new culturing and staining methods for microbial cells which greatly expanded laboratory testing capabilities. Simultaneously methods to destroy or reduce microbial populations were developed and refined. This included the mild thermal treatment, *pasteurization*, discovered by Louis Pasteur, which had the ability to kill pathogens (Wilson, 1943; Knechtages, 2011). At the same time scientists were demonstrating that not all health problems are caused by chemical or microbiological contamination of food. Some, such as goitre, are caused by lack of elemental dietary requirements (Carmalt Jones, 1928).

By the early 20<sup>th</sup> century science was providing powerful insights on disease and allowing the development of new tools and approaches to control food safety and public health problems. Since World War II, science has become an increasingly important component, enabling the modern global food manufacturing and distribution economy and overcoming food safety problems (De Solla Price, 1965; Clark & Majone, 1985; Cassell, 1986; Baggott, 1990; SAGE, 1999; WHO 2003). Science now also underpins a vast regulatory apparatus and the work of the food regulatory industry at local and global levels. The United Nations Food and Agricultural Organization (FAO) and the World Health Organization (WHO), the World Trade Organization (WTO) and other national food safety authorities promote scientifically based food safety practices, including the risk analysis framework, as the best strategy to eliminate food safety problems (WHO/FAO, 2006).

Scientist's ability to see and explain how pathogens infect human bodies held promise that all infections could be contained, commanded and conquered (Cockerill, *et al.*, 2017). Further, science is increasing expected to play a fundamental role in finding solutions to the world's food safety problems. Indeed, within government institutions there is a mantra of '*solutionism*', the belief that for every problem there exists a solution (Baker, 1984).

### **1.3 The Limits of Science**

Food safety, however, is not a once and forever solvable problem. Food contamination and outbreaks of food-borne disease still occur, which is not surprising given the complexity of biological, economic and social actors involved in getting foods from plant or animal to the plate. The New Zealand milk powder contamination incident is just one example confirming that biological actors still cause significant food safety problems and are not yet fully subjugated to scientific control (Hinchcliffe, 2001; Barry, 2002; Lewis, Le Heron & Campbell, 2017). Indeed, a joint FAO/WHO Expert Committee on Food Safety admits that illness due to contaminated food is probably the most widespread health problem in the contemporary world and an important cause of reduced economic productivity (WHO, 1984). The speed of change is challenging regulators and their critics to more wholly realize the full value of scientific

knowledge in the regulation of food safety (Lang, 2005; Devaney, 2013). In short, established processes of national and international food governance are struggling to meet the level of food safety assurance expected and required.

The reasons for today's food safety problems are multiple and complex. They include the evolution of new pathogens, changing environments, national differences in access to science and technology, along with new food production and processing methods. The industrialization of food production, expanding international trade, the use of rapid transport links to move even fresh produce to often distant markets, and the spectre of increasingly manufactured 'Frankenstein' foods are all stretching the capacity of food science and associated regulatory initiatives to secure food safety. Consumer expectations about the continuity, diversity, quality, and safety of food are also changing, along with rising expectations with respect to its ethical production (Lupton, 2005; Devaney, 2013).

While the need for a safe food supply is not a modern concept, it has taken on new dimensions due to increasingly sophisticated and globalised industrial production and distribution systems, today's degraded environments and new regimes of risk calculation (Consumer's Association, 1999; Friends of the Earth, 2003). Food safety issues remain as pressing as ever in contemporary globalised times (WHO, 2003; Ababouch, 2006; Tirado & Clarke, 2010).

Science is at core a transparent, testable and public enterprise, producing results that provide common currency across different cultures and language groups<sup>1</sup>. Its practices along with the knowledge science generates have significant authority, utility and demonstrated value (Salter, 1988; Marchak, 1991; SAGE 1999; Otto, 2011). This has resulted in a persistent and powerful discourse of 'solutionism' (science can solve all problems), in turn, leading to public and policy understandings about the potential of science and integration to wider social governance. Yet, there are significant limits on its capacity to deliver universal solutions. There are many reasons for this: uncertainty and the inherent incompleteness of scientific findings, a lack of public trust in the answers that scientists provide, social resistance to change, and the many barriers that exist to the formation of science-led food safety policies (Bowler, 1992; Bromley, 1993; Von Schomberg, 1993; Doble, 1996; Dovers 1996; SAGE, 1999; OXERA, 2000; PCE, 2004). The latter includes the failure of policy-makers to act upon new science, conflicting values in society, political objectives, the use of scientific uncertainties as an excuse, or lack of policy implementation (SAGE, 1999; PCE, 2004; McCoubrey, 2007). Science is a fractured set of practices with numerous flaws and is always only one of multiple forms of social practice engaged with complex food safety questions. Science as a social practice must compete with other information sources and societal dynamics, for example, economic impacts, social values and equity considerations (Brooks, 1981; Von Schomberg, 1993).

Nonetheless policy makers, publics and the science establishment continue to see science as the solution to food safety problems (WHO, 2002; FAO, 2007). This dissertation uses the case of the oyster

---

<sup>1</sup> Equally there is evidence that the scientific peer review system has its own limitations and weaknesses (Travis and Collins, 1991; Bacchetti, 2002; Rennie, 2003).

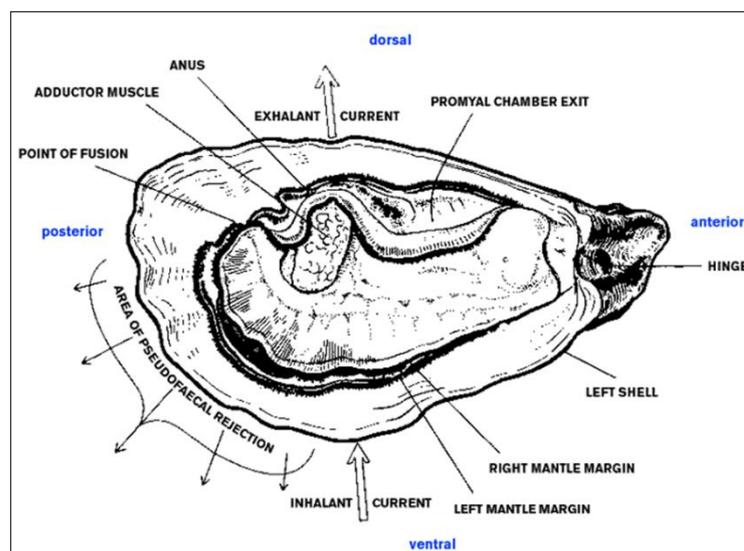
and vibriosis to ask how we might better position its practice, purpose and possible contributions in relation to food safety.

## 1.4 The Oyster

The oyster epitomises today's food safety science and governance challenges. Globally there is an insatiable appetite for oysters, yet the oyster's physiological attributes cause them to be ranked high on the global food safety risk list (FIICC,1995). This situation has created a host of oyster food safety interventions and management practices which science has been prominent in framing. These interventions and practices have been applied at various points in the oyster food chain, including oyster cultivation, gathering, transportation, food technologies, along with food distribution and trading systems. Such practices include environmental controls to ensure oysters are not contaminated with food safety pollutants; epidemiological investigations; interpretation of scientific information; national and international food safety strategies; and globalized trading requirements linked to food safety. In many ways, the food safety world and the role of science in shaping it can be found within the oyster.

Oysters belong to the biological class of Bivalvia which contains more than 20,000 species of marine and freshwater molluscs, commonly called bivalves. The distinguishing bivalve class characteristic is the lamellibranch gills which enable filter feeding (Villev, Walker & Barnes, 1978). This specialized feeding assists oysters to filter large volumes of water, which passing across the gills enables the oyster to obtain oxygen and food. Figure 1 depicts the digestive system of the oyster. Particulate matter from the water, including micro-organisms, is trapped in the mucous on the gills and transported to the mouth by ciliary action, then passes through to the stomach where they mixed with digestive enzymes. This process requires <2 hours in actively feeding adult oysters.

Figure 1: Pacific oyster with right valve removed. (Source: Department of Fisheries and Oceans, Canada)



Oysters have long been a common human food with archaeologists finding evidence of shell middens (kitchen dump of shells) throughout the world: on coastlines, near lagoons and tidewater flats, along

major rivers and small streams from much of all prehistory (Daniel, 1950). They have long been the “food for gourmets, gourmands and those who were simply hungry: tantalizing the wealthy in stately homes and sustaining the poor in wretched slums: a part of city commerce and a part of international trade.” (Kurlansky, 2007).

Aside from being a food staple, oysters have commonly been credited with special powers over the human mind and body. Napoleon ate oysters pre-battle and even when he was deposed and exiled, he continued to insist on a steady oyster supply (Kurlansky, 2007). Danton, Diderot, Robespierre, Rousseau and Voltaire are all believed to have eaten a few dozen oysters when in search of inspiration. Casanova, the renowned 18<sup>th</sup> century lover, famously used to breakfast on 50 oysters to enhance his sexual drive and performance (Weisbecker, 2010). Modern science now tells us that the association of oysters with aphrodisiac qualities is probably because oyster meat is rich in zinc, a mineral linked with healthy sperm quality and testosterone levels (Prasad *et al.*, 1996; Colagar, Marzony & Chaichi, 2009). In more humble settings, raw oysters are still linked to celebratory occasions such as Christmas, Thanksgiving, Valentines and family banquets.

Oysters can vary in shape, size, colour and taste depending on where they are grown. Colder waters tend to produce oysters that have a stronger taste. The salinity of water and the type of oyster food available in the water can also affect their taste. Historically, this association between place and oyster qualities was registered in a price premium; Belon or Concale oysters in France, while in England Colchesters were a preferred oyster and Amercian Long Island Blue Points were the desired oyster in later 19<sup>th</sup> century. Modern chefs and food marketers attach increasing importance to the oyster’s *terroir* to add credence and provenance values in much the same way as winemakers. Oyster platters, made up of named oysters from different sources, are a common feature in many United States of America (USA) restaurants, with some restaurateurs importing oysters from distant countries, such as New Zealand, to ensure that they have up to six live oyster choices from a range of locations (Coomes, 2014).

Harvesting and selling oysters have long provided opportunities for people to make their livelihoods. Many oyster species grow in the intertidal zone, which means that they can be easily hand gathered from the substrate when the tide is out. Other species, such as the *Ostrea* flat oyster species, grow sub-tidally so must be raked, dredged or tonged from the seafloor. Different oyster habitats combined with regional climatic and geographical differences have meant that they have been harvested differently from place to place across history, for example, intertidal gathering by Maori and with specifically designed sailing boats, known as skipjacks, in Chesapeake Bay, USA (Wennersten, 2007).

Gathering oysters from the wild is not the only form of oyster economy. Oyster cultivation (aquaculture) has been practiced since the time of Aristotle. Aristotle noted that fishermen had taken natural oysters and moved them to a more favourable spot in a current where they “fattened greatly”. Romans also found that oyster spat (seed) also seemed to like attaching itself to broken pottery shards, so broken pots were dropped into the local bays. Sergius Orata, a first century BC Roman, used rope and stakes to catch the fertilized eggs and then harvested the oysters when they grew to the right size (Hackney & Pierson, 1994). Since the nineteenth century, the Chinese, French, Japanese and Meso-Americans in Mexico have all used methods of collecting and farming oyster seed when their local oyster beds were

depleted. Modern international oyster farming practices use lines, racks and stakes as the oyster substrate in both the intertidal and subtidal marine zones.

With increasing demand for oysters in many parts of the world, the oyster industry is vibrant and expanding. The contemporary oyster industry employs large numbers in aquaculture, harvesting, transportation, processing, wholesale and retail, restaurants, marketing, regulation and science. It is a significant sector in many nations and oysters are shipped all around the world. In 2014, New Zealand sold 1,392 tonnes of oysters worth NZ\$14.6 million dollars to major markets including Australia, USA, China, Hong Kong, French Polynesia and Singapore ([www.aqnz.org](http://www.aqnz.org) accessed 23<sup>rd</sup> March 2018). Gaps in supply to rapidly growing markets in the USA and the European Union (EU) are being filled by the world's major aquaculture producers: China, India, Vietnam, Indonesia, Bangladesh, Thailand, Norway and Egypt (FAO, 2012).

Oyster consumption practices and patterns vary from country to country. USA surveys have found that 13% of the American population had eaten raw oysters during the previous 12 months (FDA, 2010), and that USA oyster consumption rates have been increasing (Coomes, 2014). 'Buck a Shuck' happy hour prices can be found in cities near the oyster supply source, but in some oyster bars such as San Francisco the oysters cost US\$2.50 – US\$5.00 each (Coomes, 2014). A FSANZ (Food Safety Australia New Zealand) assessment of the New Zealand National Nutritional Survey found that 0.3% of the NZ population were consuming oysters daily (ANZFA, 2001). Seafood is an important component of cultural and dietary practices among Maori and studies have shown that, along with Pacific Islanders and some East Asian groups, they commonly gather their oysters from non-commercial harvesting areas (Hay, Grant & McCoubrey, 2000).

Written records do not indicate clearly when people first became aware that edible shellfish could transmit communicable diseases, but illnesses are ascribed to Romans who gorged themselves on oysters sent from Britain for their feasts (Hackney & Pierson, 1994). In 1603, written records show oysters were incriminated when King Henry IV of France became ill with an intestinal disorder. By 1816 the medical profession had become alerted and a French physician, Pasquier, produced a book entitled *The Oyster from the Medical Point of View*. He observed that workmen had laid down 60,000 oysters for temporary storage in a moat receiving sewage from the French garrison. These oysters, once consumed, caused typhoid fever (Reille, 1907), but pre-dating Pasteur and the germ theory of disease transmission meant Pasquier was unable to explain the correlation. The Industrial Revolution attracted more people to cities, causing overcrowding and inadequate sewage disposal, and oyster beds near the cities became contaminated with sewage-based pathogens such as cholera, typhoid and enteric fever (Baggott, 1990). This resulted in cholera and typhoid outbreaks caused by oyster consumption, with public oyster beds often closed by the authorities to prevent illness (Hackney & Pierson, 1994).

It was Louis Pasteur's revealing "germ theory" which unravelled the mystery as to why oysters pose a significant food safety risk. It is the oyster's specialized filter feeding system which enables them to accumulate micro-organisms, viruses, protozoa, helminths, marine biotoxins or toxic substances and autochthonous (indigenous) micro-organisms such as the *Vibrio* species (FIICC, 1995). The bioaccumulation and concentration of such organisms within the shellfish was highlighted when

scientists found that *Vibrio* species may be present at concentrations that are 100-fold higher in oysters than those in the surrounding waters (Morris & Acheson, 2003). Significantly, many microorganisms ingested survive the oyster's digestive process (Butt, 2004) and once the oyster comes out of the water further microbial multiplication is likely.

Although oysters can be cooked in many ways, the oyster is possibly the only food that is eaten alive (Kurlansky, 2007). Indeed, oyster eaters have a high preference for eating them alive and raw (FIICC, 1995), so generally no thermal process is applied to oysters before sale. Nor are oysters gutted before consumption. These features mean that raw molluscan shellfish receive the second highest food safety hazard rating for all foods (ICMSFS, 1989). In an endeavour to manage this high risk most countries have implemented some form of governmental food safety regime<sup>2</sup> to control oyster pre-and post-harvesting conditions. These 'oyster-safety' regimes all build upon scientific understandings of the oyster, the bacteria that live within them and the environments in which they grow, along with the human health risks posed by the ways in which oysters are cultivated, harvested, processed, transported, stored and prepared for eating (BMRCS, 2006; NSSP, 2015).

## ***1.5 An Opportunity to Explore Further***

Traditional wisdom, science and societal governance have all been used in different forms and combinations in the quest to manage food safety and mitigate the risks involved in producing, distributing and consuming foods. Yet food safety regimes have been far from universally successful. In this thesis, I ask whether there are different ways of understanding the potential of science and of utilising it more effectively to build better food safety understandings, science-governance relations and ultimately food safety regimes.

Food safety is not only an important personal health issue, but also imperative for trade and economic reasons. The holy grail for many working in the field of international trade and food safety is a set of effective global food safety standards, leading all food actors to constrain their actions and redesign their processes. The aim of such standards is to eliminate risk to the full extent that this is ethically acceptable, economically viable and culturally appropriate, through some combination of regulatory force and/or self-interest. The ideal would be to ensure equivalent safety for all consumers. However, this goal is, of course, complicated by incomplete understandings of contemporary food safety relations - from the environmental to the biological and the sociological; the frailties of the science systems currently used to underpin food safety governance; the social and cultural factors linked to consumer confidence and dietary choices; competing regulatory ideologies; and the politics of national and international policy-making. Any new framework needs to find new ways of incorporating sound science

---

<sup>2</sup> Regimes are described by Rothstein (2004) as the rules, institutional arrangements and culture used to deal with a governance issue. FAO (2006) defines the elements of a national food safety regime to be food laws, policies, regulations and standards, institutions with clearly defined responsibilities for food control management, scientific capacity, diagnostic and analytical laboratories, an integrated management response, monitoring structures and capabilities, including inspection and certification infrastructure and equipment, surveillance of human health problems related to food intake, training, and public information, education and communication.

with often contradictory socio-cultural, political and economic imperatives. To do this requires a better, fuller understanding of the dynamics of science and governance.

My professional expertise is embedded in the implementation of food safety regulations in the applied world, but my interest extends to the relationship between science and food safety governance. My career includes 30 years employment in New Zealand's public health service as a health inspector, tasked with understanding and regulating factors in the environment that impact health, including food and drinking water, communicable disease control, occupational health and air/water/noise pollution. This role eventually led to my appointment as a government expert specializing in seafood safety matters, thrusting me into the international arena of seafood safety and market access. I also became (and remain) an active member of the USA Interstate Shellfish Sanitation Conference (ISSC) and the International Conference of Molluscan Shellfish Safety (ICMSS). The ISSC is the food safety forum responsible for establishing the USA shellfish food safety regulations, while ICMSS is the international forum which shares shellfish food safety science. For the last ten years I have been contracted as an international consultant for global governance agencies, including the United Nations Food & Agriculture and World Health Organizations. These postings have taken me from countries as diverse as Afghanistan to Zimbabwe, while working on various food safety/public health/governance projects. This international work consolidated my public health training, while also leading me to understand that while all humans have much in common, significant differences occur due to their biophysical, social and cultural environments.

In 2013-14 I took-up a food safety education scholarship offered to me by the U.S. Food and Drug Administration (FDA). Amongst, other opportunities, the two years provided time to reflect on science, public health and food safety. As a public health scientist, with now more than 40 year's food safety experience, I began to question why modern science had not delivered on its early promise to eliminate food safety problems.

My public health forbearers had achieved much by combining science and governance. I pondered why today such achievements are not always possible. Is this failure due to the current systems used to gather and disseminate scientific information? Has the relationship between science and government agencies weakened? Is there something about the risk analysis and assessment framework that is not fully understood? In other words, why is it that modern food safety science systems seem to have reached the end of a cul-de-sac? Do we need to retrace our steps to find the right path to eliminate food safety problems? Or is there an unidentified path, at the end of the cul-de-sac, with the potential to lead us to the lofty goal of global food safety?

The oyster is a helpful case for addressing these questions. As described in Section 1.4 it is internationally recognised as a problematic food. Oyster safety poses deep challenges for scientists, regulatory agencies and the food industry. Chronic vibriosis (illness caused by *Vibrio* bacteria) linked to eating oysters is one of those problems. My PhD project is a late-career exploration of new ways of framing the science-policy relationship in respect of this problem. It explores the oyster as a field of food safety which poses specific questions and is a field in which I have developed internationally recognised expertise. In short, it is a helpful case to make the point that more science per se may not be the answer

to enhancing food safety as the science between the oyster and *Vibrio* bacteria is relatively well established. Rather the PhD directs attention to how that science is deployed in mediating complex, political and messy relations among humans and non-human actors (biological and technological) and in spheres of economic practice, regulation and public knowledge. My prior work with scientists, industry, policy makers and public educators resourced me with rare insights into the complex of relationships amongst them, whilst also enabling access to documents and potential research participants in multiple nation-states, along with sub and supra-national science-regulator networks.

In this research, I ask how science is deployed in the management of oyster food safety, and to what ends; and in turn, what can be plausibly expected of science when it comes to tackling oyster food safety. When I began the project, I asked myself why science had not solved the problem of oyster food safety, but as the project progressed I came to recognise that this question was laden with a set of disabling assumptions – that the problem could be specified, that a solution was possible, that the behaviour of any of the key actors involved (*vibrio*, marine environments, oysters, oyster farmers, taste makers, scientists of different stripes, oyster sellers and eaters, and many others besides) could be predicted or redirected, and that the relationships among the actors were either instrumental or stable. My question needed to be subtler and framed in a way that would accommodate the complex politics and relationality of the agency involved. The thesis explores the nature of the shifting relationship between science and food safety policy in relation to oysters and asks what science might offer in designing and implementing better food safety regimes and what altered frameworks might be required to achieve that end.

In the end the thesis presents a new way of thinking about the agency at work that ought to cause scientists to pause and ask different questions about the contribution of their work, questions that transcend solutionism *per se*. I develop ideas from actor network theory and the wider science technology studies (STS) tradition to argue that it is the relationship between the ‘matters of fact’ and the ‘matters of concern’ that are important. The STS literature questions the objectivity of science and its various claims to present lasting and universal solutions. Actor-network thinkers go further to deconstruct science into its constitutive practices. Drawing on key concepts from actor network theory, I put the science of oyster food safety under the microscope by examining the ISSC as an assemblage of scientists, regulators, industry actors, the oyster, the *vibrio*, and various established practices, rules, knowledge claims, expectations, and other discourses. The analysis shows the problem of oyster food safety to be far more complex in practice than it is generally portrayed by lab-based food safety scientists; and that science itself is far less cut and dried a process than normally understood, in form, practice and potential. At the core of these realisations lie the messiness of human and biophysical (natural) worlds and the relationality of agency.

In the course of the work, the notion of ‘science’ itself comes under intense scrutiny and morphs in meaning. In this opening chapter, I treat science as a singular and unproblematic object composed of an established and stable set of practices. I define it in effect as the natural, health and social sciences, mathematics, engineering and technology (SAGE, 1999), each of which ‘disciplines’ a process of gaining knowledge and the knowledge gained by this process (PCE, 2004). This disciplining is to do with both epistemology and methodology, or the way certain processes are identified and interrogated, and

delimiting of the field of inquiry. I also talk here of science as a subject, a collection of actors and interests with a stable agenda and ways of knowing. By the end of the thesis, I interpret 'science', as both subject and object, in much more fractured and multiple terms. It is composed of myriad experiments, relations, actors (human and non-human), interests, institutions and so on – an assemblage held together and made to work for political reasons in a politics of knowledge production, influence, and resource seeking. The thesis is very much a story of this translation.

In carrying out the research, I draw on my own experience as policy official and consultant along with the rich database of observations, exchanges and documents that come with that experience. I also draw heavily on my role as part of the international shellfish food safety team, which gave me access to the key actors involved in crucial science-policy networks that fashion oyster food safety regimes in NZ, the USA and internationally.

My posting in the FDA also offered the opportunity to mobilise my professional background and obtain unique access to a prominent food-safety regulatory network. I interviewed all the ISSC scientists and the regulators responsible for determining the USA oyster food safety regulations. In all, I conducted 73 semi-structured interviews, providing a novel and information-rich source about the factors underpinning the USA vibriosis food safety problem. I was able to compare this information with similar informal discussions held with senior shellfish food safety scientists and public policy colleagues in other countries (Australia, Canada, Chile European Union and NZ) over the research period. When put together with my long-term work in the field, these formal interviews and informal discussions provide an unusually rich database for a PhD project in this field.

## ***1.6 Thesis Structure***

This thesis is presented in three parts. Part I (Chapters 1 and 2) further argues for a need to rethink food safety management and regulation. Chapter 2 develops an account of contemporary food safety, while exploring the role of science and its relationships with food safety and public policy. It traces the history of food safety science to identify definitive shifts in food safety regimes, from prohibition, food hygiene through to the contemporary regime of risk analysis. Chapter 2 goes on to argue that mainstream approaches to science policy studies have proven unable to offer ways of breaking certain impasses in our understanding of the science-policy nexus. The chapter explores ideas from Science Technology Studies (STS) as a source for new insights that are not normally considered in mainstream accounts of the relationships between science and policy. It highlights the work of actor-network (ANT) theorists including, Bruno Latour, Michel Callon, Gilles Deleuze and Annemarie Mol.

Part II (Chapters 3 – 5) explores the potential of ANT to extend the established ideas of science, public policy and politics. Specifically, ANT is used to recognize the agency and messiness of humans and the natural biophysical world, using the oysters as the lens to focus on food safety matters. Part III (Chapters 6 and 7) considers my research findings in relation to oyster science and policy in the USA to test the potential of actor thinking as a platform for enhanced food safety.

## CHAPTER 2: REVIEWING FOOD SAFETY, SCIENCE, PUBLIC POLICY AND SCIENCE TECHNOLOGY STUDIES

Societies have developed an extensive set of expectations of science with respect to food safety. Escalating challenges have put pressure on its capacity to respond and in turn, on the trust society has placed in science to render food safe, either through production or regulation. In its organization, the quality of its results and its implementation, food safety science is under increasing pressure to demonstrate that it is up to the job of making food safe. But are these realistic expectations to have of science? And are there more helpful ways of seeing the relationship between science and food safety than as either the food safety guardian or even the solution to the food safety problem? This chapter introduces three broad sets of literature to problematise the relationship between food safety and science: the mainstream food safety literature, the critical science-policy studies, and the actor-network tradition derived from science and technology studies. The chapter asks progressively more challenging questions about the nature of the science-food safety relationship and how science is deployed in food safety and to what effect. It develops conceptual tools from actor network thinking that I use later in the thesis to frame my analysis of the ISSC as a particular assemblage of science, food safety concerns and the diverse human and non-human actors involved in addressing oyster food safety.

### ***2.1 Food Safety in Changing Times***

A safe food supply is valued by all societies and enshrined by the World Food Summit 1996 as “the right of everyone to have safe and nutritious food, therefore national governments have the mandate to ensure the provision of a sufficient and safe food supply.” (FAO, 1996). No one wants to eat and then suffer the ill effects of unsafe food. Yet despite the Summit’s declaration of rights to safe food, each year, millions of people around the world suffer from some sort of ‘food poisoning’ (FAO, 1998; McCabe-Sellers & Beatie, 2004; Griffith, 2006; FAO/WHO, 2007; Jacob *et al.*, 2010; Powell, Jacob & Chapman, 2011; Fukuda 2015).

*Safe food* is defined by the World Health and the Food and Agriculture Organizations as “that which does not cause harm to the consumer when it is prepared and/or eaten according to its intended use” (FAO/WHO,1997). This definition of food safety, however, is deceptively simple. Food safety is measured not only in the social good of illness prevention, but also the economic costs of illness and food spoilage, the politics of nutrition, health and food security for all, and the human relationships between food, contamination and disease. In application, rather than directing attention to unsafe food, food safety requires attention to different sources and forms of harm caused by the multiple practices of food sourcing, distribution, preparation and eating. Not only that food safety requires the intervention by multiple other agents at any point within those practices, including movements in time and place associated with their interrelationships. Turned around again, food safety must not only confront different configurations of problem, risk and cause in different places, but also changes in the organisation of food supply systems, and the social, biological and chemical environments of food. What is in the frame

of concern is the complex architecture of harm and risk, chemistry, biology, economy and culture at both the local and global scales and across the various moments of food's life from production to consumption.

As a result, societies have always been concerned with food safety with governments historically adopting a food safety oversight and enacting wide-ranging public policies to secure it (Draper & Green, 2002; FAO, 2008). Indeed, food safety has traditionally been a means to achieve a socially desirable level of human public health protection (Caswell & Johnson, 1991; Antle, 1995; Henson & Caswell, 1999; Henson, 2008). Even in today's most neoliberal societies and economies, interventions<sup>3</sup> to ensure safe food are legitimate (Sachs, 2009).

Outbreaks of foodborne disease and food scares in recent years have led to heightened consumer interest and concern and a demand for safer food (McKechnie & Davies, 1999; Friends of the Earth, 2003; Grunert, 2005; Cheek, 2006). We only need to read Marion Nestle's *Food Politics: How the Food Industry Influences Nutrition and Health* or Michael Carolan's *The Real Cost of Cheap Food* to understand that food politics feature high on the public agenda. Foodborne outbreaks involving agents such as *Escherichia coli*, Salmonella, BSE (*Bovine Spongiform Encephalopathy*) and chemical contaminants have increased public anxiety and raised concern that modern farming methods, food processing and marketing provide inadequate safeguards for public health (De Marchi & Ravetz, 1999; FAO, 2003). Effective food safety governance requires public confidence, but this is challenged by food scares and scandals and adds new complexity to the food safety problem (McKechnie & Davies, 1999; EUFSA, 2006; McKenzie, 2006).

Globalising food systems have added new complexities to the source, nature and spread of unsafe foods. For thousands of years, long haul trade networks such as the Silk Road allowed the global movement of special, high value products, but since the 1980s international trade in mundane, daily foods has become routine. New demands for a year-round supply of exotic and seasonal produce mean further movements of food. Food exports are now a fundamental component in the global economy; and exports and imports of food are of fundamental importance for many individual countries. Seafood is in many senses, the example par excellence, and is now recognized as the world's most heavily traded commodity with 2012's global seafood trade reaching a record value of more than US\$129.3 billion (OECD-FAO, 2013).

The creation of a global mass-market for food has massively increased the interdependence, integration and interaction between people and companies around the world. The establishment of large international food corporations means ingredients can be sourced and prepared in one country, final products manufactured in another and then quickly distributed in large batches around the globe. And if this is not conducted within a single firm it is carried out in complex supply chains involving multiple moments and conditions of transformation and exchange. Each of these moments exacerbates the risk of contamination and the complexity of controlling for safe food. If for any reason any batch of food or

---

<sup>3</sup> Activities carried out to ensure the quality, safety and honest presentation of the food at all stages from primary production, through processing and storage, to marketing and consumption.

ingredients is contaminated, large scale food safety incidents can result. It is imperative that such incidents do not occur, not only for reasons of human health, but to avoid the financial costs they incur.

Increasing global connectedness, however, does not mean food safety problems are now the same the world over. Food safety problems vary depending on cultural and geographical differences (Dubos, 1959; Echols, 1998; Ababouch, 2006). Researchers, such as FAO (1995 & 1996) and Gupta (2002) highlight the sharp differences in food production and processing, food safety risks and problems between the 'global north' and 'global south' countries. In industrialized (global north) countries food production is now another industrial product, exemplified by intensive agriculture and animal husbandry and the associated extensive distribution systems. An industrialized food supply carries both benefits and risks. While the benefits include lower production costs, risks associated with contaminated food products in such systems can rapidly emerge and spread over wide geographical regions (Ababouch, 2006; Trienekens & Zuurbier, 2008).

In poorer, less developed regions (global south) producers and processors are commonly small-scale enterprises that operate in the absence of food safety regimes. Distribution and consumption are often localized with large volumes of fresh food traded in open markets (Unnevehr, 2000; Unnevehr & Hirschhorn, 2000; Cadilhon, 2006). Here food can be fresh but may be subject to less rigorous food safety provisions. Malnutrition continues to afflict people in the global south. Motarjemi *et al.* (1993), FAO (2003) and Maxwell & Slater (2003) declare that foodborne diseases are significantly more prevalent amongst poor consumers in developing countries because of insanitary surroundings and the habitual and necessary reliance on street-vended foods of dubious origin and quality. Those global south countries that export food products or have an extensive industrial food supply system can end up with two sets of food safety problems, one linked with their domestic consumers and the other associated with their export markets (Henson, Masakure & Boselie, 2005; Henson & Jaffee, 2008).

Transporting food across these different contours of food safety adds further complexity to the nature of the problems and the challenges of addressing them. Food safety of course remains a political priority (Vogel, 2003; Bergeaud-Blackler & Ferretti, 2006), such that globalization is forcing a rethink of how science and food safety governance are formulated and applied. Traditional wisdom and national food safety policies are no longer considered or accepted as sufficient to deal with the complex, persistent, pervasive and the rapidly changing food safety problems of a global economy. High-profile food scares and the economy and biology of globalising food supply networks has prompted reviews of food safety regulatory regimes and legislative action such as those following the 1996 BSE crisis (Halkier & Holm, 2006). Indeed, according to Giddens (1991) and Beck (1992) a new consciousness of the hazards and risks to health and wellbeing, produced by modern technologies in an increasingly globalized economy, have provoked new politics of consumption as well as government. They have in turn yielded new demands on science at the same time as a new scepticism about scientific solutions which has challenged confidence in governments and scientists and food safety regimes. I take this up this concept again towards the end of the following section.

## **2.2 Science and the Making of the Food Safety Problem**

John Snow made himself a place in history as the father of epidemiology on determining that London's water supply was the reason for an outbreak of cholera. He recognised that all kinds of disease, including water and foodborne, could be addressed and even eliminated by understanding the triangular relationship between the human, the agent (or disease) and the environment (CDC, 2006). In the years since Snow's discovery, science has added much more to the understanding of food safety. Other epidemiologists, such as Marks *et al.* (1998), have identified that the disease triangle within the human gastrointestinal tract involves a complex series of interactions and solving food safety problems is complicated by the lack of understanding about the linkages between human behaviour, contaminants and environmental conditions (Hedberg *et al.*, 1994; McCabe-Sellers & Beattie, 2004; Scholthof, 2007). Today the mechanical interactions between the human, disease agent and the environment are understood to differ under various circumstances and that there is much more to be learned about them.

Many of today's food safety scientists tend to classify foodborne risks to human health into three types of hazards: biological, chemical and physical (FAO/WHO, 1995; FAO, 1997; Reilly & Käferstein, 1997; Koren & Bissessi, 2002; Codex, 2003a). Within these three categories there is a complexity of problems stretching from natural environmental contamination of unprocessed foods through to poor hygiene practices by the domestic food handler when undertaking meal preparation (Holleran *et al.*, 1999; Kuiper, 2001; Powell, Schlosser & Ebel, 2004; Wilcock *et al.*, 2004; Ercsey-Ravasz, 2012). While more traditional food safety science directs attention to chemical and biological agents, another branch of food safety science directs attention to human behaviour and social causes (Cohen, 2000; Weiss & McMichael, 2004; Nachman & Lawrence, 2013). Here researchers highlight consumer and producer behaviour and social changes such as the commercialization, industrialization and globalization of food production; more frequent preparation of food outside the home; the shift of women from home to the work force; the rise of aged-care institutions; and other factors. Dietary changes, such as the increased global consumption of fresh and minimally processed foods, fish, seafood, meat, and poultry, are particularly significant in altering food safety risks (Roizman, 1995).

Understanding the causes and associated risks with unsafe food is not enough to protect people from unsafe food. Scientists have identified the causes of many historical food safety problems, such as cholera and tuberculosis. Yet, these diseases have yet to be eliminated (Barrett *et al.*, 1998; Käferstein, 1999; Morens, Folkers & Fauci, 2004; Newell, 2010; Knechtges, 2011). Indeed, some historical food safety problems which were thought to be under control are regaining prominence, such as acrylamide residues in baked and fried starchy foods, methylmercury in fish, *Campylobacter* in poultry and pathogens associated with raw milk supplies (Keener, 2004; Björnberg, 2005; Bolton *et al.*, 2008; Jackson, 2009). At the same time, food adulteration has long been recognized as a food safety problem, yet the literature reminds us that even today adulteration remains a risk. For example, in Spain in 1981, 600 people died while many others became ill due to the sale and use of rapeseed oil as olive oil (Knechtges, 2011; Ellis, 2012).

Unresolved historical biochemical food safety challenges are compounded by new contamination problems. Serageldin (1999), Käferstein (1999), Scott (2002), FAO (2004) and Knechtges (2011) have

all identified contributory causes for today's problems, including the application of agricultural chemicals, environmental contamination, use of unauthorized additives, microbiological hazards and other abuses that occur along the food chain. Many food safety pathogens that scientists have identified, such as *Listeria monocytogenes* (Kathariou, 2002) and *Vibrio* species (McCoubrey, 1996) remain poorly understood. Indeed, some of the pathogens of concern today were not even recognized as the cause of foodborne illness twenty years ago (Tauxe, 1997 & 2002; FAO, 2002).

New food safety problems are also constantly emerging (Tauxe, 1997 & 2002; Nair *et al.*, 2006; Skovgaard, 2007; Newell, 2010). These include the mutant protein (technically a prion) that causes "mad cow disease" (De Marchi & Ravetz, 1999); large food poisoning outbreaks associated with *E.coli* 0157:H7 (Buchanan, 1997); and the bacteria *Aeromonas hydrophila* and *Plesiomonas shigelloides* which have been associated with foodborne illness (Knechtges, 2011). Some new hazards have arisen indirectly from new food practices, such as the use of antibiotics in poultry factory farming. As a result, there is an increasing presence of bacteria in foods that are resistant to antimicrobial agents (Silbergeld *et al.*, 2008). Newly emerging zoonotic diseases such as swine disease (Davies, 2012) also provide many more questions than answers, while the potential food safety consequences of new food production methods, such as the genetic engineering of crops, remain uncertain (Kuiper *et al.*, 2001).

Food safety hygienists (Latour, 1993; Amjad & Hussain, 2005; Seaman & Eves, 2006; Hayes & Forsythe, 2013) have historically argued that to prevent foodborne disease it is important to prepare food in a clean and hygienic environment. Recent research shows it is not just a dirty kitchen that affects food safety. The wider global environment also can have an adverse impact on food safety problems (Miraglia *et al.*, 2009; Tirado, *et al.*, 2010; Farkas & Beczner, 2011). This means that global climate change has food safety implications. These include changes in temperature and precipitation patterns; increased frequency and intensity of extreme weather events; ocean warming and acidification; and changes in transport pathways of contaminants, which can all impact at various stages in the food chain from primary production through to consumption (Macdonald, Harner & Fyfe, 2005; Schiedek *et al.*, 2007; Tirado *et al.*, 2010). Climate change may also affect a wide range of other dimensions that impact food safety, such as agriculture, stock raising, global trade, demographics and human behaviour (Gregory *et al.*, 2005; FAO, 2008b; Chakraborty & Newton, 2011; Vermeulen *et al.*, 2012).

Science has identified the causes of food borne illness, while at the same time providing a better understanding of food safety problems and giving impetus and form to food safety regimes. Yet despite increasingly sophisticated science and great confidence in our understanding of many of the biological and human actors at work, food safety remains a live issue. Unacceptable rates of food borne illness remain and new hazards continue to emerge in the food supply system. Ensuring food safety to protect public health, promote economic development and retain consumer confidence remains a significant global challenge (Motarjemi & Käferstein, 1999; FAO, 2006; Havelaar *et al.*, 2010).

This challenge is complicated further by the growing recognition that it is science that has made contemporary large-scale industrial agriculture possible. Science is thereby implicated (or perceived to be implicated) in the issues that occur when things go wrong or when fears build. New technologies such as the genetic modification of agricultural crops have raised additional consumer food safety

concerns that require assessment (Frewer *et al.*, 1997; Singh *et al.*, 2006). Often science is used to understand food safety risks; yet the public are suspicious of the risks associated with new science. Indeed, many food consumers see science and technology as having produced current food safety and health problems and are cynical about their use as a potential solution (Consumers Association, 1997; McKechnie & Davies, 1999). Science can be seen as a double-edged sword—it offers the capacity to increase and improve the food supply, but the public are suspicious of the risks associated with the new science that underpins this capacity.

Science, its organization, its methodologies and its capacity to know, its value and the ways in which it is deployed by economic agents and regulators have all come under increasing scrutiny (Connell *et al.*, 2008; Campbell *et al.*, 2009). Many have come to question the way in which the whole socio-biological complex of food safety is understood and reduced to a technical problem that somehow science is expected to solve (Lupton, 2005; Busch, 2008; Scrinis, 2008). At the one level, new food safety hazards will continue to emerge because the relationships between people, their environment and the agents that cause foodborne illness are constantly changing. More fundamentally, as the discussion above illustrates, as science has become more sophisticated, it has become more focussed on specific entities or aspects. The critical issue is the dynamic relations among agents, human and biological, and the way these are woven into temporary assemblages of cause and consequence. These are what must be monitored and regulated to ensure food safety, along with a regime designed to do this work. It is to food safety governance that I now turn.

### **2.3 Regimes of Food Safety Governance**

More than simply the administration of a set of rules, the governance and management of food safety involves a complex configuration of experts and authorities; rules, norms and regulation; scientific knowledge; food safety practices and responsibilities; and rationalities and technologies of governance (De Solla Price, 1965; Echols, 1998; FAO, 2003; Johncheck, 2008; Knechtages, 2011; Nachman & Lawrence, 2013). Such configurations take different forms in different places and at different times and for Rothstein (2004) these configurations can be understood as distinctive *regimes of food safety*. The notion of regime is used here as a periodising device, as it is elsewhere in the sociological literature. Each regime has been entangled with science such that food safety has been a field of social activity largely constructed by science and heavily informed by it (De Solla Price, 1965; FAO, 2003; MPI, 2013; Nachman & Lawrence, 2013). In this section, I direct attention to the different instruments and technologies of governance at work in different food safety regimes over time, from the 13<sup>th</sup> Century to today's dominant regime of risk-analysis. Looking back these periods the temptation is to see them as settled around a-priori logics of regulation and mutually supportive technologies, rules and procedures. For simplicity, this is how I treat the history of food safety that I develop in this section and through the rest of the chapter. I use the notion of *governmentality* to give the account an historical momentum by emphasise the shifting relationship between science and governance. However, it is important to emphasise at this point, that as I turn to the present and my study of the ISSC, I shift theoretical registers to emphasise instability and food safety configuration in the making. That is, I go on to discuss them as

assemblages, drawing a distinction with earlier regimes as settled because I am not studying their emergence or internal forms.

The term governmentality is an abbreviation of the words "*governmental rationality*" [Kerr, 1999, p. 174]. It was coined by Foucault (1991) to draw attention to the practices and technologies of governance, their underlying logics and the problem of government itself. The concept directs attention to the links between technologies of power (governing, or the exercise of power) and the political rationalities (modes of thought) that underpin them and take elaborated forms around them (Reid, 2013). It is a helpful shorthand for referring to the complex interactions between strategies, practices, technologies and discourses of governance, and an important directive always to explore the rationalities underlying regimes of governance in the world. A governmentality critique highlights the 'how' of governance (Lemke, 2002; Lewis, 2016).

In Huxley's (2008: 1643-44) terms, *governmentality* is a "composite of practices, programmes and projects that aspire to bring about certain aims for the government of individuals"; and "mentality, the discursive 'truths' that serve as rationales for the aims of government of others and the self." It is the "system of thinking about the nature of the practice of government", with the emphasis on the practice (Gordon, 1991, p. 3). A governmentality "constitutes the intellectual processing of the reality which political technologies can then tackle." (Lemke, 2001, p. 191). Governmentalities frame reality in a way that then shapes the intervention – they produce the problem that must be governed. This is a very helpful way of thinking about science in the governance of food safety. It directs us to consider the practices at the core of any regime of food safety and the specifics of any part played by science – the knowledge, calculations and relationships with other actors.

A governmentality critique directs attention less to the search for the best or ideal form of governance (an approach that has parallels with traditional science policy studies – see below) but rather to how governing occurs (Gordon, 1991; Dean, 1999) which then directs attention to critique of practice (Rose, O'Malley & Valverde, 2006). These various scholars suggest that Foucault directs scholars of governance to ask:

- i) how governing is represented and made visible (representation);
- ii) what technologies of government are deployed to produce authority and make governing possible (intervention);
- iii) what forms of reason are deployed in governing? (knowledge, expertise, means of calculation); and

In the sections to follow in this chapter, the notion of governmentality helps to frame discussion and to direct attention to the interplay of practice, expertise and rationality in materialised regimes of food safety governance. I direct attention to specific regimes of food safety, which are each assembled around a dominant governmental rationality.

### 2.3.1 A History of Food Safety Regimes

Traditional food safety regimes relied on directives to do with social action and prohibition based on empirical observation, indigenous knowledge, and commonly held religious beliefs. These regimes framed interventions (social rules about what, where and when to eat, taboos, and punishments) in terms of extant understandings of cause and effects. They were built around certain understandings of human's place in the wider natural world (Eckinger, 2008; Meyer-Rochow, 2009). The first formal food regulations, such as the 13<sup>th</sup> Century British *Assize of Bread*, were promulgated to deal with adulteration issues. During the Middle Ages bread was an important nutritional source, indeed 'the staff of life', so there was public concern when illegal ingredients, such as sawdust, were added instead of flour (Richardson, 2001; Carrel, 2009). When culprits were linked to food adulteration public shaming was usually part of the punishment, such as pillorying the convicted vendor and forcing watered milk down his throat until a doctor or barber declared that the man could not swallow any more without danger (Laszitivity *et al.*, 2009). In Foucauldian terms this regime involved government by sovereign decree, policing, and spectacle.

These technologies were superseded by elements of a different governmental rationality in certain sectors, including the meat sector, where regulations set legal requirements around the quality and attributes of meat. Edelman (1908) and Jay (2000) describe the 1276 compulsory slaughter and inspection requirements for public abattoirs in Augsburg, Germany. These were early examples of grades and standards, which established inspection principles using the organoleptic tests of vision, smell and touch to determine the food safety status of meat. This was not prohibition, but a different technology of control that responded to the problems of the time. It represented a clever conversion from sensory observations to a standards-based governmentality that drew on the biological capabilities of humans to match measurement by the senses to incidence of disease. The major public health concerns of the time were the potential for disease transmission from sick animals to humans and the lack of sanitary conditions for animal slaughter and production of processed products (Edwards, Johnston & Mead, 1997). The purpose of carcass inspection was to keep meat from diseased animals out of the food supply. These traditional meat inspection principles remained the primary method of determining the suitability of meat for human consumption until the 1990s. Most countries, including New Zealand, still employ meat inspectors who work under the supervision of veterinarians to check every live animal and every carcass for signs of disease (Hulebak & Schlosser, 2002).

By the late nineteenth century, a new regime had emerged, which might be termed 'the food hygiene regime'. The early concern with adulteration and meat inspection had gradually expanded to encompass bacterial contamination and risks of food poisoning (Hardy, 1999; French & Phillips, 1999). This was as a direct result of the 'golden age of microbiology' which started with Louis Pasteur's discoveries (Weeks & Alcamo, 2008), the universal acceptance of germ theory and advances in laboratory microbiological testing (Guardino, 2005). Scientists' ability to see, study and explain how pathogens infect bodies seemed to promise that infections could be contained and controlled (Cockerill *et al.*, 2017). The understanding that germs caused disease encouraged the belief that food safety could be easily controlled by finding and destroying all bacteria (Cassell 1986; Schafer *et al.*, 1993). As a result, most national governments introduced the food inspection rationality (Koolmees, 2000; Powitz, 2004).

The food hygiene regime drew on different expertise and was based on assessing the hygiene conditions at individual food premises, undertaking adulteration and fraud inspections and taking samples of the finished food product for laboratory analysis (Codex, 1969; Duffy, 1992; FAO/WHO, 2002; FAO, 2008; Malik, Masood & Ahmad, 2014). The design and facilities of food premises, in-process control, and hygiene and sanitation programmes were all considered essential for food safety (Ross, 1958; Griffith, 2006). To ensure food safety, national governments enacted food hygiene regulations, for example, New Zealand's Food Hygiene Regulations 1974. These regulations focused on the physical structure of food premises, such as light-coloured walls (so that dirt could be easily seen), smooth and easily cleanable surfaces, along with worker behaviour within the food premises (Dept of Health, 1981). Governments around the world employed cadres of food inspectors, sometimes also known as sanitarians or health inspectors (Codex, 1969), to undertake food hygiene inspections.

Traditional food hygiene regimes have been criticized because both inspection and end-product sampling are reactive procedures. They seek only to correct food safety concerns that already exist, rather than prevent future violations from occurring (Merrill, 2000; FAO, 2008; May, 2007). The processes involved by both the inspector and the inspected have been widely criticised. Hygiene inspections typically rely on snap-shot observation of products and practices; such snap-shots providing sparse information on what the hygiene conditions might be like at other times. In some cases, when inspections are scheduled, operators and food handlers make special efforts to impress the inspection team (Ehiri & Ejere, 2008). Such cosmetic efforts defeat the purpose of inspection and erode confidence that conditions observed during inspections will be maintained afterwards. According to Aston (1993), attitudes can vary greatly between inspectors, from the trigger-happy gung-ho inspection officer, to the one who lacks professional courage, fearful of the consequences. Traditional hygiene inspection procedures have also been found to lack specificity and are therefore, dependent on the subjective opinions of inspection officers, especially where the regulatory acceptability criteria incorporate words and phrases such as 'adequate', 'as far as practicable', 'suitable and sufficient'. More importantly, most of the poor practices that lead to outbreaks of food-borne diseases, for example, improper cooling or unacceptable delay between preparation and consumption may only be in evidence overnight and at other times when inspections may be impracticable (Bryan, 1988).

End-product food sampling has also been criticised as reactive (Bryan, 1992; Ehiri & Ejere, 2008). Food sampling and laboratory testing take time, which means in most cases, the food in question will have been consumed before the test results are known. There is often no connection between the visual cleanliness of a food premises and the sampling results (Tebbutt, 1986) as exemplified in a New Zealand study by Hathaway & McKenzie (1991) which determined a poor correlation between microbiological results and visual inspections. In summary, the food hygiene inspection rationality is criticised because it focuses solely on the individual food premises and not the wider food chain, such as the supplier, the transporter and broader environmental conditions. Such criticisms made it clear that there needed to be a change in the government rationality for food safety. In short, there was a desire to find more predictive and preventative food control systems; systems that had the capacity to more accurately determine the food safety risk, not only at the food processing premises, but across the wider food production and supply chain (Ababouch, 2006).

### 2.3.2 Arrival of the Contemporary Risk Based Regime

The word *risk* implies uncertainty along with possible danger, injury or loss. From an evolutionary perspective making sense of the world and ensuring survival relied upon knowing what might happen under different circumstances. Being able to readily identify a potential problem (i.e. the risk of being eaten) and then solve that problem (avoid the risk by running away) enabled *Homo sapiens* to flourish (Kahneman, 2011).

Nothing in life is without risk<sup>4</sup> and like it or not, food is included (Wilson & Crouch, 1987). As with eating, every aspect of our lives involves risk-benefit decisions, conscious or not (Roberts, 1975; Wildavsky, 1979; Slovic 1987; Lee, 1989). Coping with risk can be complex and controversial with people tolerating varying degrees of risk (Miller, 1992). The magnitude of food risks is becoming more difficult to identify, measure and prevent, yet there is heightened awareness of the risks of eating (Lupton, 2005). Fuelled by media attention on the introduction of genetically-modified foods, outbreaks of bacteria such as salmonella, the advent of BSE and the cloning of livestock, food risks are now widely recognised. At the same time, these risks cannot be delimited spatially or temporally, cross culturally or across geographical borders. Partly in response, in recent decades, governments and industry have devoted considerable resources to develop and apply techniques of risk analysis and risk characterization to make better informed and more trustworthy decisions about hazards<sup>5</sup> to human health, welfare and the environment (Stern & Fineberg, 1996). Somers (1995) writes that the concept of a formal “risk analysis system” was developed in the 1970s. Originally it was applied to engineering and nuclear safety problems, which according to Somer “resulted in the imprint of these rigid and cartesian sciences.”. In other words, the original risk analysis process was mechanical, using rigid formulas to reach detailed quantitative results on which to base decisions.

The basic strategy of risk analysis was to provide governments with a methodology to deal with risk management decisions. One of the reasons the risk analysis process became popular was because while physical scientists were familiar and comfortable with uncertainty, policy analysts and regulatory authorities were not. They wanted more certainty and information on the risks they were dealing with (Weinberg, 1972; Kahneman & Tversky, 1979; De Marchi & Ravetz, 1999). Risk analysis provided a rationale framework for laying out and systematically documenting the problem, historically using four basic elements: risk identification, risk estimation, risk evaluation and risk management (Whyte & Burton, 1982; FAO, 1997).

Governments and other authorities have established risk management systems to deal with threats to body or property, often based on the belief that if scientists provide the knowledge to eliminate risks, then individuals will maintain less risky conditions (Cockerill, *et al.*, 2017). It was assumed that the decision makers would review this information in an objective fashion so that societal risk management decisions on public health, education and economic decisions could be made equitably and openly (Starr, 1969 & 1985; Somers, 1995; FAO, 1997; OMRA, 1997). The assumption runs thus: If biophysical

---

<sup>4</sup> Risk - a food safety risk is defined as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in a food (FAO, 2005).

<sup>5</sup> Hazard – a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (FAO, 2005).

systems are unpredictable and uncontrollable only because humans lack understanding, then increased knowledge of those systems should increase humans' ability to predict and ideally control specific phenomena (Cockerill, *et al.*, 2017).

### 2.3.3 Hazard Analysis Critical Control Point as Risk Control Technology

The application of risk analysis principles to food safety was pioneered by the American Space Program to restrict food poisoning in space. The National Aeronautics and Space Administration (NASA) wanted a "zero defect" program to guarantee safety in the food astronauts would consume. The Pillsbury Company, using the risk principles previously applied to engineering and science problems, designed the Hazard Analysis Critical Control Point (HACCP) system as a means of assuring the safety of food produced for the USA space program. After surveying available control options, NASA recognized that HACCP was the system that could provide the greatest assurance of safety while reducing dependence on finished product sampling and testing (Pillsbury, 1973; Schlosser, 2002). The original Pillsbury HACCP procedure contained three components: the identification and assessment of all hazards associated with the final foodstuff; the identification of the critical steps or stages within food production at which these hazards might be controlled, reduced or eliminated; and the implementation of monitoring procedures at these critical steps (Pillsbury, 1973; Bauman, 1995).

As early as the 1980s many countries started to use these same HACCP principles in their national food safety programmes. The HACCP rationality focussed on operations at individual premises with industry taking responsibility for developing and implementing their HACCP based quality control programmes and regulatory authorities responsible for approving and monitoring the programme (Ababouch, 2006). HACCP was recognized as a science based and systematic tool that assesses hazards and establishes control systems that focus on prevention (National Assessment Institute, 1994; Ropkins & Beck, 2000; Mill, 2001) and was a way to supplement the hygiene model and move on from end-product sampling and inspections (Bryan, 1990; FAO, 2004).

Although there is evidence that HACCP based food safety regimes applied at individual premises did work there was increasing evidence of the need for an integrated system, multidisciplinary approach to food safety that embraced the whole food chain (Motarjemi & Käferstein, 1999; Ropkins & Beck, 2000; Sperber, 2005; Ababouch, 2006). Others (Buchanan, 1997; Havelaar *et al.*, 2010; Nachman & Lawrence, 2013) also recognized the need for a different food safety system due to worldwide trends affecting food safety risks, including the growing movement of people, live animals and food products across borders, rapid urbanization in developing countries, and an increasing number of immune-compromised people. These trends altered both the nature and incidence of food safety risks in the world's interdependent food production and marketing system.

### 2.3.4 Risk Regimes in Practice: International, National and Local Food Safety Governance

It is not just central and local governments that have an interest in food control; international governance agencies also have a role. The United Nations (UN), the World Health Organization (WHO), the Food

and Agriculture Organization (FAO), Codex Alimentarius Commission (Codex) and the World Trade Organization (WTO) have all taken a lead in this endeavour (FAO, 2003; [www.codex.alimentarius.org](http://www.codex.alimentarius.org)). The United Nations (UN) was established after World War II as an intergovernmental organization to promote international co-operation (<http://www.un.org/en/about-un/index.html> accessed 26<sup>th</sup> March 2018). FAO, established in 1945, is the largest autonomous agency within the UN and is charged with the specialized role of dealing with all aspects of food quality and safety throughout each stage of food production, storage, transportation, processing and marketing (FAO, 1998).

FAO went on to establish the Codex Alimentarius Commission (Codex) in 1962, assigning the Commission with the responsibility for protecting the health of consumers and ensuring fair trading practices; setting international standards for food safety and hygiene; and implementing the joint FAO/WHO food standard programme (FAO, 1998; Kimbrell 2000; Zlotkin *et al.*, 2010). Today Codex is an intergovernmental body with 185 individual country members (including New Zealand) and covering 99% of the world's population, who have signed up to abide by the established Codex process ([www.codexalimentarius.org](http://www.codexalimentarius.org)). Being a government-to-government organization Codex conducts its business through a network of committees. Once the member countries have debated and agreed to the Codex standards, these standards form the basis of their national government food safety legislation (WHO, 2002; FAO, 2008).

In 1993, the HACCP system was endorsed by the twentieth session of Codex for identifying, evaluating and controlling hazards significant for food safety (Codex, 1969, 2003). It was Codex's recommendation that the HACCP approach be used wherever possible to enhance food safety, stating that this approach was internationally recognized as ensuring the suitability of food for human consumption and for international trade (FAO, 1998).

However, Codex, FAO and WHO eventually recognized the need to change the traditional food hygiene inspection and individual premises-based HACCP system (or government rationality) due to the increasing volume and diversity in trade of foods, changing agricultural practices and climate, more sophisticated detection and management of hazards, changing human and ecology, and greater demands for health protection (FAO, 2006). Concerns about intentional adulteration of food from bio-terrorism also increased attention to food safety. As a result, Codex determined the need for a food safety rationality that took a more holistic view than HACCP's focus on individual premises (Ababouch, 2006).

By the the late 1990s Codex identified the need for governments to use a total *food chain approach*, recognizing that the responsibility for a supply of food that is safe, healthy and nutritious is shared along the entire food chain by all involved with the production, processing, trade and consumption of food. Indeed 'farm to the fork' became the new food safety mantra (Lammerding & Fazil, 2000; Opara, 2003; Loureiro & Umberger, 2007). As the food chain approach become popular, international and national food authorities began to consider the use of a formal risk analysis food safety rationality to reduce foodborne illness (FAO, 2006: [www.mpi.govt.nz](http://www.mpi.govt.nz); [www.usfda.org](http://www.usfda.org); [www.fsanz.org](http://www.fsanz.org); [eufsa](http://eufsa.org)).

The literature highlights that what pushed the international application of risk analysis was the increasing globalization of the food trade (Hathaway, 1997; Henson & Caswell, 1999; Wilson & Tsunehiro, 2001).

While FAO and WHO aspire to have global consumer protection, the World Trade Organization's aim is unimpeded global trade. In 1995, the WTO made risk analysis a mandatory food safety system to ensure a harmonized global approach, while avoiding unfair trade practices and disguised technical barriers to trade. Two binding agreements made risk analysis a mandatory food safety system; the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures (WTO, 2005a) and the Agreement on Technical Barriers to Trade (WTO, 2005b). The SPS Agreement requires that SPS measures be based on an assessment of the risks to humans, animals and plant life and health using internationally accepted risk assessment techniques. It requires that about food safety, WTO members base their national measures on international standards, guidelines and other recommendations adopted by Codex where these exist. To justify and compare the levels of public health protection and related food safety measures, risk sources must be analysed, the risk estimated, and risk management options evaluated (Codex, 1999). This required a fully harmonized global approach to ensure trading equity while avoiding unfair trade practices and disguised technical barriers to trade. Therefore, "risk analysis" has become the method for establishing tolerable levels of hazards in foods in international trade and, equally, within national jurisdictions (WTO, 2005a,b; Ababouch, 2006).

At the time of the 1995 WTO decisions FAO recognized that there was a large amount of uncertainty around the scientific understanding associated with food safety risks and that only in rare instances would all the necessary information be available for full risk assessments (FAO/WHO, 2005a; Ababouch, 2006). Never-the-less Codex felt a responsibility to be "technology forcing" and strongly recommended the development of such data (FAO/WHO, 2005a). In response FAO and WHO jointly launched what they described as a 'structured decision-making process', developing a systematic framework for applying the principles and guidelines for food safety risk analysis. (FAO, 1997). There is now consensus between Codex, FAO, WHO and WTO who have agreed to accept scientific information as the framework to address all food safety problems.

### 2.3.5 Science and the Food Safety Risk Analysis Regime

The risk analysis decision-making process is structured into three distinct, but closely connected components: risk assessment, risk management and risk communication (FAO, 2006). At its base, then, lies risk assessment, which has generally drawn its understandings and practice from science and actuarial calculations that allow for making decisions to protect health in the face of scientific uncertainty (FAO, 2006). As argued by OMRA (1996) FAO (2002, 2006) and Ababouch (2006) risk assessment should consider the available scientific evidence, the relevant processes and production methods, the inspection/sampling/testing methods, the prevalence of specific illnesses, as well as other common factors.

*Risk assessment* is in turn understood to take place in a series of steps first laid out by FAO/WHO in 1995. These are:

- i) *hazard identification* - the identification of agents capable of causing adverse effects which may be present in a food or group of foods;

- ii) *hazard characterization* – the quantitative and/or qualitative evaluation of the nature of the adverse health effects associated with the agents which may be present in the food;
- iii) *exposure assessment* – the qualitative and/or quantitative evaluation of the likely intake of the agents via food; and
- iv) *risk characterization* – the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse effects in a given population based on hazard identification, hazard characterization and exposure assessment (NAS, 1983 & 1994; Paustenbauch, 1995; FAO, 2006).

Each of these steps is framed and informed by science, while the linear approach is standard science practice. This risk assessment process is now accepted by all Codex countries as the framework in which to consider food safety problems (Zsidisin, 2004; WHO, 2006; van Leeuwen & Vermeire, 2007).

The FAO risk analysis formula has been used to measure and describe many pathogens of food safety significance, including FAO/WHO's *Risk Assessments of Salmonella in Eggs and Broiler Chickens* and *Risk assessment of Listeria monocytogenes in ready-to-eat foods* ([www.fao.org](http://www.fao.org)). Pathogens associated with shellfish food safety concern have also been the focus of risk assessments, for example, norovirus in bivalve shellfish (Suffredini, *et al.*, 2014). Furthermore, there are multiple national and international risk assessments that have measured the risk associated with eating oysters contaminated with *Vibrio* bacteria (McCoubrey, 1996; FAO, 2005a; USFDA, 2005; FAO, 2011). These include the USFDA's report *Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus In Raw Oysters* and FAO/WHO's *Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus In Raw Oysters*. The latter risk assessment estimates the risk of illness from Vp due to eating raw oysters in Australia, Canada, Japan and New Zealand (FAO, 2011). Much of this *Vibrio* risk assessment work was based on scientific evidence gathered from the USA where vibriosis illness is the most prevalent.

Risk analysis frameworks are underpinned by the separation of the risk assessment (scientific) step from risk management (the decision-making step). The orthodox split of science from public policy is separation was recommended by the joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues held in Switzerland, March 1995 and has been reinforced in their risk analysis guidance literature (FAO, 2002; FAO, 2004; FAO, 2005a,b; FAO, 2006). This functional separation is considered essential to maintain the scientific integrity of the risk assessment process and to avoid political pressures that would undermine the objectivity and the credibility of the conclusions (FAO, 2006). The National Research Council of the USA Academy of Sciences also makes an explicit distinction between risk assessment and risk management: risk assessment is to be based on scientific judgement alone and must find out what the problems are; it should be protected from political influence (Nowotny, 1990; NAS, 1983). Therefore, it is international norm that national food safety authorities require the separation of risk assessment and risk management, on the understanding this separation helps ensure assessments are not biased by pre-conceived opinions related to management solutions (OMFRA, 1997; FAO, 2006).

Proponents of food safety risk analysis state that the value of risk assessment lies not only in its ability to estimate human risk, but also in its use as a frame for organizing data as well as allocating responsibility for analysis by policy makers (Somers, 1995; OMRA, 1997; FAO,1997). It can however, document and clarify the components of risk, leading to a more efficient and effective utilization of resources and better decisions. In addition, risk analysis identifies gaps and uncertainties in scientific knowledge of risks, which can help set research priorities and contribute in the long term toward improved understanding of food-related impacts on public health (FAO, 2006).

There is, however, a growing realization that the use of the risk analysis/assessment system is not straight forward (FAO, 2006; Shumway & Rodrick, 2009). It has been criticised by regulators, critics of regulators, and scientists (Royal Society,1992; Somers, 1995; Hanson *et al.*, 2003). OMFRA (1997) insists that it does not provide a 'magic black box' solution to our problems. Much of this criticism relates to the use of science within the model. In their 1996 publication *Understanding Risk Informing Decisions in a Democratic Society* the National Research Council explains that risk characterization as determined by the risk assessment step is "often conceived as a summary of translation of the results of technical analysis for the use of a decision maker". Seen in this light, a risk characterization may fail for two reasons: it may portray the scientific and technical information in a way that leads to an unwise decision, or it may provide scientific and technical information in a way that is not useful for the decision maker.

An objective of the risk assessment is to promote harmonization of methodologies across chemical and biological disciplines (OMRA,1997). Yet the food safety problems associated with chemical versus microbiological hazards differ (FAO/WHO, 1995) are not the same. Modern chemistry has allowed the identification and quantification of chemicals, even down to a few molecules. Yet even for a well-researched field such as ionizing radiation the choice of models for extrapolation has been the subject of much controversy (Beir & Moslei, 1990; Somers, 1995). Any method used to assess the risks of hazards from foodborne bacteria will be complicated by factors resulting from methods used to grow, process, store and prepare food for consumption. These can vary greatly depending on cultural and geographical differences. Science is uncertain, particularly when it comes to biological problems which are inherently difficult to assess (FAO, 1995; Cockerill, *et al.*, 2017).

Risk assessment is also compromised by its resource intensiveness in terms of scientific input and time. Effective incorporation of risk assessments in the development of food safety standards requires systematic and transparent application of a framework for managing food-borne hazards (FAO, 2002). It is important that risk assessments are comprehensive because as Taylor (Public Service Volume 20) concludes risk-based disputes may arise when risk assessments are based on limited information, inconsistent methodologies, uncertainties and assumptions (stated or unstated) which produce varying risk estimates. Others (Coppock, 1983; Royal Society, 1983; Nowotny,1993) point out that risk analysis has been confronted with the problematic situation that while the intention is to provide clear and careful hazard analysis, the analysis, selection and implementation of intervention measures generally involve balancing scarce resources, political goals, changing social values, and sometimes a somewhat unpredictable public opinion.

The separation of risk assessment and risk management has also been vigorously criticized by sociologists as being simplistic and fundamentally unrealistic (Royal Society, 1992; Somers, 1995). It has even been stigmatized by Watson (1981) as “the phlogiston theory of risk”. The postulated distinction between pure, objective science as opposed to subjective, social and political management of risk has led to a mechanistic approach to decision-making whereby too great an emphasis is placed on quantification. Governments must continually negotiate risks and costs of intervention to the individual and population, often in heated debates over ethics, rights and responsibilities (Cockerill, *et al.*, 2017). The Public Health Protection Branch of the Canadian Health Association recognizes a simplistic application of the purported objective methods of science can lead to serious miscalculation of the public’s reaction to risks (Hanft, 1981; Somer 1995; PCE, 2004; Cockerill, 2017).

Hanson *et al.*, 2003 has pointed out that trust in experts, and in scientific institutions, is decreasing, often in the wake of earlier crises and problems caused by an uncritical reliance on expert knowledge. A case in point is the BSE debacle, where experts first assured the public that there was no danger to humans and then admitted that this was not the case (Jasanoff, 1997). In this climate, the suggestion that experts should simply raise public awareness of the ‘real’ extent of a hazard appears simplistic: there is little prospect of this happening until the relationship between the experts and lay people has been addressed directly and improved. Finally, people may have concerns other than those addressed by science—indeed other than those science can address. They may therefore disagree with experts and their science-based recommendations for numerous reasons other than lack of understanding (Poortinga, Wouter & Pidgeon, 2005). Increasingly policy makers have come to realize that the only sensible future for the development of public policy concerning food safety must depend on sound science and on the development of processes and procedures that utilize the available science in a rational way to arrive at public policy decisions (FAO, 1995).

There is a growing realization that the use of risk assessment in developing risk management strategies is not straight forward. (FAO 2006; Shumway & Rodrick, 2009). Structuring an effective analytic-deliberative process for informing a risk decision is not a matter of set formulas. Every step involves judgment and the right choices are situation dependent. Still it is possible to identify objectives that also serve as criteria for judging success. These objectives include getting the science right; getting the right science; getting the right participation; getting the participation right; and developing an accurate, balanced, and informative synthesis. (Stern & Fineberg, 1996).

Despite improvements made in the risk assessment area, it is recognized that improved scientific tools must be adopted and novel flexible approaches to food safety sought (Ababouch, 2006). The quest for the perfect food safety system which adequately manages the public health and economic risks to individuals and wider societies continues. Meanwhile, despite the criticism risk analysis and assessment remains the framework for developing food safety standards and controls. This supposedly objective science-based framework is used by international, national and local government agencies tasked with the responsibilities of protecting public health, valuable food resources and the significant economies associated with the food trade.

### 2.3.6 Messiness of Universal Food Safety Regimes

While Codex has produced generic food safety guidelines, the formulation of appropriate standardized regulations, that can be uniformly applied across all regions and nations remains problematic. Specific interests in the global food supply system vary enormously from country to country; the food security and food safety issues of Zimbabwe, for example, are very different to those of the USA. Work experience by the author of this thesis as the sub-Saharan Food Safety Advisor for the United Nations in 2011, highlighted the fact that in Zimbabwe, as in the rest of sub-Saharan Africa, it is critical that freshly harvested corn (*Zea mays*) is stored in dry, vermin-proof storage facilities. Damp storage causes the growth of fungal species, such as *Aspergillus flavus* and *Fusarium* spp., which in turn produce aflatoxins. Aflatoxin contamination has been associated with growth stunting in children, immune suppression, micronutrient deficiencies, and higher prevalence of cancers in sub-Saharan Africa, East Asia, and China (Moturi, 2008; Hell, 2010; Oyekale *et al.*, 2012; Smith, Stoltzfus & Prendergast, 2012). On the other hand, the safe storage of raw corn is not a significant USA problem, where instead food safety issues are usually linked with highly processed foods, such as the wide use of corn syrup in the national food supply (Bell *et al.*, 1994; White, 2008).

National rules serve to meet national goals and expectations as to what is acceptable, although other nations may reject these same rules as inappropriate to their own needs. This is evidenced and highlighted in the current shellfish trade embargo between the EU and the USA, due to disagreement over the equivalency of national food safety governance frameworks. Both the EU and the USA have their own individualized shellfish food safety regime. Both systems aim to protect consumers, but use different scientific parameters (EU, 1991; NSSP, 2015). The EU imposed its USA trade ban in 2010, the USA reciprocated in 2012 and to date there remains no consensus on the way to manage shellfish sanitation controls. This embargo exemplifies the difficulty in formulating national food safety governance policies that can be aligned across nations, even when science is used as the basis for governance controls. Importantly, this embargo also has had a significant ripple effect. Many other nations model their own governance practices based on either the USA shellfish model or that of the EU. The result is that there are now two different “silos” or food safety philosophies. Consequently, global traders find that unless they can comply with both the USA and the EU regulatory requirements, their international market access is seriously constrained.

The on-going EU/USA shellfish trade embargo is not unique. Other countries have experienced similar problems. For example, for many years Australia would not import New Zealand apples because of the perceived biosecurity risk, even when scientists declared that such risks were insignificant (Higgins & Dibden, 2011). Undoubtedly, more similar issues will emerge. Even when there is enough scientific evidence of a problem, governments, for other reasons, still often may not permit trade. For example, the failure of the New Zealand Food Safety Authority in 2007 to ban the import of contaminated Korean oysters is explained by New Zealand’s determination to retain the lucrative Korean beef market (Simmons *et al.*, 2007). Therefore, the concept of overarching international food safety governance, allowing easy market access, remains increasingly problematic.

Given the multiplicity and diversity of national food safety problems, Codex quickly recognised that:

Food regulations in different countries are often conflicting and contradictory. Legislation governing preservation, nomenclature and acceptable food standards often vary widely from country to country. New legislation not based on scientific knowledge is often introduced, and little account may be taken of nutritional principles in formulating regulations. (FAO, 1950. <http://www.fao.org/docrep/w9114e/W9114e03.htm> accessed 1st May 2018).

In 2010 FAO launched a four-year programme *Science for Safe Food Strategy* with the aim “To serve in partnership with WHO as the leading global reference for scientifically based standards and guidance on science-based approaches to improve global food safety and afford adequate levels of consumer protection and facilitate trade.” Attempting to achieve international food safety uniformity Codex mandates science as the basis for forming food safety standards, with all member countries expected to also apply this framework at the national and local level. While recognizing national differences, FAO, WHO and WTO all believe that sound scientific evidence should be used to design globally accepted, unilateral standards because it considers science offers a neutral *frame*<sup>6</sup> with which to measure and manage risk.

The last sections have pointed to the part played by science in defining food safety, creating the food safety problem, and prompting and propping up various food safety regimes. They have identified some of major gains made through science, but also to various criticisms of the ways in which science has been incorporated into these regimes and the effects that it has then had on food safety. In the following sections I turn to how this critique of science might be understood in more generic and theoretical terms. I ask how we might understand the status of science in knowledge frameworks and its performative impacts, as well as its role in food safety regimes.

## ***2.4 Science and Public Policy – a History of Entanglement***

Science has made a major contribution to food safety, both through preventative actions and medical interventions. It has contributed to improvements in the manufacturing and preservation of food, extended life expectancy, improved public health and food safety, and the mitigation of environmental problems (De Solla Price, 1965; Cassell, 1986; Baggott, 1990; Clark & Majone, 1997; SAGE, 1999; WHO 2003). These gains have encouraged food producers and regulators alike to invest heavily in various forms of food science. However, such gains have been made against a backdrop of increasing public awareness of scientific uncertainty and false assurances of safety made in the name of science (Consumers Association, 1999). This has raised trust issues that have complicated efforts to institutionalise it into risk regimes and led to calls for transparency about the state of scientific knowledge on food safety issues (Judt, 2010; Jacobs, 2016). They have also led to calls for greater honesty on the part of the scientist (PCE, 2004) and improved communication (Bowler, 1992; Bromley, 1993; Doble,

---

<sup>6</sup> Frames have been defined in various ways (Gamson & Modigliani, 1987; Goffman, 1974; Ryan, 1991). At the most basic level, a frame is a ‘package’ involving a particular description or definition of an issue or problem which (implicitly or explicitly), identifies its causes and possible remedies (Gamson & Modigliani, 1987).

1996; Dovers, 1996; Von Schomberg, 1997; SAGE, 1999; OXERA, 2000; PCE, 2004). However, there are deeper issues to consider.

#### 2.4.1 Science, Nature-culture and the Scientific Method

*The Scientific Revolution was one of the great intellectual mutations of mankind (Funtowicz & Ravetz, 1993)*

Science initially evolved during the Age of Enlightenment (or Reason) in the 1600s; a period which Remple (2003) describes as a time “in which the power of human reason would sweep away ancient superstitions and allow a new social framework to emerge”. It was during the Enlightenment that ‘natural philosophy’ was replaced by new science systems, identified as having the potential to exploit and manipulate all other living things (Mulkay, 1979). Accumulation of knowledge, reason and analysis and the rise of the enlightenment contributed to the new order of science (Heilbron, 2003; Dietz, Ostrom & Stern, 2003), in turn transforming the views of society and nature (Knight, 1975). By the 19th century the concept of ‘natural philosophy’ was replaced by science, and the institution of a value free scientific method became increasingly well established (Funtowicz and Ravetz, 1993). According to Bowler (1992) and Mulkay (1979) the Revolution established the modern science paradigm which aimed to increase knowledge and govern the world.

Certainly, it was during this Age that the concept of the ‘nature-culture divide’ originated, based on the premise that *Homo sapiens* could be segregated from the rest of the biophysical (natural) systems (Brown *et al.*, 2011; Cockerill, 2017)). Horkheimer, Adorno & Noeri (2002, p.30-31) aptly describes this in their *Dialectic of Enlightenment*, “human beings distanced themselves from nature, so they might arrange it in such a way that it can be mastered.” Humans began to believe that it was possible to control external nature, elevating humans above the rest of the biophysical world. The perceived pinnacle of culture in the nature-culture divide was scientific knowledge which mastered nature and enhanced human beings (Latimer & Miele, 2013).

The cornerstone of the Scientific Revolution was the emergence and evolution of the scientific method (Bowler, 1992). The *Oxford Dictionary* defines this as “a method of investigation in which a problem is first identified, observations, experiments, or other relevant data are then used to construct or test hypotheses that purport to solve it.” The objectivity of science lies in its willingness to subject every aspect of the hypothesis to rigorous testing. The new observational methods were designed to establish rational, natural explanations rather than rely on the supernatural, traditional wisdom and Nature to provide solutions (Lucretius, 1951; Seamon & Zajonc, 1998). The traditional characteristics of science excellence were seen as originality, objectivity, rigorous methodology, repeatability, research, integrity and ethical behaviour (CSTA, 2001). The power of science was seen in its reductive analysis, in its ability to reduce a problem to measurable effects. This predilection is largely attributable to the importance of measurement in science (Latimer & Miele, 2013). The true scientist was incited to banish all relations other than measurement as these are the only objective facts that can be considered. Scientists began to perceive the problems through their measuring instruments (Carolan, 2004).

For Nowotny (1993a) the purpose of the scientific method, and indeed science in general, became the separation of scientific facts from values, ordinary everyday knowledge from scientific knowledge, scientific expertise from lay participation, and science from politics. Scientific expertise, rather than considering collective or individual values and associated action, became the path forward (Cockerill, *et al.*, 2017). Science was in effect defined as disinterested and neutral, committed solely to its own impartial and context-independent conception of Truth. That, at least, was the ideal.

#### 2.4.2 Public Science: Objectivity, Neutrality and Public Good

Salter (1988) suggests that science has three important characteristics. First, that it is value free and that conclusions drawn from it are independent of the use to which they are put. Second is the assertion that the scientific method will produce credible results. And third, and most importantly, science is an inherently public enterprise, an activity that is produced and vetted through open debate, anonymous peer review and academic publications.

The belief that science is objective and neutral, providing an accurate portrayal of the Truth has made science a fundamental component in public policy (Ravetz, 1987; Salter, 1988; Marchak, 1991; Otto, 2011). Indeed, it is specifically these attributes which have led the UN, FAO & WHO, Codex and the WTO to view science as an essential concept in setting food safety standards and enabling global trade. These agencies all rely on science to provide a common language, which makes it particularly useful. Science is also increasingly used to underpin food safety and environmental governance (De Solla, 1965; FAO, 2003; MPI, 2013; Nachman & Lawrence, 2013). There is consensus that science is useful because it works and is objective (Ravetz, 1987; Salter, 1988; Marchak, 1991; Bowler, 1992; Somers, 1995). It has proven its worth in terms of its flexibility and testability. As Latour (2008, p. 4.5.7.3) states “People talk of scientific truth in hushed tones. But there have only ever been three ways of celebrating it: consistency ‘it is logical’; representation ‘it fits’ and efficacy ‘it works’.”

It has been suggested that the New World looked specifically to science to solve issues. For example, in America Benjamin Franklin and Thomas Jefferson looked to the new technologies of the era as the means of achieving the virtuous and prosperous republican society that they associated with the goals of the American Revolution (Smith & Marx, 1994). If political order stemmed from the complete control over the biophysical realm, the impetus for control became a driving political value, one that was relegated to the sciences with an emphasis on objective, quantifiable and empirically produced knowledge. Jamieson (2000) argues that this has perpetuated an American avoidance of discussing moral and political differences, and instead, arguments that involve complex and competing values are conducted in ‘technical discourse’. The attitude that science should lead to a more progressive society continues to promulgate solutionism.

Yet science and the scientific method have come under criticism because science by its very nature can rarely provide clear, unambiguous answers (PCE, 2004). There are inherent uncertainties in scientific observations which mean that unequivocal answers are not always available, even though this is what the media and the public want and expect (Somers, 1995). Indeed, uncertainty is inherent in science which means that its findings are always open to challenge or differing opinions. It is a problem when

science is seen by government organisations as a social activity with consequent truth statements that can be used to take politics out of governance. Such perceptions undermine the value of science, especially in a context where scientific fraud and alleged mismanagement of public research funds have become highly visible and hotly debated (Nowotny, 1990).

### 2.4.3 An Inherently Compromised Enterprise

Even when honest results are produced science is not always neutral and objective as a decision-making tool, even when it meets all the tests of scientific peer review (Funtowicz & Ravetz, 1993; Nowotny, 1993; OXERA 2000). Good scientific analysis is neutral in the sense that it does not seek to support or refute the claims of any party in a dispute, and it is objective in the sense that any scientist who knows the rules of observation of the study field can obtain the same results. Yet researchers have influence that becomes entangled in personal, intellectual and organisational interests at multiple points in the science process which means neutrality and objectivity can become compromised (Von Schomberg, 1993; SAGE 1999; OXERA, 2000).

Science and its results must be understood as a social process. This must be addressed in several different domains; the production and interpretation of results within the scientific enterprise and the representation and interpretation of these results in public settings, from daily life to regulatory fora. The way scientists frame a problem, the assumptions that scientists choose to make, the methods they select, the initial results they choose to pursue (or not to pursue), the alliances with others they choose to make, the measurement devices and parameters they select, all involve choices and selection bias and are all conditioned by factors such as the state of the literature or the availability of funding (Clark & Majone, 1985; Von Schomberg 1993; OXERA, 2000). The decisions of scientists at these points mean that scientists can influence decisions (National Research Council, 1996; Stern & Fineberg, 1996).

There is a tendency of the literature and commentators to ignore politics, but much science funding and any resulting policy is ultimately a political decision, with ideology a major factor in interpretation of data and evidence and out of the hands of scientists to a large extent (Nowotny, 1990). The organisation and practice of science itself is political rather than neutral, its processes are far from fully objective, and its results compromised, even before they are deployed in the political process of governance (Clark & Majone, 1985; OXERA, 2000). Framing of any kind, including the risk assessment framework, involves selection, emphasis or omission to make salient certain aspects of a perceived reality while obscuring others to promote a specific definition or interpretation of an issue (Entman, 1993; Shah, 2002). Because of this, some scholars suggest that it might be more useful to examine the battle for framing of issues by the politicians and policy makers (Siegal, 1998).

The truth claims made by science can also be compromised by its own methods. The increasing amount of scientific data that must be interpreted have created huge data sorting problems (Clark & Majone, 1985; Ravetz, 1987; Otto, 2011). Hanft (1981) argues that decision makers when evaluating scientific information should make themselves aware of the methods used to collect data, any adjustments of the data, and any assumptions made by analysts. The growing use of scientific expertise as evidence in court cases means that protocols or guidance should be given to decision-makers on how to interpret

results and to ensure they understand that scientific results are never 'black and white'. More guidance is required with respect to the 'balance of probabilities' and 'burden of proof'. (SAGE, 1999; OXERA, 2000). Uncertainty, for example, can be managed at a technical level when standard routines are adequate, with more guidance required with respect to specific professional expertise required when more complex aspects of information is involved. Then personal judgments dependent on higher level skills are required. In such cases, it is important that the person concerned has adequate training and ability to deal with complex scientific information and make appropriate judgments (McCoubrey, 2007).

In addition, there is emerging concern about the accountability and liability of scientists and decision makers (CCSTA, 1999). Scientists who become involved in regulatory issues are in a peculiar position. Having achieved eminence in well-defined scientific fields, they serve the public through providing advice on complex issues. They are suddenly shifted from a 'science research' mode of science to what might be termed a 'forensic mode' (De Marchi & Ravetz, 1999). An expert is no longer a scientist providing facts, but a witness providing testimony. In the terms of post-modernity, in such policy debates there is no 'grand narrative' of scientific objectivity which protects the experts' assertions from doubt and criticism (De Marchi & Ravetz, 1999).

Scientists themselves no longer believe that scientific objectivity can provide all that is needed for decision making on risk issues (De Marchi & Ravetz, 1999). Science tends to be narrowly focused and to focus on specific questions which rarely pose wider social value issues, context meanings or political implications and it has become as 'a time-consuming process, with a dogmatic adherence to ideology' (Marchak, 1991). As a result, there is a strong argument that health and food safety risks cannot be accurately scientifically estimated without a good understanding of the behaviour of the individuals and organizations that control or are affected by the disease agents (Nowotny, 1990; SAGE, 1990; OXERA, 2000).

Modern, western science has succeeded through increasing specialisation or "reductionism" and this is reflected in the parallel emergence of an increasing fragmentation of established disciplines, for example organic and inorganic chemistry. While implicit in this is the assumption that at some point this fragmented knowledge will be integrated this has rarely occurred. As a result, we lose out on new wide-ranging scientific theoretical paradigms (Greene, 1997). The very success of western science was based on specialisation, but it is increasingly evident that everything is linked to everything else. Specialisation (or reductionist science) has proven to be powerful and useful but today it is accepted that many of the key food safety problems are complex, chronic and transmedia and there is a need for an overarching view of all disciplines to solve complex food safety problems (Greene, 1997; McCoubrey, 2007).

More generally, scientific practices sediment into paradigms which establish norms and standards that institutionalise conformity and suppress creativity (Kuhn, 1962). Kuhn suggests that in these circumstances, eventually a crisis is reached, and younger scientists begin to look for alternative conceptual schemes. When a successful alternative is found it becomes the paradigm for the next few generations (Kuhn, 1962). Von Schomberg (1993) confirms that history has taught us that our ethical

and scientific insights have, time and again, been shown to be fallible and that those insights had to be revised in the light of new situations and problems.

Equally, Smith (2001) suggests that emerging areas of biophysical research, such as environmental science, which address complex systems may well generate even more questions than answers. It may take many years of scientific work to generate useful findings for policy makers and even when answers become available it is likely they will have less certitude than evidence from long established disciplines such as chemistry or physics. For example, in the debate about genetically modified foods, few commentators claim that current developments will have an adverse effect on human health. Most commentators state that they don't know if there will be problems or if there are problems what the nature of these problems will be. Other commentators are more outspoken. McKechnie & Davies (1999), for example, argue that the development of genetically modified foods brings with it ethical, moral and religious and other unexpected concerns.

#### 2.4.4 Science Based Solutionism

The 17<sup>th</sup> Century Enlightenment provoked the view that nature was there to be conquered, with humans using science to elevate themselves above and control all risks associated with the biophysical (natural) world. Nowotny (1993) believes that 17th century scientists, such as Francis Bacon, conceived their activities in terms of noble aspirations. These included the desire to improve living conditions, reduce the suffering caused by lack of means, to satisfy material wants, and to alleviate degrading labour. Food safety is just one beneficiary of the early scientists' noble aspirations.

The new scientific disciplines provided humans with the ability to see, study and explain how many of the food safety risks occurred. For example, microbiologists could now see the bacteria on their agar plates or down their microscopes and this information, along with the germ theory, revealed how infections were caused. Such revelations led to the promise that all infections could be contained and controlled, and that applied science would provide governments with the tools to control all situations. There are many examples of the successful marriage of science and governance, such as potable water supplies and sewerage systems, reducing the occurrence of disease. Affirming the power of science *Life* magazine (1997) declared "The filtration of drinking water plus the use of chlorine is probably the most important public health advancement of the millennium.", while better sewage treatment and disposal systems provided oyster eaters with improved food safety (Hackney & Pierson, 1994).

The significant societal health gains by reducing urban cholera and typhoid outbreaks offered confirmation that all environmental health problems could be contained, controlled and commanded by science. This theme was by echoed by Alvin Weinberg, Director of USA Oak Ridge National Laboratory and government consultant, who in 1965 actively promoted the notion that there is a technological fix for all social, political or cultural problems (Johnston, 2018). This notion continues today with the concept of 'solutionism', defined as the belief there must be a perfect solution, somewhere, to every problem (Baker, 1984, p. 6; Maxwell *et al.*, 1991).

The notion of human's superiority, which stated during the Enlightenment, has continued and is summarised by Teubner (2006):

After the scientific revolution, after philosophical enlightenment, after methodological individualism dominating the social sciences, after psychological and sociological analysis or purposive action, the only remaining plausible actor is the human individual. The rest is superstition (p.2).

More recently, there is the belief that science can solve wider environmental problems, such as global warming. There is a social expectation that scientists and those who use scientific data, can and should produce impossibly precise knowledge of biophysical systems and subsequently provide accurate prediction of potential impacts so that individuals can avoid harm (Cockerill, *et al.*, 2017). Simply labelling a 'problem' creates the pervasive belief that science can, should and will generate solutions. There is also the expectation that individuals will maintain less risky conditions once scientists provide the knowledge to reduce or eliminate risks. As a result, when faced with a public health problem there is a natural urge to find solutions. For many public health problems "we hire consultants, gather data, test hypotheses and examine *P*-values to identify risk factors: data-driven technological fixes get implemented every day." (Bishai *et al.*, 2015, p.1).

Further, the word 'solution' as commonly used and understood implies an end state where a problem has been 'fixed' and therefore will no longer require attention (Cockerill *et al.*, 2017). It also implies the construction of processes and events as 'problems' and reassembling our knowledge of them in 'problem' frameworks. On the one hand, critics such as Ravetz (1987), McKechnie & Davies (1999) and Otto (2011) argue that science does not have all the answers and that unexpected problems often occur after new scientific developments, or even scientific solutions to earlier defined problems, have been put into practice. They offer the examples of the nuclear industry and genetic engineering. When the nuclear industry was first established there was no knowledge or expectation that nuclear waste would be difficult to neutralize and dispose of safely. Genetic engineers who worked on manipulating food crops had no warning that the public would feel such intense anxiety and loudly express their food safety concerns. Such unintended consequences are difficult to predict (Somers, 1995; Cockerill, *et al.*, 2017). McKechnie & Davies (1999) state that the triumphs of science-based technology have now produced problems that science cannot solve unaided. On the other hand, as Cockerill and colleagues suggest, framing the world in this way produces unreasonable expectations of science, while in the same move it over-privileges science and presents our different worlds as amenable to progress through techno-scientific mastery and problem solution. In the simplest and bluntest of terms, why do scientists and governments struggle between Vibrios and humans and the raw oyster to the point of total scientific victory? There is a point at which the multiple players in the game need to be comfortable with resolution over solution.

It is acknowledged that it is not a simple matter to conquer all problems using science (De Marchi & Ravetz, 1999). For example, the WHO now recognizes complex public health problems usually have elements that defy planning, because health involves people and people are unpredictable (Bishai, 2015). Not only that, it is increasingly realized that the biophysical world (nature) is also unpredictable and complex (Cockerill, *et al.*, 2017). More and more there is talk about wicked problems that defy simple or long-term solutions; 'wicked' because they are embedded in complex systems and can be defined in multiple ways and at their core the situation relates to human values (Rittel & Webber, 1973).

Even so, stymied solutionists say that the solutions they came up with were good, but the implementation failed (Braithwaite, Marks & Taylor, 2014). Rather than question solutionism's unassailable worth, we blame the immature science of implementation (Bishai, 2015). Therefore, scientists continue to work in their technical fields, including risk assessment, expecting to find the ultimate solutions to solve food safety risks.

#### 2.4.5 Science-Policy Relations; A Troubled Space

Media, textbooks and general social discourse often portray the history of science as a 'narrative' of achievements that sets science apart from social and political systems. This perpetuates both rhetoric and behaviour focused on seeking the impossible: a stable, science-driven, and a permanent solution to a perceived problem (Cockerill, *et al.*, 2017). Yet there is increasing evidence that we are learning, sometimes painfully, that while science is necessary for solving many of our problems, it is never usually enough to address the expectations (De Marchi & Ravetz, 1999; Funtowicz, Munda & Ravetz, 1999). Today's complex problems require research to be more integrative across time and space, and more open to exploring the social dimensions of the issues (Hanft, 1981).

Food safety authorities around the world use scientific research in a pivotal role to identify, assess and manage food borne risks to human health, but science funding, capacity, capability, structures, and relationships influence the extent to which this role is affected (Smith, 2001; Millstone & Van Zwanenberg, 2002). Uptake of scientific advice by policy-makers depends on identifying the problem, correctly framing the questions to be addressed by science, communication and trust between scientists and policy-makers and understanding the capabilities and limitations of science, and time pressures (Smith & Halliwell, 1999; SAGE, 1999; OXERA, 2000).

Scientific discovery alone cannot 'contain, command and control' food safety problems no matter how simple the solution seems to be. Defining disease control as a human problem necessitates recruiting citizens to respond, for example, their participation in vaccination programmes. There is always the need for an associated social act, for example, people fronting up to be vaccinated or only consuming pasteurized milk (Cockerill, *et al.*, 2017). While individuals bear responsibility for their biological and social self to promote health, disease control becomes the work of nations and governments (Cockerill, *et al.*, 2017). It is up to governments to define 'normal' for its population and then define deviance (Cockerill, *et al.*, 2017).

Measuring and reporting what is easy, technologically possible or fashionable, convenient, popular or traditional may well lock decision-making into the cyclic non-achievement, of framing 'pseudo-problems' and 'pseudo-solutions' (Dery, 1984). Consequently, for example in the case of food safety, the actual problems may not be identified or solved.

Brooks (1981) states science cannot provide a solution in itself. It can only generate the conditions in which a society can develop a solution. Even if scientists and policy makers align themselves with a cohesive vision of what is required, it remains true that science does not provide conclusive solutions, and, in such cases, it is important that there are policy rules around inference. Bowler (1992) and Von Schomberg (1993) reinforce this point stating that policy inputs (including science) must be considered

in conjunction with social values and address: ethics (How do we want to live?); morals (What norms should be in the interest of all society?); and justice (What social and technological aims should be promoted or limited within the framework of the rules of law).

The information and values that come from stakeholders and communities, the political context and the expectation of the various sectors of society must all be recognized and assessed. Science that improves food safety, for example bacterial destruction, create effects within populations because they operate through social acts and political systems. In effect, policy-makers need to consider more than just the data from scientific research. They must also recognize and assess the information and values that come from stakeholders and communities along with the political context and the expectations of the various sectors of society (OXERA, 2000; PCE, 2004; Wesselink *et al.*, 2013). In response to changing needs and demands, the UK Office of Science and Technology and the Government of Canada are examples of countries that have established guidelines for the use of scientific advice in policy making in response to public concerns and the public's scepticism of science, government and industry (SAGE, 1999; OXERA, 2000). Both country's guidelines for policy-makers using science information recommend the need to work through the following steps: issue identification; asking the right questions; transparency; uncertainty and risk; implementation and review. Issue definition is important, as what is measured and thus believed to be known determines how we frame our problems.

OXERA, in *Policy, Risk and Science* (2000), point out that there are usually several stakeholders who should be involved when formulating policies based on science. For example, in the case of shellfish food safety, there is the public who eat oysters (as the main risk bearers and potential beneficiaries), the oyster industry (as providers and generators of risk) and consumer pressure groups. In this context, scientific advice is just one of many inputs for policy-making, so any scientific evidence must be weighed against competitive scientific claims as well as other factors such as social values, economic impacts and equity considerations.

The relationship between science and policy has been categorised in two ways: science led policy and policy-led science (OXERA, 2000). Science-led policy is where new information uncovered by science requires a policy decision. An example of science-led policy in the British and American shellfish programmes was the identification of a relationship between typhoid and indicator microbes (Hackney & Pierson, 1994). This led to the establishment of international classification systems used for oyster harvest areas. However, there are many barriers to the formation of science-led policies. These include the failure of policy-makers to act upon new scientific evidence, conflicting social values, political objectives, the use of scientific uncertainties as an excuse, or that the science is too ambiguous to provide answers. On the other hand, policy-led science is where scientific advice is needed to justify and determine how policy goals can best be achieved. An example of policy-led science is the request from policy makers for food safety solutions to vibriosis (illness caused by *Vibrio* bacteria). Barriers to the formation of policy-led science include scientists being unable to deliver or policy decisions being driven solely by ideology (Smith, 2001; 2002).

However, there are still problems in formulating and implementing successful food safety policies. Scientists do not always have well developed theories to explain and predict effects (Consumers

Association, 1997; OXERA, 2000; PCE 2004). Technological developments such as genetically modified foods and irradiation bring with them ethical dilemmas. Scientists can live comfortably with uncertainty for it is at the heart of the scientific approach, but policy-makers and the public crave certainty (Funtowicz & Ravetz, 1993; Von Schomberg, 1993; Barnett & O'Hagan, 1997). Acknowledging uncertainty and ethical dilemmas of suitable findings is important as society debates the policies required to manage emerging scientific and technological opportunities. Consequently, in an applied sense, governments need to ensure that the scientific advice that forms the basis of their policies is well communicated, understood, credible and reliable. They need to make explicit what science can and cannot resolve, address issues of implementation and acceptance and have monitoring systems in place to evaluate policy success. Once governments set objectives, for example in food regulation and policy, these objectives can only be reached by operating within a coherent administration system. A robust, modern and comprehensive legislative base, implementation tools and mechanisms to ensure its effectiveness are all necessary system assets (NZFSA Policy website nzfsa.govt.nz, 2006).

There will never be enough scientific information to answer all the questions that policy-makers must address nor will there ever be policies without some uncertainty or risk (Barnett & O'Hagan, 1997; PCE, 2004). Nevertheless, there will always be the need to act—to make complete and adequate social and economic decisions with or without complete and adequate data. Policy-makers are faced with various demands and expectations from interested parties, statutory requirements, and other pressures and constraints.

While science is only one input in the policy process it remains an important one, with science expected to contribute to food safety and public health (Brooks, 1981). Science is often viewed as a 'black box' 'whose content and behaviour is assumed to be common knowledge (Layton, 1977, quoted in Pinch & Bijker 1984, p 404). The term 'black box' was originally used in information science to make opaquer the inner complexity of technologies in order to reduce complex technology to its inputs and outputs (Cressman, 2009).

Kuhn's (1962) classic and influential study *The Structure of Scientific Revolutions* did more than just introduce the concept of 'paradigms'. Possibly even more importantly, Kuhn's work questioned the central belief that science and technology are founded on objective reasoning. Bijker, Hughes & Pinch (1987) claim that Kuhn helped crystallize a new approach to science studies in which scientific facts were products of scientists' socially conditioned investigations rather than as objective representations of nature. From the late 1970s other researchers explored this concept and became interested in what happened in the black box, along with the relationship between scientific knowledge, technological systems and society.

## **2.5 Science and Technology Studies**

In the late 1970s and 1980s social scientists began doing field studies of the actual work undertaken in laboratories. In contrast to scientists' retrospective accounts of their work, these researchers used direct observation to document the messy work of science, in both its material practice and its social

relationships. They revealed the “bricolage, tinkering, discourse, tacit knowledge, and situated actions that build local understandings and agreements” (Fujimura, 1992, p. 170). Rather than focusing critique on the so called black and white metrics of science supposedly formulated in a sterile vacuum, these new researchers explored scientific practice and culture. They began to confirm that the treasured features of the scientific method, including objectivity, problem reductionism and solutions based on calibrated measured effects, were largely illusory.

The challenge to objective science intensified as researchers followed scientists around during their daily work, not only in their laboratories, but also at field sites, offices, meeting rooms, conference centre, and wherever else scientists do their work (Latour, 1987; McGinn & Wolff-Michael Roth, 1999). Others examined policy documents and the politics of policy implementation through discourse analysis. Other began to ask who decides what science should focus on, how science research topics are prioritized and the social processes for disseminating and using the results scientist offer up (Pickering, 1992; Button, 1993; Jasanoff *et al.*, 1995). This new tradition of science technology studies (STS) exposed myths of the exceptionalism of science as practice as well as in the embodied form of the intellectually superior and morally unencumbered scientist and the impartial pursuit of truth that joined them (Zbilut & Giuliani, 2008).

Science and technology studies (STS) scholars came increasingly to view science as socially embedded (Nowotny, 1990), rapidly broadening the technology policy agenda (Williams & Edge, 1996). Schools of STS developed in history (Proctor, 1991; Golinski, 2008); sociology (Shapin, 1992; Barnes, Bloor & Henry, 1996); political theory (Rouse, 1987); philosophy of science (Hacking, 1999); and anthropology (Mol, 2010). These scholars have played an epiphenomenal role in our understanding of science, by demystifying science and deconstructing what has become widely described as its “social construction” (Nowotny, 1990; Jasanoff, 1992). They have directed attention to the way scientists construct stable structures and networks which consider how social, political and cultural values affect scientific research and technological innovation, and how these, in turn, affect society, politics and culture (Cutcliffe, 1990). There is now a vast STS literature covering from laboratory practice to science findings, the social constructions of disciplines, science-policy relations, science ethics and effectiveness, the social life of diseases, food scares, the rise of genetic modification and climate change science. This literature divides into two broad streams of scholarship.

The first stream consists of research on the nature and practice of science and technology. Studies in this genre approach science and technology as social practices and discursive formations. They ask questions such as: Is there a scientific method? What makes scientific facts credible? How do new facts emerge; and how does science relate to religion? The second stream concerns itself more with the impacts and regulation of science and technology and how to make it more effective. This stream investigates the risks that science and technology may pose to peace, security, community, democracy, environmental sustainability and human values. Driving this body of research are questions including: How should states set priorities for research funding? Who should participate? How, in technological decision making should life forms be patented? How should societies measure risks and set safety standards? And, how should experts communicate the reasons for their judgments to the public? (Law *et al.*, 1987; Jasanoff *et.al.*, 1995; Hess; 1997).

The second stream emerges from early laboratory studies and directs its attention to practice. Probably the best known of the laboratory studies is Latour and Woolgar's *Laboratory Life the Construction of Scientific Facts* first published in 1979. This book shows exhaustively that facts become stabilized only through a process of social negotiation among scientists who have a stake in the outcome. Laboratory studies, and ethnographic studies more generally, have remained a mainstay of STS, confirming that science is an active process that should be studied to ascertain how scientific knowledge is constructed because knowledge and artefacts are human products and marked by their circumstances of production (Sismondo, 2004). Many of these studies have become shaped by Latour and the ideas of actor network theory (Callon, 1986; 1987; Latour 1988), to which I turn in the following section.

### 2.5.1 Actor-Network Theory

Latour came to understand science as made by practice after concluding that the established history and sociology of science were unable to provide a 'social' explanation of scientific facts. Instead he concluded that it was "the project of a social explanation of everything that was itself wanting" (Latour, 2003, p. 35). After *Laboratory Life*, Latour published his 1987 landmark *Science in Action* in which he claims to "open the black box" of science to study "science in the making", the construction of scientific "facts" and the closure of controversies (Latour, 1987). He then stepped away from the laboratory to study the history of pasteurization and the emergence of modern bacteriology or what Latour terms 'Pasteurism' (Latour, 1988). He argued that historical transformations involved interactions among socio-political, scientific and material characters, and had as much to do with the agency of the microbes and the contingencies of politics as with the individual scientific "genius" of Louis Pasteur.

Actor network thinking has built a rich tradition (Latour, 1987; Akrich & Latour 1992; Lee & Brown, 1994; Latour, 1996; Callon & Law 1997; Callon, 1999; Hassard, Lee & Law, 1999; Latour, 1999; Latour, 2005; Neyland, 2006; Mol, 2010). It has, however, become synonymous with the work of three writers: Bruno Latour, Michel Callon and John Law. They aim to explain how material-semiotic networks come together to 'act as a whole'. Their approach is grounded in qualitative, empirical case-studies, and they map relations that are simultaneously material (between things) and semiotic (between concepts). Objects, subjects, practices, technical, rules, technical devices, and beliefs take form and exercise agency only through the connections and heterogeneous associations that emerge from the relations of their coexistence. As John Law states "interaction is all that there is", but interaction creates actor networks or assemblages (Cressman, 2009) that take on temporary stabilities created by ongoing interactions among the 'actors' enrolled. The longer these networks last the more entities that are enrolled in them, and the stronger and more durable they become.

Latour began to see science as a network of heterogeneous associations, with resources concentrated in relatively few places that are connected to one another, like nodes in that network. All actors in the making of science are related and exercise agency through these relations. He began using the term 'Actor-Network Theory' (Latour, 1988) to think through how these networks took form and expanded and how agency was exercised. Actor-Network Theory (ANT), as proposed by Callon and Latour, offers a framework for exploring the relational ties within a network (which can be a multitude of different things). Cressman (2009) echoes Latour's description of ANT as an attempt to "open the black box" of science

and technology by tracing the complex relationships between governments, technologies, knowledge, texts, money and people. ANT approaches 'science in the making' as opposed to 'ready made science' (Latour, 1987). This entails micro-level studies of the places where science comes into being: laboratories, institutes, government departments, boardrooms and funding agencies (Cressman, 2009). Latour observes that ANT studies reject the notion of science as a stable linear model of scientific and technical change and with it any hint of social, technical or scientific determinism, reductionism or autonomy (Cressman, 2009).

At its core, ANT makes a fundamental proposition about agency – agency is relational. It emerges out of the heterogeneous associations that constitute networks; that is the interplay among actors in networks and the processes of translation that moderate it and relations with others. ANT, then builds a theory of social action on three constitutive planks: actors, actor-networks and translation.

### 2.5.2 Actors

The use of the term 'actors' in ANT is somewhat duplicitous. Actors are not understood as pre-formed independent agents but as elements that perform or do things in heterogeneous associations with others. The world is composed of myriad 'doings' some associated with aspiration, strategy etc, some not; some performed by humans, some not; some that can be traced to effects; and many that are simply part of the maze of open-ended things that are done. All this means that effect cannot be traced back to a stable cause or the work of an 'actor' strategic or otherwise (Mol, 2010). It also means that agency is not the exclusive property of human beings (Latour, 2005, p. 63). Actors (or in Latour's terms actants) need not always be human; they may be animals, objects or concepts that accomplish or undertake an act (Greimas *et al.*, 1982). In this ontological levelling the activities in labs, research centres and field tests, including texts, technologies and humans can all play equally important roles in the construction of actor-networks (Callon & Latour, 1981; Latour, 1987; Law, 1994). There is no difference in the ability of technology, humans, animals, or other non-humans to act (there are only enacted alliances in actor-networks).

### 2.5.3 Actor-Networks

Actor-networks are formed when two or more actors are connected and establish associations and aligned interests (Dankert, 2010). An actor-network is an agency composed of heterogeneous elements, but one that can redefine and transform the stuff of what it is made (Callon, 1987). The actors, both human and non-human, within a network begin to take shapes set by their relations with one another (Cressman, 2009). In other words, actors are co-constitutive – they become in relation and 'act' in relation. They enrol each other in the network. ANT studies the heterogeneous associations that emerge and those that are proposed and attempted, both failures and successes. It follows that any act carried out is a result of this relationality.

This is exactly what the term actor network accomplishes. An actor network is the act linked together with all its interlinked influencing actors. This idea can be understood narrowly to interpret an 'actor-network' as many entities or actors that enter an alliance to satisfy their diverse aims (Spinuzzi, 2008),

although for Latour it is crucial not to imagine any predetermined, overarching or over-determining strategy, logic, or project. He argues that "network" is a fitting term, because "it has no *a priori* order relation; it is not tied to the axiological myth of a top and of a bottom of society; it makes absolutely no assumption whether a specific locus is macro- or micro- and does not modify the tools to study the element 'a' or the element 'b'." He observes that:

Instead of dividing science from the rest of the society, 'reason from force', I make a no a-priori distinction between the various allies that are summonsed in times of war. Recognizing the similarity amongst allies, I offer no a-priori definition of what is strong and what is weak. I start with the assumption that everything is involved in the relation of forces but that I have no idea at all of what a force is. (Latour, 1988, p.7).

A network can be considered in terms of both form and process. On the one hand, a network refers to an architectural form, or organizational structure, wherein people and institutions (among other entities) interact. On the other hand, it is also a verb referring to a process that occurs within the networks and simultaneously brings them into being (Cressman, 2009). It also suggests instability and temporariness. Networks do not solidify and transcend context; they are temporary stabilisations that can order practices, or at least order the relationality from which practices emerge. As Mol reflects:

Actors are enacted, enabled, and adapted by their associates while in their turn en-acting, enabling and adapting these. While the verbs keep on moving between active and passive, the relations that make actors be, may take the form of stable syntaxes or, alternatively, of fluid associations. But as actors come to participate in different "networks", discourses, logics, modes of ordering or practices then things get complex. The "ac-tors" start to differ from one network, discourse, logic, mode of ordering, practice to the other. (Mol, 2010, p.256).

The relationships between the heterogeneous actor-network are never static or unchanging. Instead, they are constantly being performed. Culture, society, and nature are constructed simultaneously (Latour, 1992, p. 281) and are in a perpetual state of becoming. Social and organizational life may be viewed as an attempt to form and stabilize networks, a goal achieved only temporarily and transitionally in an unending process. Actor networks are in a continual state of change, including possible dissolution (Murdoch, 1997). One consequence of this argument is that it is mistaken to claim that social causes can explain nature, or that natural science can explain the construction of culture. All are part of an interactive network of constant transition and translation. The social should not be privileged over the natural or the technical and cannot exist independently of them. Other factors, natural, economic or technical may be more obdurate than the social and may resist the best efforts of the system builder (or primary actor) to reshape them (Law, 1987, p. 113).

The term *primary actor* is used to describe those who are the network builders or the actor that defines the problem, the solution and identifies the relevant actors involved (Macome, 2008; Cressman, 2009). For example, in Callon's famous 1986 scallop study the primary actors were the three marine biologists who proposed to design the conservation strategy for St Brieuc Bay and who then went about engaging with the other human and non-human actors to enact the strategy. From the network of the primary

actor, networks demand continual maintenance or order. Among the on-going processes or in actor-network are challenges to the role of the primary actor; desertion and, betrayal of actors; recruitment by competing networks; and all manner of other changes in the constituent elements of the network (The Bug's Blog, 2009).

#### 2.5.4 Translation

How then do networks form and transform and how are associations mediated? ANT uses the metaphor of *translation* to capture the process of making connections, of forging a passage between two domains, or simply as establishing a connection. For both Callon and Latour, translation refers to 'all the negotiations, intrigues, calculations, acts of persuasion and violence which an actor or force takes, or causes to be conferred on itself, authority to speak or act on behalf of another actor or force' (Callon & Latour 1981, p. 279). Dankert (2010) defines it more simply as the work that is necessary to displace and transform a network. It is an act of invention brought about through a combination and mixing of various heterogeneous elements (Brown, 2002). Translation is the mechanisms by which the social and natural worlds progressively take form. For example, the development of scientific knowledge over time might be thought of in terms of translation; that is the work that turns ideas and plans into staffed research labs, leads people and institutions to believe the same thing that scientists believe, and enables users to transform science to better meet their goals. In the words of Callon (1987) "translation is a process before it is a result."

In his widely debated 1986 study of how marine biologists try to restock the St Brieuc Bay to produce more scallops, Callon explicitly assembled the ideas of the non-human, the actor-network and translation in one of the most cited works in the ANT tradition. He named and described four pivotal moments of translation as problematisation, interessement, enrolment and mobilization of allies.

*Problematisation* is the formulation of questions and determination of the set of actors' obligatory passage points. (An *obligatory point of passage* (OPP) can be thought of as the narrow end of a funnel where the interests of actors in relation to certain matters of concern converge and relational agency emerges. The OPP mediates all interactions between actors in a network and is a necessary element in the formation of a network).

*Interessement*, the group of actions by which an entity attempts to impose and stabilize the actors defined in problematisation.

*Enrolment* designates the socio-technical devices by which a set of interrelated roles is defined attributed to actors.

*Mobilization of allies*, the point at which primary actors assume a spokesperson role for passive network actors and seek to mobilize them to action.

Callon (1986) uses this repertoire of translation to impose a conceptual order on complex and always situated processes that continuously mixes together a variety of heterogeneous social and natural entities. He also suggests that it helps reveal the exercise of power at the points at which it begins to dissipate. As Latour observes, it is from such relational fields and the wills of many that power emerges. He points, for example, to the processes by which scientists move from weaker to stronger rhetoric,

making their claims stronger; from weak points to strongholds, gathering allies and resources; and from short to longer networks. For Latour, “power is always the illusion that people get when they are obeyed... people who are ‘obeyed’ discover what their power is really made of when they start to lose it. They realize, but too late, that it was ‘made of’ the wills of all the others” (Latour, 1986, p. 268).

While the concept of translation is designed to account for relational processes that must always occur around passage points, it has been used more widely in non-Latourian STS to refer to a sociology of translation, in which actors seek to shape networks. One example is when innovators attempt to create a forum or a central network and solicit commitment from others to building and defending it. It also permits an explanation of how a few obtain the right to express and to represent the many silent actors of the social and natural worlds they have mobilized. In the section that follows I highlight concepts drawn from ANT which, alongside relational agency and its constituent elements of actors, actor-networks and translation, form the conceptual repertoire from which I aim to rethink the entanglements of oyster worlds and science in contemporary food safety regimes.

## **2.6 Mobilising ANT Concepts to Theorise the Food Safety Regimes**

The ANT influenced literature has developed a repertoire of concepts with which to mobilise this formative architecture for dealing with relational agency. In later chapters, I work with five of these: i) *assemblage* ii) *metrology* and *qualculation* iii) *matters of concern versus matters of fact* and iv) *social life of things*.

### **2.6.1 Assemblage**

Callon (1986) and Latour (1986) presented ANT as a framework for theorising relations among human and nonhuman actors, including physical objects, happenings, events, signs, utterances, and so on. Later branches of ‘after’ actor-network theory literature (Hetherington & Law, 2000; Latour, 2005; Hinchliffe, 2007; Sassen, 2008) have turned to the question of how the heterogeneous relations of these networks are arranged (Phillips, 2006). Here the notion of *assemblage* has offered a more open conception of the actor-network, and one that is less mired in the formal framework of ANT.

There are many roots to the term *assemblage* (Greenhough, 2011), which at base is used as a descriptor for some form of provisional unity across differences. For the most part its use relies on taken-for-granted dictionary definitions of the term (e.g. Sassen, 2008) such as the state of being “gathered or collected” as well as “a number of things gathered together”. Once deployed in this way, *assemblage* may then be connected to a potentially limitless array of concepts and used in relation to any provisionally structured formation. It is, however, incorporated into various broader and differentiated bodies of social theory. In these deployments *assemblage* thinking brings to bear different configurations of tightly interwoven politics and philosophy of knowledge and knowledge production; a politics of ontology. Thus, for Dewsbury *assemblages* are “ontological statement (s) that parse out the world and frame it in particular ways” (Dewsbury 2011, p. 149). Anderson and McFarlane (2011, p. 162) hold that “*assemblage* is an ethos of engagement attuned to the possibilities of socio-spatial formations to be otherwise within

various constraints and historical trajectories". It in turn a conceptual framework within which complexity and indeterminacy can be considered across diverse epistemological perspectives (Lewis & Rosin, 2013).

Dewsbury (2011) recommends adopting a more radically open conception of the world; one always in the making and always encountered as situated, through text, perception and imagination as well as through embodied experience, assemblage thinking. The adoption of this process focusses less on the "that of assemblage" and more on how assembling is achieved and what assemblages 'are able to do, affect and bring about' (Dewsbury 2011, p. 150).

Le Heron and colleagues (2013, p. 222-223) go on to observe that assemblage thinking 'prioritises a questioning of practices and the immanence of assemblage over fixity' emphasising a consideration of relations 'not only as they are and were, but also as they might have been and could become'. Drawing on Greenhough (2011), they argue that this facilitates a threefold politics of knowledge production that is pursued differently by three different traditions of assemblage thinking:

...a Deleuzian view that asks 'what is possible' and what possible assemblages might have existed or be latent, a Latourian view where the interest is on 'what is required' to bring into existence an assemblage and hold it together, and a Haraway inspired line of questioning that stresses becoming worldly and responding from situated understandings.

In a less abstract sense, the 'what' of an assemblage is that it is first and foremost a configuration of heterogeneous elements that keeps them together. Greenhough (2011, p. 135) grounds the concept by referring to Haraway's conception of "assemblages" as "attachment sites" where new relations and assemblages are formed. However, these sites and assemblages can only ever be provisional: relations may change, new elements may enter, alliances may be broken, new conjunctions may be fostered. In Deleuze and Guattari's (1983, 1987) conception of assemblage, an assemblage is a co-functioning resolution of two mutually constitutive axes of potential instability: the interplay between machinic elements (qualities, things and relations) and enunciation elements (languages, words and meanings); and the contradictions between territorialising and deterritorialising tendencies. Assemblages always 'claim' a territory or instantiation as heterogeneous parts are gathered together and hold together, but they are constantly being opened up to new lines of flight and new becomings by internal relational instabilities or contradictory external relations. For Anderson & McFarlane (2011, p. 125), drawing on Bennett (2005) it is used to name "an uneven topography of trajectories that cross or engage each other . . . [in place and] . . . to different extents over time, and that themselves exceed the assemblage".

Assemblage then offers an alternative entry point enabling the emphasis of temporally and spatially contingent webs of economic, social, cultural, and material relationships that frame and give shape to trajectories of problematization and experimentation. Henry & Roche, 2013 describe the 'analytics of assemblage' as having three dimensions. First assembling and the ways heterogeneous objects might be made able to stick together, if only temporarily. Second, work of sticking together involves practices. This includes problematization practices through which problems come to be identified and defined. Thirdly, the process of assembling (and reassembling) consistently calls in the attribution of agency to

specific. Agency, then, is constituted both by the relationships that are fashioned with constellations of assembling work, but also by the relations of exteriority that that work has. The exercise of agency by both the assemblage and its multiple internal relationalities can transform both the parts and the whole (Anderson & McFarlane *et al.*, 2012 p.180).

Understanding and recognizing assemblages (actor-networks), both as noun and as a verb provides a new framework with which to understand the ever-changing relationships. It releases interpretation from the binds of Latour's ANT early formalism, to focus attention on a more open conception of relational agency. All this leads me to draw on the term in later chapters to interpret the ISSC as what Featherstone (2011, p.141) terms a "site of co-existence of different trajectories" where multiple heterogeneous elements are brought into a particular ordering frame with its own sets of rules and where new alliances and commitments may be formed (and broken) and new knowledge may be made.

## 2.6.2 The Politics of Metrology and Qualculation

For those who argue science to be apolitical, the use of numbers is seen as separating science from politics (Salter, 1988; Nowotny, 1993). Numbers and the calculations made from them and made possible by them, are argued to allow information to move. They are argued to have an objectivity in their production and to hold their shape and meanings as they move and translate science from the laboratory and field into decision making arenas. For Latourian scholars, however, they are far from objective or immune from political pressures. In this section, I explore the politics of numbers.

STS scholars have launched two broad criticisms about the perceived apolitical nature of metrology and qualculation. First, these metrics can never be apolitical, and second by masquerading as such, they have become 'anti-political' devices that strip out the possibility of political contestation (Barry & Slater, 2002). Numbers are abstractions to which qualities are attached, commonly through practices of calculation. Callon (1998) and colleagues use the term *qualculation* to capture this effect and the way it makes objects and events commensurable for exchange through markets or meanings commensurable for politics (Callon & Law, 2005). The idea of qualculation refers to the creation, stabilisation and alignment of qualities from measures, to standards, certification procedures and trade law, which allow for various dimensions of exchange to be made commensurate (Lewis, Le Heron & Campbell, 2017). Qualitative methods, qualitative procedures, professional judgements or the tinkering of daily practice are all qualculative (Callon & Law, 2005). Callon and Law (2005) include examples such as electoral systems, presenting symptoms in the doctor's surgery, the use of a library catalogue that offer the possibility of qualculation.

*Metrology* is understood as the rationality and logic or science of measurement (Latour, 1988). Mallard (1998, p. 574) argues that metrological systems 'inscribe various forms of equivalence in enduring objects and replicable procedures'. This does not only mean that they tend to coordinate activities, but that they shape possibilities, practices and relations; that is, they are performative.

In practice, 'techno-scientists' construct 'facts and machines' and calculative equations in their laboratories which are then distributed to the world outside of the laboratory. Both are borne of measures and qualculation. Latour sees no reason to doubt that techno-scientists can create effective facts and

machines in their laboratories or that they travel effectively to other sites, but he challenges the claim that laboratories can ever be isolated from the worlds outside or that the experiment can be insulated from them (Latour 1983, p. 166; Biesta, 2007). They are bent to the influences of other worlds, just as these other worlds transformed to fit laboratory prescriptions, before and after the situation of any experiment is defined and conducted. Metrology incorporates society into the network of techno-science so that facts and machines can 'travel' without any visible effort. It is a transformation of society even before calculation is put to work to transform society. As Latour explains there is "no outside of science, but there are long, narrow networks that make possible the circulation of scientific facts" and the incorporation of these facts into processes of translation and diverse elements into new actor-networks (Latour 1983, p. 167).

Qualculation can take very different forms and materialise in different regimes of governance in different contexts, but they share the feature that all take time, money and social efforts to produce. In other words, qualculation is impossible without material arrangements, such as paper and pencil and systems for tallying. Both practice and tools, rules and bodies are deployed in calculation work (socio-technical devices), so qualculation is better understood as a process in which entities are detached from other contexts, reworked, displayed, related, manipulated, transformed and summed in a single space (Callon & Latour, 1997; Muniesa, Milo & Callon, 2007). Callon and Law (2005) describe this work yet insist that it cannot be imagined as simply a predefined project playing out in sequence in place – the number regimes and socio-technical devices at work impose their own transformative forces once measurements take place, that cannot be assumed to be imagined or scripted into the initial application and design of measures.

When relevant entities are sorted out, detached and displayed within a single space, new relations among them are created making certain manipulations and transformations possible and suggesting others (for example, writing algorithms to manipulate spreadsheets). New entities are also produced, such as rankings and objects of governance, sectors and economies, as well as the altered worlds made by the new decision and judgement frames created. Qualculation involves judgement in relation to qualification and the definition of the attributes and qualities in question, as well as setting out the practices and routines of measurement (Cooper, 2015). Metrological practices, such as food quality control or environmental monitoring, do not just record reality as it is, but create new realities (calculable objects) that can, in turn, be the object of economic calculation.

Latour uses the phrase "when things are drawn together they are simplified". Furthermore, they are realigned into new configurations or assemblages. Qualculation requires boundary making (what's in and what's out) and create new boundaries and categories and the inclusions and exclusions that go with them. This means creating outsides, as well as insides, thus placing, actors, processes and political projects that are beyond the calculatory order of concern. Qualculation always discovers (and produces) its own limits (Callon & Law, 2005). The boundary is important, not only with what inclusions it allows, but also in defining what must be left out.

As Moser & Law (2006) point out the drawing together of things in measurement and calculation at the same time juxtaposes and new categories of knowledge, governance and 'being' are created. When

understood as *qualculation*, it is clearer to see that these categories are political and ethical as well as technical. Something is made that was not there before, because information is bounded in a new way, but in far from innocent ways. Such *qualculatory* orders in food safety set different boundaries in different political, ethical and regulatory settings, often configured nationally by the assembling force of national political, regulatory, and legislative frameworks. For example, European regulators use oyster samples to determine food safety, whereas in the USA seawater samples are used.

Michael Carolan (2004) makes these points more directly. He argues that “method makes reality” and “through translation reality shifts”. He uses the example of water quality which in reality is to speak of the water quality methods employed, such as individual tests for nutrients, pH, or oxygen levels. In other words, scientific practices or methods used to understand a problem do not just describe it; they help produce or enact it. Science uses methods to make problems visible, usually with the aim of forging links and enrolling others to make appropriate social changes. Carolan asserts that translation must first occur in our perception of nature through phenomena, such as machines, models and computer printouts (Carolan, 2004, p. 504). Therefore, what we observe is not nature itself, but nature exposed to science’s questioning.

For Callon, interested in how objects are commensurable for market exchange, measurement involves a wider set of categories of action than the application of a scientific device. Callon draws on Cochoy’s (1998) notion to insist that calculation is far from innocent – it involves the manipulation of objects into a single spatiotemporal frame, which might just as easily be done in other ways (Callon & Law, 2005). The idea of *qualculation* refers to the creation, stabilisation and alignment of qualities from measures, to standards, certification procedures and trade law, which allow for various dimensions of exchange to be made commensurate (Lewis, Le Heron & Campbell, 2017). It is a political move in terms of process and the reframing of realities that it produces.

It is important, then, to recognise that metrology is not just a technical exercise, but also a governmental process. More than this, however, it is political and ethical. The capacity to calculate depends on a set of technical devices and discursive idioms that make calculation possible. It also depends on the stability of the governmentality that allows them, indeed makes them, perform the work that they do. This is not pre-given or guaranteed. Callon assumes that calculations are always, in principle, contestable; and they will be contested. In his words “As AST (studies in the anthropology of science and technology) came to admit for the natural sciences, there is no reason to imagine an end to these debates and controversies; [there is] no theory or concept that can provide a final solution.” (Callon 1998a, p. 29).

As theoretical concepts, metrology and *qualculation* invite us to question the social, political, and scientific conditions under which agreements about measurement and commensuration do or do not occur, and the consequences or effects of metrological systems (Cooper, 2015). It disturbs any claims that measurements are objective; rather they are specific accounts that direct us to what various powers want the world to be. Metrics are neither inert nor innocent; they make reality by creating new objects, and very often escape even the designs of those who bring them into being to prepare ground for answering specific questions. They imply continued work and a continued material and ethical politics. In Latour’s terms “Science is not politics; it is politics by other means. But people object that science

does not reduce to power. It does not reduce to power. It offers it to us by other means” (Latour, 1988, p.218). Measurement is a significant strategic move in “this gigantic enterprise to make of the outside a world inside of which facts and machines can survive” (Latour 1987, p. 251).

STS ideas about metrics, therefore, echo the concerns of Cockerill and colleagues (2017) about solutionism in science. Metrology and qualculation create new entities and points to the alignments and key sites and moments at work in a creative process. Despite its potential force, qualculation is always fragile, contested, incomplete; yet this often incoherent regulatory, institutional and metrological apparatus makes trade possible. As Spinuzzi (2003) observes of Mol’s (2002) STS-based work on the interplay of humans and diseases, ‘the things we take as settled, scientifically quantifiable and observable phenomena are not really just objects-in-the-world; rather they are always multiple’. Translation is creative, and we cannot know for sure what new entities it will create. Qualculation is a creative governmental force that has anti-political potential yet cannot be neutral. Instead, it is a political move in terms of process and the reframing of realities that it produces. In the next section I turn to how politics and ethics are accounted for more directly in Latourian thought through the notion of matters of concern.

### 2.6.3 Matters of Fact Versus Matters of Concern

Having made a career out of criticizing the perceived objectivity of the science world Latour became concerned he had lost perspective. In his 2003 essay Latour asks why critique had ‘run out of steam’ and draws the distinction between ‘matters of fact’ and ‘matters of concern’ to answer this question. Matters of fact are considered as objective data, separate from political conditions. By contrast, matters of concern, are perceived situations and their consequences; they are subjective experiences that constitute political conditions (DiSalvo *et al.*, 2014). Matters of fact are directed at uncovering the indisputable and framed without consideration of judgement (moral, ethical or other), while matters of concern are centred in desire and judgement. Matters of concern gather context(s) within themselves, disputing both the possibility and the efficacy of indisputability (Roemer van Toorn, 2004). In the words of Ivakhiv (2014) “matters of concern involve us, touch and brush up against us, envelop us, or otherwise call on us to respond to them.”

Latour asserts a ‘matter of concern’ is what happens to a ‘matter of fact’ when you add to it its whole scenography, much like you would do by shifting your attention from the stage to the whole machinery of a theatre. Putting science under the STS microscope in these terms, he claims that:

Now instead of simply being there matters of fact begin to look different, to render a different sound, they start to move in all directions, they overflow their boundaries, they include a complete set of actors, they reveal the fragile envelopes in which they are housed. Instead of ‘being there whether you like it or not’ they still must be there, yes (this is one of the huge differences), they must be liked, appreciated, tasted, experimented upon, mounted, prepared and put to the test (Latour, 2003, p. 40).

Crucially, whether interests are matters of fact or concern depends upon how they are constructed, and the politics of knowledge embedded in this framing. Consider climate change as an example. Treated

as a 'matter of fact' we record various environmental conditions, compare data and make computational models. Treated as a 'matter of concern', climate change includes the science facts, plus the lived experience of rising tides, severe storm damage and value charged public debates about science, economics and religion. The example demonstrates that, to the extent that either of these domains can be isolated from each other, they are intricately entangled in co-constitutive relations. The computational model arises from sets of assumptions and scenario-building that embed data created by projects, funded by and forged from relations, with identified matters of concern and often also precautionary sensitivity analyses. Thus, the computational models often create their own matters of concern; while it was matters of concern that provided the conditions for formulating the models.

For Latour (2003) making the distinction between matters of fact and matters of concern is generative. It leads to "a multifarious enquiry launched with the tools of anthropology, philosophy, metaphysics, history, sociology to detect how many participants are gathered in a 'thing' to make it exist and maintain existence." (Latour, 2003, p. 40). Acting effectively in a democracy does not mean abandoning rationality, but it does mean placing the experiential, the affective and the desired alongside the presumed objective (Di Salvo *et al.*, 2014). This position has underpinned the work of a new strand of STS explorations of diverse matters of concern (DiSalvo, 2014; Hill, 2015; Andersen *et al.*, 2015). Examples include environmental matters such as smog and pollen pollution; economic matters such as food economies; and social matters such as communication between social workers and children in foster care. Di Salvo *et al.* (2014) argue that the distinction between matters of fact and concern offers a framework for a new politics of knowledge production embedded in an active and experiential process of coming to know the qualities and factors of a condition. Focussing attention on the instabilities of both matters of fact and concern, their co-constituiveness, and the translation work that shapes their relationality is crucial to understanding and engaging enactively in the political work of science.

#### 2.6.4 Social Life of Things

It is not just facts that change their iridescence depending on who and where the light is shining, what kind of torch is being used, what it is that the explorer hopes to find and so on. Others have noted that inanimate objects or 'things' can quickly take on a life of their own. Such 'things' can include commodities and social mores. What value do objects hold? According to Appadurai (1986) as things come in and out of our lives, they take on 'social lives' – the meanings we give them. Appadurai (1986) and Igor Kopytoff (1986) suggest that things, like persons, have social lives. Objects take on agency and values in relation to other elements or actants in an actor-network. They judge, they form networks, they speak, and they work performatively. They are never just things and need to be understood in those terms. It follows as a corollary that they have the capability of doing social work; that is, they may be things in a certain situation, but are enmeshed in the exercise of relational agency in other situations. And of course, such situations are themselves an assemblage of elements including the things of interest.

One consequence of this observation is that the dominant divides between subjects and objects and between ideality and materiality are inevitably called into question. A second is that "natural objects are naturally recalcitrant. While a scientist might think that natural objects are fully masterable, on the contrary they always resist and make a shamble of our pretensions to control". (Latour, 2000). Objects

are not 'just given': objects are constructed by actors as they make sense, name, stabilize, represent and enact foci for their actions and activities. At the same time, it would be a mistake to assume that objects are constructed arbitrarily on the spot; objects have histories and built in affordances, they resist and bite back (Engestrom & Blackler, 2005). This means in turn, that commodities are more than just things, rather they are assemblages of various forms of labour and the conditions in which labour is generated and put to work. It also means that even science's own objects, such as their puzzles, hypotheses and theories quickly form their own social life.

Significantly, Appadurai and others (e.g. Cook, 2004) have recognised therein lies another consequence. That is, there is much to be gained from a methodology that focuses attention on the social life of things, and moreover, in the case of commodities, this ought to involve tracking them in motion. In his book *The Social Life of Things* Appadurai argues for a 'methodological fetishism' of commodities in analysing the societies in which they circulate:

We have to follow the thing themselves, for their meanings are inscribed in their forms, their uses, their trajectories. It is only through these trajectories that we can interpret the human transactions and calculations that enliven things. Thus, even though from a theoretical point of view human actors encode things with significance, from a methodological point of view it is the things in motion that illuminate their human and social context. (p.5)

Pawson & Perkins (2013), for example, bring interests in metrology and qualculation to the social life of things when they write of different 'worlds of wool' defined by different measures. They contrast a commodity world with a world of wool enlivened by a complexity of fluid socio-spatial, economic, environmental and cultural relationships, interactions and conventions, all of which produce meanings and values. The mistake would be to imagine that wool as commodity was absent of a social life – it too is qualculated and entangled in the land tenure systems, supply chain logistics, investment flows and concerns of multiple practices that enliven that world. In both worlds, wool has a social life; the infused socio-technical processes, measurement technologies, status calculations, and experiments that create 'wool'. These worlds can be uncovered by following wool from the pasture to the suit or the jumper through scientific research entanglements, measurement and other technical regimes, local and global distribution practices, processing and marketing strategies, marketing and advertising. Pawson and Perkins (2013) conclude, that it is in its social life that wool comes into being in different worlds, where "value is recreated and realized not only in financial terms but in a myriad of metrological, social and environmental ways, creating new artefacts and sustaining the actors who constitute the assemblages that we have categorised."

The biography of an object is thus entangled in the social and political mechanisms that socialise its life, bringing the norming of regulation, taste, trade and desire to bear on its various transformations. Other researchers focus more tightly on the non-human. Fudge (2013), for example, describes how the historical slippage of the cow, from a being with a face, to a resource, effaced and without dignity as it turns in a slab of meat sold in a supermarket. In a similar vein, Nimmo (2011) suggests that prior to the 1870s it was impossible to think of milk as separate from cows and calves. Warm milk was good and

fresh; considered “warm from the cow”. However, pasteurization changed things. Now milk was a commodity purchased in a bottle. Suddenly warm milk became bad milk, synonymous with bacterial growth, infant mortality and risk to health. Cold milk was now the desired product. The social and bio-material lives of things are entangled in complex co-constitutive relations that fundamentally disrupt the human-nonhuman binary in western thought. It quickly becomes unclear what is shaping what, and how. The reflection is immediately deeply troubling to a science that sees itself as objective and seeks to stand outside of the natural world, disinterested, objective and detached from all emotion – the scientist as flaneur (Latimer & Miele, 2013).

This in turn means that we have the politics of value; expressed in the politics of fashion, of sumptuary law and of taboo, all of which regulate demand. The consequences of this observation are particularly striking at the margins, such as in the emergence of ‘quasi-objects’ or ‘monsters’. Such objects are assemblages of qualculation, politics, and often questionable moral substance such as gene technologies, ozone layers and computer systems which have become so powerfully omnipresent that their existence can no longer be ignored (Law, 1991; Latour, 1993). The examples highlight two key lessons provided by the social life of things: there is always a moral economy standing behind any apparently objective economy; and relations between humans and non-humans are mutually affective (Krarup & Blok, 2011). To the extent that we might consider the USA Interstate Shellfish Sanitation Conference (ISSC) as an economy for example, it is a moral economy composed of myriad actors, ‘quasi-actors’, socio-technical devise, things with complex social lives, and symbolic and moral forms. All these elements affect the form and agency of any assemblage.

## ***2.7 Science and Food Safety: An ANT Inspired Rethink***

Both Latour and Annemarie Mol claim ANT is less a theory than a way of thinking or a set of sensitivities that might be described as an open and adaptable repository. It helps to examine cases, draw contrasts, articulate silent layers, turn questions upside down, focus on the unexpected, add to one’s sensitivities, propose new terms, and shift stories from one context to another (Latour, 1996: Mol, 2010, p.253). Mol (p. 262) later adds playfully that ‘having said all this, I propose that we may call ANT “a theory” after all’. Her point is that all ANT perspectives radically reinterpret theory. As a final introduction, while reflecting on how it might used to disturb established thinking about food safety, it is worth quoting the passage that follows in its entirety:

For if ANT is a theory, then a “theory” is something that helps scholars to attune to the world, to see and hear and feel and taste it. Indeed, to appreciate it. If ANT is a theory, then a theory is a repository of terms and modes of engaging with the world, a set of contrary methodological reflexes. These help in getting a sense of what is going on, what deserves concern or care, anger or love, or simply attention. The strength of ANT is not in its coherence and predictability, but in what at first sight, or in the eyes of those who like their theories to be firm, might seem to be its weakness: its adapt-ability and sensitivity. ANT does not offer a consistent perspective. The various studies that come out of the ANT-tradition go in different directions. They do different things. They not

only talk about different topics (electric vehicles, music, anaemia, organisations, cheese, childbirth, blood pressure in the brain and so on) but also do so in different ways. ANT is not a theory. It offers no causal explanations and no consistent method. It rather takes the form of a repertoire. (Mol, 2010, p. 261-262)

Both STS and ANT have received their fair share of criticism. On the one hand the principles of STS and ANT are questioned by defenders of science who criticise the lack of solution orientation and the anti-science politics of its deconstruction of the scientific enterprise (Martin, 1993); and on the other hand, by political economists who claim that its ontological flattening disregards the power relations embedded in a-priori structural relations such as race, class, gender and colonialism. In Harris's (2005) terms structure and agency are replaced by 'a single plane of endlessly entangled translations' that renders ANT incapable of challenging the inscribed powers of racism, oligarchy, patriarchy, or euro centrism. They worry that ANT's vocabulary and analytical tools cannot challenge power structures, but only describe them (Marsden, 2000; Castree, 2002). In this there lies an impasse; ANT scholars suggest that they have a compelling and politically potent understanding of agency, providing clear views of the power relations in fixed and stable categories, but at sites and in moments of translation where they are endlessly reconfiguring and where/when they might be contested.

STS scholars maintain that their deconstruction of science has provided crucial challenges to the formation and practices of the science establishment and demonstrated the value of opening their gilded cage to social scientists (Jasanoff, 2003). Their interventions have led to emphasis on collaboration, interdisciplinarity, the co-design and co-production of knowledge with lay actors, improved science communication and scientific literacy, and indeed vastly improved scientific practice through reflexive practices. Public concerns about relationships between technological change and food, public health, animal safety, the environment and employment have been improved, allowing science to do its work more effectively and appropriately. By tracking the BSE crises, and the cautious (and sometimes hostile) reaction towards genetically modified food, STS scholars have demonstrated public distrust of governments and their official representatives (Hagendijk & Irwin, 2006; Lengwiler, 2008; Jasanoff, 2012). The flatness of ANT has helped to analyse large technical systems and extend it to include political, organizational, and legal factors. The flatness has also aided building improved food safety relational regimes, for example, those associated with the *E. coli* -157:H7 outbreaks (Stuart, 2010).

Most significantly, however, STS and ANT have shown that when viewed "up close," traditional descriptions of scientists, scientific activities, and scientific intellect are no longer tenable. Science is not as objective, not as special, not as effective, and not as scientific as it has claimed. Its privileged status in claims about truth in nature-culture and claims regarding its apolitical nature have not stood up well to the scrutiny of STS (Nowotny, 1990; Jasanoff, 1992). The claims of the scientific method and reductive analyses, experiments, and measures by which we have come to know our worlds and make the choices that shape them have come under significant challenge. Science itself has been put under a microscope and revealed to be a social practice.

Science, as a process of gaining knowledge, has of course frequently delivered on its promise; by providing, for example, crucial understandings of food safety matters, new food production and

preservation methods, new management solutions to foodborne illness, and a raft of measures that form the basis of today's risk management, standards and qualculatory order of food trade. These successes are reflected in the place of science at the core of food safety governance. However, the traditional characteristics of the science process, including its rigorous method and its objectivity and neutrality are no longer taken for granted. The traditional scientific process is no longer seen as sufficient to grapple with the full, human-entangled complexity of food safety matters of fact, let alone the matters of concern that co-constitute food safety as a problem. Ensuring food safety remains a significant contemporary challenge, and science remains intricately bound into defining and addressing that challenge, while also alerting us to emerging problems. The rising levels of vibriosis (illness caused by *Vibrio* bacteria) amongst oyster eaters is one such example. In the chapters that follow, I hope to demonstrate how actor-network thinking can assist open the 'black box' of complex relationships existing between governments, technologies, knowledge, money and people. Further, such ANT thinking might help develop innovative and generative ways of considering relations nature, culture, science, food safety and governmental rationalities.

## CHAPTER 3: METHODOLOGY

This research aims to better understand the role science plays in food safety and the shifting relationship between science and food safety policy by considering the issues associated with raw oyster eating. The research seeks to gain an in-depth understanding of the concerned people and their views on vibriosis. While there is significant scientific literature on the biophysical science attributes of *Vibrio* bacteria there is little data available about the relationships between the scientists and the personnel responsible for determining the vibriosis food safety policies. This chapter sets out the methods used to investigate the entanglement of science, *Vibriosis*, oysters and food safety policy, with the aim of investigating the actual and potential role of science in oyster food safety.

### ***3.1 An STS Inspired Approach Anchored in Ethnography***

As discussed in the previous chapter, Science Technology Studies (STS) offer an alternative approach to addressing the human and non-human relations while also gaining an understanding of the knowledge and policy producing relationships at the core of eating oysters safely. This alternative goes beyond the efforts of constructing improved policy by criticising policy formation frameworks; such efforts are often based on the unstated assumption that policy efficacy might be improved with better science and neutralising the various politics of science and policy formation. STS studies emphasize practice itself, often through ethnographic studies of the making of science or policy. They eschew a search for truth in respect of efficient policy or its making. There is for these scholars, no right or best approach; only case specific experiments emerging from contests over resources, knowledge making, political encounters and ideas.

The recent trends in ethnography, led largely by Mol (2010), attempts to understand case-specific assemblages from the inside, keeping an open mind and using the perspectives of research participants (members of a community) to understand assemblages in their own terms. (The assemblage of oyster food safety knowledge making offers such a case). It is “about telling a credible, rigorous and authentic story” giving voice to people in communities and using that voice to provide a “thick” description of events and daily practices (Fetterman 2010, p. 1). At its core, ethnography relies on participation and an embodied experience in the field giving researchers a privileged access to the practices and beliefs that make up everyday life (Herbert, 2000). Researchers observe ‘what people *do* as well as what they *say*’, and the effects of actions (Herbert, 2000, p. 552). Developed as a core methodology in Anthropology, it has traditionally involved extended periods of immersed observation in communities. In the last two decades scholars in other disciplines have begun to work with less immersed forms of observation, such as working within organisations (Barley, 1996), attending trade fairs, participating in social movements or alternative food initiatives (Escobar, 1998) or studying conferences as a participant (Ford & Harding, 2008). In these cases, observation is commonly supplemented with interviews, document analysis and other techniques of data gathering. These methods allow the ethnographer to be “both the storyteller

and the scientist” (Fetterman 2010, p. 2) and to develop concepts from the field (Hage, 2005; Hine, 2007; Das *et al.*, 2014).

Ethnography is then an approach to knowledge making that, as Mol observes, assembles material and enriches repertoires. In my case I assemble my own observations from deep immersion in the policy and scientific worlds of food safety over a long period of time, as well as more specific ‘scientific instruments such as semi-structured interviews and document analysis. These materials allow me to understand these food safety worlds as they are understood by those who occupy them, including myself. I could not be other than the fellow professional, with deep commitments to food safety and knowledge of the various associated politics of knowledge making that I was studying. In this sense, my research was enactive as well as ethnographic; I am committed to more appropriate use of science to achieve food safety and sought through the very exercise of my research, to make a better world.

### ***3.2 The ISSC as the Object of Research***

The USA has an extensive vibriosis epidemiological record. It also has a well-recorded history of attempts to employ science and public policy to mitigate and/or eliminate the illnesses caused by eating raw oysters containing *Vibrio* bacteria. It offers a helpful context in which to explore the role of science and its potential to underpin effective food safety public policy. As a dominant food safety assemblage in this context, the Interstate Shellfish Sanitation Conference (ISSC) is an almost perfect ‘laboratory’ for the analysis. However, as actor-network thinking dictates I recognise, there is no simple science behind my choice of ISSC as case, experiment or laboratory for this thesis. Rather it is itself an outcome forged by experiment, historical contingency, good fortune, and institutional framings. As discussed in Chapter 1, a career opportunity saw me stationed in the U.S. Food & Drug Administration (FDA) and provided with a unique opportunity to explore the USA situation and to interact directly with the scientists and public policy personnel responsible for dealing with vibriosis. It combined, in relations of contingency rather than necessity, with my earlier exposure to the ISSC and allowed me deeper access to it and an opportunity to study it as well as within it.

The research focuses attention firmly on the ISSC, which also provide both research site and sampling frame for data collection. The ISSC brings together scientists, industry, consumer group representatives and regulators of various jurisdictional scales. I have observed and participated in this conference since 1994. The conference is itself a key moment in the practice of oyster food safety, as well as an exemplar for, and a constitutive site in the formation of the oyster food safety assemblage. It is a platform upon which the USA oyster food safety regime is built and a key part of the architecture that frames the development of the science-policy linkages at its core. The pivotal relations among all the key actors are not simply on show, but in action. Regular conferences, the networks forged around them, and the roles given, and trust put in them by multiple experts and other authorities make the ISSC a crucial translation site, and each conference a key moment of translation.

Oyster safety worlds are forged in and through the ISSC, which I use as a site to study them and their constituent actor-networks. I do this through my own experiences of the conference (going back over

25 years), analysis of background documents and the ISSC proceedings, and a series of 73 key informant interviews with other serial attendees (see Section 3.4.1). The ISSC is only one of multiple sites through which I follow myself as an oyster-food safety actor (Cook, 2004; Fitzherbert, 2015). Other sites include oyster food safety in Australasia, Canada, Europe, South America and within FAO and WHO. In each of these sites I have engaged directly with actors (scientists presenting their work, regulators commissioning research and oyster consumer groups making impassioned pleas for their habits), including the non-human actors (oyster farms, lab tests for *Vibrios*, metrology data). I have eaten oysters with many of the actors and talked to oyster harvesters and industry folk. I have presented material to these different groups through conference presentations, invited talks and my research reports. Significantly these encounters have occurred in many different national, sub-national and supranational settings. I draw on these observations throughout this dissertation, and in the final chapter use the international experiences to reflect on the specificity of the USA case and how the findings might be used more generatively with other countries. As STS theory suggests, the information rich material used in this research proves there is no right or best approach. Instead, there is only a contest between the actors.

### **3.3 Positionality**

All research bears the mark of the researcher (Strauss, 1987), from imagining and identifying the research problem; to framing the research question; to the nature of ideas brought to bear and their assemblage into a specific theory and methodology for tackling it; to the resources that are then brought to bear on them; and the interpretations made of the research results. As Latour & Woolgar (1986) demonstrated, this can be as much the case for lab-based positivist science as it is for qualitative research. In the case of the latter, the question of access to research sites and the embodied and socially embedded relationships between researcher and research participants adds new situated dimensions to knowledge making. All knowledge is thus situated (Haraway, 1988; Fisher *et al.*, 2015) and by the entire research process rather than just by the perspectives of the researcher.

This research derives from a career long commitment to improving food safety and a scepticism of approaches that believe the answer to its problems lie simply in applying more science. I have been involved in public health for 42 years, specialising in environmental agents and food safety. My initial training was in the biophysical sciences and public health inspection, but many years of employment as a health inspector charged with enforcing regulations, necessitated a deep engagement with regulation and policy formation. In 1983, in my role as Senior Inspector of Health with the Department of Health 1983 I investigated an outbreak of food poisoning associated with New Zealand Greenshell mussels (*Perna canaliculus*). It was the middle of summer and people were suffering from diarrhoea. Their faecal specimens came back positive with something we had never heard of – *Vibrio parahaemolyticus*. I have now completed 34 years of work with this naturally occurring marine bacteria. This work included an appointment to the Ministry of Agriculture and Forestry as one of two NZ regional shellfish specialists responsible for implementing the country's shellfish sanitation programme. It was in this role that in 1994, I became a member of the USA ISSC and began working with colleagues and the FDA on how

best to deal with Vibrios, now framed as a rapidly emerging USA shellfish food safety problem (see Section 5.2.3).

As an ISSC member I attended the 1994 *Vibrio vulnificus* Workshop held in Washington DC. Following the 1994 Vibrio workshop I participated with fellow ISSC colleagues in later workshops and was thereby party to the tabling of the first *Vibrio vulnificus* policy in 1997 and *Vibrio parahaemolyticus* policy in 1999. The experience began to confirm for me that science was political, from hypothesis setting right through to application and take-up, and that it was uncertain and shifting. The initial ISSC workshops, for example, suggested that vibriosis could be eliminated by banning the sale of summer harvested Gulf of Mexico oysters or by using scientifically validated post-harvest treatments.

Over the ensuing 23 years I participated professionally in New Zealand and international Vibrio risk assessments. Such work included my Masters in Public Health thesis (McCoubrey, 1996) and FAO/WHO Vibrio Risk Assessments (WHO, 2005; WHO, 2011). In 2007, I left New Zealand government service to become a self-employed public health consultant. I have undertaken public health/food safety projects in many different parts of the world including New Zealand, Australia, USA, Africa, South East Asia, Afghanistan and Europe. This has involved work for national and international food safety governance bodies, science agencies and private companies. Several contracts have been with FAO, including nine months as the Food Safety Advisor for the African continent based in Harare, Zimbabwe. I have become a food safety translator.

This diversity of experience re-confirmed my appreciation that food safety problems and scientific advice about them are entangled in a host of cultural, political, environmental and other factors. Place and time add further contextual complexity to science-policy-public-industry-nonhuman relations. The food safety issues of Africa are very different from the food safety problems of New Zealand or the USA, not because of different disease agents but because of different social mores, different governance systems and the different use of science in different contexts. And of course, the policy frameworks involved include the work of international agencies, such as WTO, FAO and WHO, who have different trade and public health agendas.

In 2013 I was offered an ORISE (Oak Ridge Institute for Science and Education) study scholarship by the FDA which provided the opportunity to focus on shellfish food safety. This two-year scholarship provided a unique opportunity to read, observe and question the use of science and public policy in providing solutions to the vibriosis food safety problem. While based at the FDA 2013 undertaking my scholarship the USA Communicable Disease Center announced that the incidence of *Vibrio vulnificus* illness had not changed since the 1990s and that *Vibrio parahaemolyticus* cases were increasing. (See section 5.2.3). I asked myself, 'how could this possibly be'? I had participated in ISSC meetings and worked with the FDA and their scientists long enough to appreciate their professional competency and to recognise the extent of the science-based public policy initiatives to address the vibriosis food safety problems associated with oyster eating. The biophysical scientific solutions seemed relatively easy to implement, and therefore public policy easy to design. My two-year placement with the FDA provided an opportunity to ask more pointedly why science had failed to mitigate, or indeed eliminate, vibriosis. I hoped the answer might inform my wider consultancy work by offering insights on how this failure might

relate to other food safety issues and why it is not always possible to quickly and easily design and adopt effective science-based international food safety governance. My experience suggested that more refined understandings must, and perhaps an answer, might lie outside the biophysical science disciplines.

This consolidated my desire to undertake a PhD: to research further the relationship between science and public policy. I wanted to contribute to the knowledge base, enabling societies to determine the best way to manage food safety matters. I did so as a mature, New Zealand professional woman with a long career in environmental health and seafood safety. My career has involved a diversity of roles in diverse places, alongside people from diverse professional and cultural backgrounds. Working in the USA with members of the ISSC, I had built professional networks based on mutual respect for expertise and political and ethical commitments to food safety. This gave me rare access to participants involved in the oyster food safety and to public and classified documents that charted the history to the 'vibriosis problem'. My background in biophysical sciences, research in oyster-vibriosis relations, and applied work in seafood food safety have given me a set of understandings and the language to converse with others in the field, such as scientists, policymakers and oyster fishermen. It allowed me to build rapport that fostered positive communication experiences in the research fields. At the same time, my professional familiarity with Vibrios, the ORISE scholarship and my professional national and international networks meant I was well positioned to contribute knowledge to this important area of food safety, and thus further strengthen research relationships and render them 'enactive'. I take up the dilemmas of insider-outsider positioning in the next section.

### 3.3.1 The Insider-Outsider Conundrum

A long experience working in the same occupational field can mean the entrapment within traditional paradigms. Long tenures can also mean investment in the procedures and occupational mores of the day, potentially resulting in one being less critical and inflexible in the face of new ways of thinking. However, moving from New Zealand to live in the USA for two years jolted me from comfortable paradigms. Being in a country so different to New Zealand meant exposure to different ways of thinking and doing things. However, I still endeavoured to maintain awareness of engrained paradigms, while consciously considering new ways of thinking. When working on my MSc thesis, which focused on Science and Public Policy, "social science" and later the emerging field of Science Technology Studies (STS) were newly introduced to me. STS had placed "science" under its own microscope, concluding that science is in fact not such a special, unique or unbiased discipline. I wanted to explore if these conclusions might hold the answers in solving the chronic vibriosis problem linked to oysters.

As an ORISE student based at the FDA I found myself both an "insider" and an "outsider", particularly when dealing with the ISSC group. An "insider" because of my ISSC attendance and participation since 1994, making me a familiar face who had formed networks with other conference participants. My "insider" qualities offered advantages in understanding the conversations and norms of all the ISSC participants, including discussions about shellfish industry practices, the status of food safety science, public policy and politics associated with the ISSC. Arriving to take up the USA research position I was quickly welcomed as part of the FDA national team and given the privileged position of being able to

speak freely with scientists, epidemiologists and others, including state and federal regulatory agencies. My role as a long term ISSC member helped me identify, and gain access to, potential research respondents. Not everyone interviewed was previously known to me, but my background and contacts provided a point of reference to introduce myself to those who might otherwise have reluctant to be involved.

Originating from New Zealand meant ISSC members considered me to be an “outsider”; outside the ISSC silo of federal or state regulators, scientists or industry representatives. New Zealand, being a foreign entity does not have voting rights at the ISSC, therefore is perceived as a neutral participant. Although based in the FDA during the ORISE scholarship I was not perceived as a federal regulator, but simply as a neutral visitor. This perception meant an openness towards me when they expressed their views on the USA governance system. Those interviewed generally expressed trust in me to both understand their views and use the knowledge gained appropriately. Being both an “insider” and “outsider” during my USA research offered many advantages. It allowed me to appreciate all that I learned while working inside the USA borders, while providing the opportunity to compare and contrast with my experiences outside of the USA.

Throughout my fieldwork there was an awareness, as others have discussed, that positionality is not a fixed or static state and may shift along a continuum of possibilities (Merriam *et al.*, 2001; Labaree, 2002; Mercer, 2007; Chavez, 2008). Mercer (2007) states that the boundaries between “insiderness” and “outsiderness” are permeable and highly unstable. All researchers are both multiple insiders and outsiders, moving back and forth across different boundaries. Dwyer and Buckle (2009) equally argues that it is restrictive to lock the researcher into a dichotomy that emphasizes either/or, one or the other. While the literature recognizes the advantages and disadvantages of insider and outsider, experience has made me recognize the claim made by Dwyer and Buckle (2009, p. 59) that “the core ingredient is not insider or outsider status but an ability to be open, authentic, honest, deeply interested in the experience of one’s research participants, and committed to accurately and adequately representing their experience”. Sultana (2007) extends this argument stating that the researcher needs to pay greater attention to the issue of reflexivity, positionality and power relations in the research process, not only during fieldwork but also during the data analysis process. This became a conscious component in my research and in writing this thesis, at which time I reflected on the diversity and commonalities of the USA vibriosis situation compared with the international scene.

### **3.4 Mixed-Method Qualitative Approach**

I assemble material from multiple sources: my own observations of the policy and scientific worlds of food safety, more specific ‘scientific’ instruments such as semi-structured interviews and document analysis. Such use of multiple sources for knowledge making is often termed the ‘mixed-method approach’; an approach that frequently results in superior research when compared to mono-method research (Johnson & Onwuegbuzie, 2004; Tashakkori & Teddlie, 2010). Greene, Caracelli & Grahame (1989) reviewed 57 mixed method studies (i.e. using both quantitative and qualitative methods) and presented five purposes or potential advantages of using mixed qualitative methods: (a) initiation—

discovering fresh perspectives through paradoxes and apparent contradictions; (b) triangulation—testing the convergence or validity of results; (c) complementarity—elaboration, enhancement, illustration and clarification of results; (d) development—using the results from the first methods to inform, design and implement the second method; and (e) expansion—extending the breadth or scope of the project. Therefore, while the thesis fieldwork focuses on the USA situation, it is also possible to compare and contrast the findings with the wider global vibriosis food safety science and public policy issues (Johnson & Onwuegbuzie, 2004; Hammond, 2005; Tashakkori & Teddlie, 2010).

### 3.4.1 Semi-structured Interviews

My secondment with the FDA provided the opportunity to question and converse with my ISSC colleagues about their opinions on vibriosis. The ISSC is the organization empowered with the with legal mandate to assimilate scientific information and develop food safety regulations for oysters ([www.issc.org](http://www.issc.org)). The specific features of the ISSC will be described in Chapter 5, Section 5.3, meanwhile it is to be noted that the ISSC has a diverse professional membership of shellfish harvesters and processors, scientists, state and federal regulators. My research provided the unique opportunity to not only interview 100% of the voting ISSC officials responsible for determining USA oyster food safety regulations, but also many other ISSC colleagues representing the viewpoints of this diverse professional group.

Five radically open interview questions were designed to ensure a consistent framework was used to gather these opinions, namely:

- 1) Do you think that Vibrios are a significant food safety problem in the USA that should be addressed? (noting any difference between *Vibrio parahaemolyticus* and *vulnificus*).
- 2) Why do you think we have not been successful in reducing the number of Vibrio cases?
- 3) Is more science the answer? If so, what science is required?
- 4) Do you think that the FDA has a role to play in the Vibrio food safety situation?
- 5) If you had the ability to fix the Vibrio problem what would success look like?

These five questions were chosen to explore the theoretical considerations of problematization, interessement, enrolment and mobilization of allies as previously described in Chapter 2. Five questions also seemed an adequate number to deal with the thesis subject scope, while not being a numerical burden to those interviewed. The interviews were designed less to gain answers to five set questions, but more as a starting probe to gather interviewee's views and perceptions. To this extent the questions were designed to open thematic conversations and to elicit and explore information rather than to gain specific factual responses. The choice of semi-structured interviews was premised on the need to provide all 73 respondents plenty of 'elbowroom', or flexibility and to encourage their free response and avoid either constraining their views or "leading" the witness. Such an approach is well accepted and long established as an appropriate and useful means to gain insight on research issues (Abrahamson, 1983; Legard, Keegan & Ward, 2003).

The selection of the specific wording of the five questions was on the basis that respondents would understand and relate to them. To pilot the usefulness of the questions they were first tested on five people randomly selected ISSC members. This pilot test validated the five questions: they were understood by the interviewees, served well as conversation starters and elicited the conversational responses necessary to gain useful insights. As there were no adaptations to the five questions, the five pilot interviews were included in the final set of interviews.

Consideration was also given to ensuring that the chosen interviewees represented the various occupational and geographical groups within the ISSC membership. A review of the ISSC membership list identified five distinct occupational groups: federal regulators (FDA), state regulators, shellfish industry personnel, FDA scientists and private scientists actively engaged in *Vibrio* research. The USA is a large continental expanse with different geographical, climatic and marine features. To ensure I gathered interviews representing this geographical diversity I divided the USA into four different regions: Pacific Coast, Gulf Coast, North and South Atlantic Coasts. Each of these four regions exhibits differentiating features: commercial shellfish species, industry practices, consumption patterns, tidal and hydrographic features, and climates. Taking account of the geographical spread, 10 were interviewed from the Pacific Coast, 20 from the Gulf Coast, 20 from the North Atlantic coast, 16 from the South Atlantic, along with the voting members from the seven inland states who are ISSC members.

From the 2014 ISSC membership list, I randomly selected members' names from each of the four coastal regions, the inland states and the five occupational groups. My selection criterion was biased towards members who had at least ten years' experience in the ISSC *Vibrio* discussions. However, in some situations the states had recently appointed regulatory personnel responsible for *Vibrio* food safety management, so these officers were also interviewed. The decision was made to eliminate foreign country (Canada and New Zealand) members. Foreign countries have ISSC observation rights, but no voting rights. Having participated in the ISSC since 1994 I noted that the consumer lobby group *Centre for Science and Public Interest* (CSPI) was an active participant in the ISSC *Vibrio* discussions, albeit not a voting member. Therefore, the CSPI member who attends the ISSC conference was also included in the interview process.

Having determined a list of people of potential interviewees I contacted them by phone or email to ascertain their willingness to participate in a five-question semi-structured interview. Verbal informed consent was gained from all participants and confidentiality assured. Initially I started out with a short list of contacts to interview representing each region and occupational group. However, having successfully interviewed this short list I continued to contact other ISSC members. There was 100% response rate to my interview request, in other words no one turned down the opportunity to be interviewed. Eventually I interviewed 73 persons, 72 ISSC members and the CSPI member who attends the conference. Members from each of the five ISSC occupational groups were interviewed; 28 state regulators including all (100%) voting state regulators, (100%), 11 of the 18 (61%) of the federal regulators, 24 of 38 (63%) industry, five federal scientists (100%) and four (100%) scientists from other agencies. The following codes for these professional groups will be used in this thesis report: CSPI = Center for Science in the Public Interest; FedReg = Federal Regulator; Ind = Industry; Sc = Scientist; StateReg = State Regulator.

The interviews were undertaken between 18<sup>th</sup> February 2014 and the 26<sup>th</sup> November 2014. All interviews were recorded by writing in notebooks. The notebooks have been retained as raw data for later interpretation and analysis. The duration of the interviews ranged from 30 minutes to three hours long.

### 3.4.2 Documents

During my career I have collected and collated a library of grey literature on: oysters as a biological species and as a human food source, human epidemiology, environmental sources of pathogens, the attributes of *Vibrio* bacteria, regulatory food safety policies, science, public policy and governance. I was able to complement a close reading of this scientific and political material with insights drawn from my professional experiences with the many non-public documents I have read over the years.

During this research, a wealth of unpublished information was accessed, including environmental and food safety databases, unpublished reports, and other sources of information that may provide valuable information. This information was sourced from the files of government agencies, the ISSC, industry bodies and other stakeholder agencies and my professional network throughout the USA. This access was greatly facilitated by my position within the shellfish food safety section at the Head office of the FDA, based in Washington DC. The FDA Head Office seafood section is tasked with establishing the agency's preferred national food safety policies for oysters (and other seafood species). While determining these policies the agency collates and analyses information, including scientific data, along with trends in industry and regulatory practices. The FDA uses such grey information to underpin the agency's arguments when debating the ISSC food safety policies. Available information included the meeting transcripts of the ISSC and file notes at the FDA which I had permission to access. My interest extended beyond the USA as other countries are also struggling with how best to deal with the vibriosis food safety problems. Specifically, I gathered more grey literature from Australia, Canada, European Union countries, Japan and New Zealand. My international network of food safety professionals also enabled me to discuss the vibriosis science and public policy relationships in each of these countries.

This library of grey literature was collated, read and analysed and used to establish an historical overview of the problem, and to explore and unravel how actors relate to one another. In turn, this information was further synthesised and analysed to determine the valuable information with which to formulate the answers to the thesis questions.

### 3.4.3 Observation and Participation

Qualitative techniques, such as observation and participation, are well established and commonly accepted as the best means to understand people's behaviour and actions. Denzin & Lincoln (2000) and Flick (2015) state that these techniques offer an interpretive, naturalistic approach to the world. They also allow for the study of phenomena in their natural settings, providing a means to make sense of phenomena in terms of the meanings people bring to them.

Ethnography is typically characterized as involving an extended degree of participation in the field by the researcher. As described by Hammersley & Atkinson (1995).

In its most characteristic form, it involves the ethnographer participating, overtly and covertly, in people's daily lives for an extended period of time, watching what happens, listening to what is said, asking questions - in fact, collecting whatever data are available to throw light on the issues that are the focus of the research. (p.1).

My fieldwork with oyster food safety professionals from various backgrounds was always participatory, even if not strictly ethnographic in terms of immersion in an unfamiliar environment for a period of time. My participation allowed me to gather information from conversations and observations. In this sense, I follow elements of this assemblage through time and across multiple sites (Marcus, 1995; Cook, 2004). There are dimensions of auto-ethnography in my approach, that is by following myself and my encounters with others, many of whom I know from other times and places, ethnography becomes auto-ethnography. As an active and committed participant, I am not, however, a disengaged observer; rather one who is deeply engaged in enacting improved policy-relations. Like others who have placed themselves into motion with enactive intent, I use "myself as a means of gathering evidence in a particular place" (Einagel 2002, p. 223).

The research involved extensive and varied opportunities to observe and interact with a wide group of national and international oyster stakeholders. Such experiences included participating in the 2013 biennial International Conference on Molluscan Shellfish Safety (Sydney, Australia), 2014 ISSC meeting (San Antonio, Texas) and forums with other international shellfish control authorities. I had the opportunity to meet and collaborate with international and national scientific agencies. The international agencies included the European Union Food Safety Authority, UK Centre for Environment Fisheries and Aquaculture Science and New Zealand's Plant and Food and Cawthron Research Institutes. The USA science agencies included the Communicable Disease Center, Environmental Protection Agency, National Oceanographic and Atmospheric Administration (NOAA), FDA Gulf Coast Seafood Laboratory and USA state laboratories. My experiences included multiple field trips to the Atlantic, Gulf and Pacific coasts to learn about local conditions and industry practices. I participated in regional meetings with stakeholders, state regulators and USA Congress Members on Capitol Hill. During my tenure in Washington DC I was encouraged to talk to all FDA staff, not just seafood safety officers. I attended food safety meetings, national webinars held for government departments and conference calls regularly held between stakeholders, for example, the webinars with the Communicable Disease Centre. I kept a written logbook of all meetings, interactions and field visits, noting all the persons I met, and any new potential contacts referred to me. All these observation and participation opportunities enabled the gathering of rich material which was analysed and used for the conclusions of this thesis.

The process of textual production and reproduction which Atkinson (1992) and others regard as the creation of ethnographic work, begins with day-by-day writing up of notes of observations, and reflections concerning 'the field' (Emerson, Fritz & Shaw, 2001). Writing field notes is an important activity in participant observation. This study uses field notes as a key tool to record observed events, conversations, people and places. Observation, talking, asking questions and interacting with community members was viewed, and is, an integral part of this approach.

There is, in all of this a dimension of following my own journey (Fitzherbert, 2015). My own journey through the food safety world had become institutionalised in the ISSC and materialised in the relationships I shared with the various research participants. There are elements in the research of 'following' my own career path through the food safety policy-science assemblage, in a sense what FitzHerbert has called 'following myself' (Fitzherbert, 2015). Taking my lead from an invitation to circulate in this world, I followed the insights derived from my career and my own end-of-career pathway through the ISSC as a researcher 'interned with' the FDA. I studied my encounters in the field, which gathered momentum from the interests of the researched. I put myself in motion, followed, listened and watched, and waited for appropriate moments to engage more directly. My quest was not to contain wild happenings in an a priori framework or project, but to allow the 'what' and 'how' to take form in the wild. The initial encounters proved crucial and framed the engagement in terms that ascribed agency to the wild and let the wild situate and mobilise me. I was then free to 'theorise away' from the wild. It required me to embrace uncertainty, nonlinearity, being enactive, and the importance of affect and learning to be affected.

### **3.5 Data Analysis**

It was determined prior to starting the interviews that I would use Grounded Theory to analyse the information. Grounded theory is a systematic methodology formulated by Glaser & Strauss (1967), involving the discovery of theory through the analysis of data (Henwood & Pigeon, 1996). One goal of grounded theory is to formulate hypotheses based on conceptual ideas. Another is to discover participants' main concern and how they continually try to resolve this concern. From the data collected, key points are marked with a series of *codes* extracted from the text. The codes are grouped into similar *concepts* to make them more workable, and from these *categories* are formed, which provide the basis to build or construct a *theory*. In applying grounded theory the researcher repeatedly poses questions as to "What's going on?" and "What is the main problem of the participants?" and "How are they trying to solve it?" (Henwood & Pidgeon, 1996).

After each interview my notes were re-read, with summaries made of key topics or themes which emerged. Individual interview notes, along with the summaries developed from them were used to provide a holistic perception of the reasoning why scientific knowledge alone has proven inadequate to solve the vibriosis food safety problems. The interviews and summaries were read and reread to support detailed analysis. The key points from each of the interviews were recorded into summary charts for later meta-analysis. Many common themes were identified from the responses for each interviewee. These thematic perspectives are analysed in two ways in relation to the three key themes: by frequency counts of answers coded and categorised by class of answer; and then by thematic discourse analysis designed to capture the full richness of the narrative responses from interviewees. Direct quotes support the presentation and interpretation of the results and are used to highlight key dimensions of practice and discourse. These interview themes are then used to shape understanding and are explored further in Chapters 5 and 6.

The data analysis is inherently an iterative process. A question emerging from analysis of the transcripts was directed towards an exploration of the original interview notes; this in turn identified more questions and themes, stimulating a rereading of the interview transcripts. The writing process itself has been described as a form of analysis (O'Leary, 2005; Hunt 2010). In turn, writing up the results continually demanded a re-examination of transcripts and documents to ensure their interpretation was anchored in the voice and words of the interviewees and in the literature. In practice, the process of data analysis follows that recommended by Glaser & Strauss (1967).

### **3.6 Research Integrity**

A copy of the research proposal for this thesis was submitted to the University of Auckland Human Participants Ethics Committee (UAHPEC). Full approval was granted by the UAHPEC and with it an acceptance that it complies with both the requirements of the UAHPEC Application Manual and the Privacy Act 1993 (particularly Principles 10 and 11). See Appendix I for a copy of UAHPEC's rationale.

In line with the UAHPEC approval, the principle of 'protecting participants from harm' (Lewis, 2003) was consistently observed and applied with the interviewees and others consulted and, in the selection and use of the information provided. Equally, accepted norms of ethical conduct in research involving human participants were followed: the purpose of the research was presented to those interviewed and their informed consent obtained. Individual name confidentiality was assured, and all participants were offered the opportunity to express any concerns or questions before gaining their formal agreement to participate in the research. The need to protect confidentiality was an important consideration in the presentation of the results, particularly when choosing direct quotes for use in the research thesis. It was for this reason that when direct quotes are used the individual names have been replaced with an occupation and date identifier.

### **3.7 Conclusion**

Vibriosis, in particular *Vibrio vulnificus*, is currently deemed the world's most lethal food safety pathogen, killing 50% of those who are infected by the bacteria. With such a high fatality rate this bacterial illness causes international alarm. As such vibriosis was identified as a focus of study and as a lens to explore wider food safety issues and the application of science-based policies.

The methodology used for this research was shaped by the initial decision to focus on the USA oyster vibriosis problem and the opportunity presented by being offered by the food safety education scholarship to study for two years in the USA. The choice, use and application of a range of different research tools, was made in a conscious attempt to balance practical constraints of time and cost, with academic needs. The different tools used are based on established, tested practice and designed to obtain a range of perceptions, and insights from the different actors involved in vibriosis food safety problems. These tools include STS and ANT concepts, together with the ethnographic practice of assembling materials. These materials were gathered using a mixed-method qualitative approach; from

semi-structured interviews, documents (grey literature), and by observing and participating with others. This extended to the sample of people interviewed, their role in the oyster story and their geographical location and experience. An international perspective was obtained through reading and discussing material with food safety regulators and industry personnel from Australia, Canada, the European Union, Japan and New Zealand.

## CHAPTER 4: SCIENTISING VIBRIOSIS

Chapter 1 introduced the oyster, highlighting the animal's historical and contemporary gourmet appeal and the associated potential food safety consequences. These food safety problems are exacerbated by the oyster's filter feeding system, causing the accumulation of micro-organisms, viruses, protozoa, helminths, marine biotoxins or toxic substances and autochthonous (indigenous) micro-organisms such as the *Vibrio* species (FIICC, 1995).

This Chapter introduces the *Vibrio* as a biological and social agent, while also providing an overview of the global food safety problems associated with *Vibrio* bacteria. Vibriosis, the term given to human illnesses caused by *Vibrio* bacteria, is an international food safety and market access concern. Scientists, the food industry and food safety authorities have and continue to focus on measurement, prediction and management of the vibriosis food safety problems linked to the oyster. Or using ANT's terminology the raw oyster is constantly exposed to the processes of scientising, metrologising, managing and qualculating. An assessment of the volumes of published literature confirms that significant international resources have been spent on 'scientising' vibriosis. The following sections attempt to summarise this vast literature, providing a synopsis of vibriosis associated with eating raw oysters.

### **4.1 Biology of the *Vibrio* genus**

When an Italian anatomist, Filippo Pacino, first viewed the cholera bacteria through his microscope he named them "vibrions", because of their motility (movement) (Lippi & Gotuzzo, 2014). Since Pacino's original discovery other microbiologists have revealed at least 78 more *Vibrio* species within the genus (Zhang & Austin, 2005), each exhibiting the distinguishing features which differentiate them from other microbial groups. They are all halophilic (salt-loving), gram-negative, test positive for oxidase, have a curved-rod (comma) shape with a polar sheathed flagella tail used for motility and they do not form spores (Joseph, Colwell & Kaper, 1982; Farmer & Hickman-Brenner, 2006; Drake, DePaola & Jaykus, 2007).

Being halophilic *Vibrio* species are found naturally and ubiquitously around the world in marine and estuarine environments. Indeed, Vibrios are one of the world's most common organisms (Veenstra, *et al.*, 1994). As reported by DePaola (1994) *Vibrio* species are often harboured in the intestinal tract of fish with higher levels occurring in the more benthic (bottom-dwelling) fish. They can also be transported around the world's marine environments by ship ballast water, migratory bird and fish species, tidal currents and imported and exported seafood (DePaola, Caper & Alexander, 1994; FAO/WHO, 2011; Martinez-Urtaza *et al.*, 2013).

*Vibrio* species play chemical, physical, symbiotic and commensal roles in the marine environment. They all produce chitinase, a digestive enzyme that breaks down glycosidic bonds in chitin and mineralized chitin which are both factors in the attachment and biofouling of surfaces (Daniels, 2011). This enzyme

contributes to the degradation of chitinous detritus and the ecological balance in estuarine environments. Vibrios also appear to be able to adsorb onto chitin, which can account for their association with shellfish and zooplankton (Plotkin, Kilgore & McFarland, 1990; Daniels, 2011). As well as chitinase Vibrios produce other enzymes, probably essential for interactions to sequester nutrients in nutrient limiting environments as well as from oysters, fish, plankton and other entities on which Vibrios survive and proliferate (USFDA, 1994). Vibrios play an important nutritional role in the food web, being fed upon by other marine ciliates. Some species can exhibit bioluminescence (Oliver, *et al.*, 1986) and this feature has been used in symbiotic relationships. For example, *Vibrio fischeri* is a bioluminescent species which is frequently found living with marine animals such as bobtail squid. This Vibrio species is helpful to the squid, a nocturnal forager, by erasing the shadow that would normally be visible seen as the moon's rays strike the squid, protecting the squid from its predators. The squid, in turn, provide the bacteria with shelter and a stable source of nutrients.

The Vibrio species are metabolically very diverse and not all of them cause disease in humans or other animal species (USFDA, 1994; Sims *et al.*, 2011). Of the 78 species identified so far more than 20 have been described as causing disease in animal species (EU, 2001). For example, Vibrio species have been associated with shrimp disease (Moriarty, 1998) and *Vibrio vulnificus* Biotype 2 is associated with infections in cultured eels (FAO/WHO, 2005b). Their interactions with humans are probably purely accidental (USFDA, 1994).

Twelve Vibrio species have so far been reported to be pathogenic to humans (EC, 2001). Some of these, such as *Vibrio alginolyticus*, cause skin and ear infections when humans are exposed to marine waters (Pien, Lee & Higa, 1977; Daniels & Shafaie, 2000). Eight of the 12 Vibrios known to be pathogenic to humans are associated with foodborne disease. However, it is only three Vibrio species which represent a serious and growing public health hazard: *Vibrio cholerae*, *Vibrio parahaemolyticus* and *Vibrio vulnificus*. For the purposes of this research the focus will be on *Vibrio parahaemolyticus* (Vp) and *Vibrio vulnificus* (Vv) because these two pathogens are internationally associated with seafood safety problems.

#### 4.1.1 Introducing Vp and Vv

Unlike *Vibrio cholerae*, which can be associated with human sewage pollution, neither Vp nor Vv are related to human pollution. Instead both are found naturally in tropical and temperate coastal and estuarine (brackish) environments (Colwell, 1984; EC, 2001; Codex, 2010). They live not only in seawater and sediments, but also in association with marine species such as plankton, arthropods and crab larvae (USFDA, 1994; Turner *et al.*, 2013; Huehn *et al.*, 2014). Researchers have found that the prevalence and density of Vp and Vv in the marine environment and in harvested seafood products is highly dependent on the ambient temperature with the largest numbers occurring at high sea temperatures (20-30°C) (EU, 2001). While both Vp and Vv live in the marine environment, stimulated by salt concentrations, the two species have slightly different environmental preferences.

*Vibrio parahaemolyticus* are detected throughout the year in tropical waters (Natarajan *et al.*, 1980). In other geographical areas where Vp have been detected, the prevalence and concentration of these

bacteria follow a distinct seasonal cycle, with highest counts recorded in the summer and autumn and lowest counts in the winter. In temperate waters Vp has an annual cycle, surviving in the sediment during the winter and being released when the water temperature rises to between 14 and 19°C (Kaneko & Colwell, 1973; EC, 2001; Codex, 2010). Vp is rarely found in marine waters below 10°C though they have been isolated from shellfish growing in water at 0.6°C and from sediments at these cooler temperatures (Baross & Liston, 1970; Kaneko & Colwell, 1973; Strom & Paranjpye, 2000; Desmarchelier, 2003; Bauer *et al.*, 2006). Seawater temperatures above 20°C favour Vp multiplication and their concentration can reach 100 cells/ml when seawater temperatures increase to 25°C (Kaneko & Colwell, 1973; DePaola *et al.*, 1990). Vp can grow in sodium chloride concentrations ranging from 0.5% - 10% with optimum levels between 1% and 3% (FAO/WHO, 2011). The relationship between salinity and Vp appears to be variable and complex (Johnson *et al.*, 2012). Salinity appears to be a major factor in the prevalence of Vp in tropical waters but in temperate regions, it seems that the salinity relationship may vary with different regions and sites (FAO/WHO, 2011; Lopez-Hernandez *et al.*, 2015).

*Vibrio vulnificus* - both biological and physico-chemical factors are important to Vv's survival and the prevalence and density Vv in the environment and in oysters is highly dependent on the ambient temperature. The organism is rarely isolated from marine waters at temperatures below 10°C although the organisms can be cultured from sediment and oysters at those temperatures (USFDA, 1994; Strom & Paranjpye, 2000; Desmarchelier, 2003). They may grow in the marine environment at temperatures around 13°C, but numbers generally remain low (i.e. close to or below the limit of detection) at temperatures below 20°C (FAO/WHO, 2005; Johnson *et al.*, 2012). Highest concentrations of Vv have been detected when the water temperature was between 20 and 30°C (Desmarchelier, 2003; FAO/WHO, 2005; Wetz *et al.*, 2014). As with Vp the evidence for salinity being an important influence over the presence of Vv is less clear compared with temperature (Froelich & Noble, 2016). The salinity optimum appears to vary depending on the geographical site, but the highest Vv numbers are usually found at low to moderate salinity levels of ranging from 5-25‰ ( Tamplin *et al.*, 1992; Motes *et al.*, 1998; Desmarchelier, 2003; Wetz *et al.*, 2014). Based on data from the USA 17‰ is the optimum salinity for growth of Vv (FAO/WHO, 2005).

The literature review confirms global ubiquity of Vp and Vv. Both pathogens have been identified in marine environments and seafood samples around the world, including Australia (Maxwell *et al.*, 1991), Brazil (Rodrigues, Ribeiro & Hofer, 1992), Canada (Banerjee, Pagotto & Farber, 2007), Chile (FAO, 2011; ICMSS, 2015), France, (Geneste, 2000), Korea (Chong, Park *et al.*, 1982), India (Sawaswathi, Barve & Deodhar, 1989), Italy (Ottaviani, 2005), Japan (FAO/WHO, 2011), Korea (Park, Sun Shon & Joong, 1991), Mozambique (Ansaruzzaman, 2005), New Zealand (Wright, 1991; McCoubrey, 1996), North Sea (Veenstra, *et al.*, 1994), Thailand (Wongpaitoon *et al.*, 1985), Taiwan (Chuang *et al.*, 1992), Russia (Nair *et al.*, 2007), Saudi Arabia (Chagla *et al.*, 1988), Scandinavia (Norway, Sweden and Denmark) (EU, 2002; Bauer, Ostensvik & Florvag, 2006), United Kingdom (Wagley *et al.*, 2007) and all USA coastal regions including the Hawaiian Islands (Nip-Sakamoto & Pien, 1989). These identifications highlight that Vp and Vv occur naturally, both in tropical and temperate marine waters throughout the world, and therefore available to be uptaken by bivalve shellfish, including oyster species.

### 4.1.2 Vibrios and Oysters

Similarly, to other seafood-borne bacteria and viruses, Vp and Vv lodge in the tissues of filter-feeding molluscs, such as oysters, clams and mussels (USFDA, 1994; EU, 2001; FAO, 2005; FAO, 2011). Indeed, Vp and Vv have been found associated with many species of oysters including American oysters (*Crassostrea virginica*), Pacific oysters (*Crassostrea gigas*), European flat oysters (*Ostrea edulis*) and Sydney Rock Oyster (*Crassostrea commercialis*) (Eyles, 1984; Harris-Young *et al.*, 1995; Beaz-Hidalgo *et al.*, 2010). It is therefore assumed that all oyster species have the capacity to accumulate Vp and Vv when they are present in the aquatic environment.

The number of Vp and Vv accumulated in oysters depends on the general environmental conditions and on the health of the oyster itself. The concentration is primarily influenced by water temperature and salinity, but also by the level of dissolved oxygen, the amount of zooplankton in water and the rate of tidal flushing, since these factors influence both *Vibrio* populations and the feeding behaviour of oysters (Kaneko & Colwell, 1977; Venkateswaran *et al.*, 1990). The amount of particulate matter in the water, as measured by turbidity, has also been positively correlated with *Vibrio* concentrations in oysters, water and sediment (Zimmerman *et al.*, 2007; Johnson *et al.*, 2010). Increased concentrations of Vp have also been measured in oysters experiencing one or more causes of stress, for example, heat (Aagesen & Hase, 2014). In any case, DePaola *et al.*, 1990 found that during summer shellfish often had Vp concentrations two hundred times greater, on average, than those found in the corresponding seawater. Likewise, Vv can be accumulated to concentrations 1-2 log higher than found in surrounding waters (O'Neill, Jones & Grimes, 1992; Johnson *et al.*, 2010).

Once inside the oyster both *Vibrio* species persist, even reproducing to high levels in the oyster's tissues and haemolymph (blood) (FAO/WHO, 2011). Selective retention in oysters was also demonstrated by the isolation of Vv from oysters when no Vv was detected in the surrounding waters (Harris –Young *et al.*, 1995). Even so, each oyster may shed up to one million *Vibrio* cells per day into the water (Tamplin and Capers, 1992). Both Vp and Vv will grow in oysters when they are out of the water if the ambient temperature is suitable. Summer conditions permit *Vibrio* multiplication in oysters exposed by the receding tide because the temperatures of the exposed shellfish can be up to 10°C above the air temperature. Research has confirmed intertidal oysters can contain *Vibrio* concentrations 4-8 times higher when exposed on sunny mudflats than later when the tide has re-sub merged the oysters and filter-feeding recommenced (Nordstrom *et al.*, 2004; Kinsey *et al.*, 2015; Jones, *et al.*, 2016).

Oysters are not fragile and can live out of water for at least several days or weeks under refrigeration. Indeed, Sydney rock oysters (*Crassostrea commercialis*) can remain alive for up to two weeks once harvested at ambient air temperatures (Nell & Holliday, 1988). If they are shipped live to markets for raw consumption, any *Vibrios* inside the oyster also remain alive through to the point of human consumption. Florida oyster retail outlets were sampled monthly for one year (March 1989 to March 1990) and *Vibrio* species were found in the oyster samples throughout the year, though Vv only during the warmest months. This finding refutes the widely held USA belief that raw oysters are safe to eat in any month spelled with an "R" (September – April) suggesting that raw oysters may serve as a vehicle of transmission for *Vibrio* infections throughout the year (Klontz *et al.*, 1993).

Human illness occurs when viable Vp and Vv are present in oysters, though the incidence and severity of the Vibrio infections depends on both bacterial and human host factors. The following sections summarises the state of knowledge about the relationship of Vp and Vv with humans.

### 4.1.3 Vibrios and Humans

*Vibrio parahaemolyticus* (Vp) was first recorded to have caused human illness in Osaka, Japan where in the fall of 1950 there was an outbreak of food poisoning associated with boiled and semi-boiled young sardines (*Engraulis japonica*) (Hara-Kudo & Kumagai, 2014). Of 272 persons affected with acute gastroenteritis, 20 died. These deaths led to an intensive outbreak investigation and ultimately to the identification of an etiological agent that was named *Vibrio parahaemolyticus* (Joseph, Colwell & Kaper, 1982). The first major USA Vp outbreak occurred in Maryland in 1971 and was associated with improperly cooked crabs (EC, 2001). Before 1980, Vp outbreaks in the USA were associated with seafood but not specifically with raw oysters. In contrast, in the 1990s raw oysters were the vehicle of transmission in 69% of the Vp outbreaks reported to CDC (Morris & Acheson, 2003). Since then Vp illnesses associated with oyster eating have been recorded in many places around the world including Asia, Australia, Canada, Europe, Mexico, South America and USA (FAO/WHO, 2011).

The most common clinical syndrome caused by Vp infection via food is gastroenteritis, including vomiting, nausea, abdominal pain, and watery (sometimes bloody) diarrhoea. (FAO/WHO, 2011; Odeyemi, 2016). The incubation period is short (4-96 hours). The median incubation period is 17 hours (range 4-90hrs) and the median duration of illness is 2.4 days (range 8 hours to 12 days). Infection can lead to hospitalisation and treatment with antibiotics, but the disease is usually self-limiting. The long-term effect of reactive arthritis has been reported (Tamura *et al.*, 1993). Mortality rates for the USA, where Vp is a nationally notifiable disease, are 1-2% per year (this includes cases with wound infections). Vp infection may occasionally lead to septicaemia, a severe, life-threatening disease caused by the multiplication of pathogenic microorganisms and/or the presence of their toxins in circulating blood. These rare cases are usually linked to patients with some other underlying chronic disease.

While the whole population is considered susceptible to Vp infection, pre-existing medical conditions may make some people more susceptible. Case control studies have found that Vp infection was six times more likely in people having a pre-existing chronic disease (Odds Ratio (OR) 6.0, 95% Confidence Interval (CI) 1.5-23.7), and eight times more likely in people who had taken antibiotics during the four weeks prior to illness (OR 8.1, 95% CI 1.2-56.4) (Liao *et al.*, 2015; Yan *et al.*, 2015). Illness is more likely to progress to septicaemia in people with underlying immunocompromised chronic disease, and the probability of this occurring has been estimated as 0.025 (or 25 in every 1,000 people in this subpopulation) (USFDA, 2005). An estimated 20% of people with septicaemia caused by Vp infection die (USFDA, 2005).

*Vibrio vulnificus* (Vv) illness may have been first referred to by Hippocrates, when in the fifth century BC he described a fatal illness in a man living on an island in the Aegean Sea. As the acute infection was characterized by black bullous skin lesions, rapidly progressive septicaemia, and death on the second day it is now hypothesized that this death was caused by *Vibrio vulnificus*. (Baethge & West, 1988). The

first confirmed reported clinical case of Vv infection occurred in 1970 in a patient who, after exposure to New England coastal waters, presented with a leg wound infection and endotoxin-related septic shock that necessitated below-the-knee amputation. Vv was recognized, identified and described as a human pathogen in 1976 by the USA Communicable Disease Center Enteric Disease Laboratory, when it was referred to as the lactose positive or the halophilic *Vibrio* species (USFDA, 1994). At that time, Hollis *et al.* (1976) described the characteristics of 38 isolates of halophilic bacterium isolated from blood cultures, cerebrospinal fluid and wound infections. This same bacterium, along with three other species, had earlier been isolated by scientists from the Pacific Ocean near the Hawaiian Islands by Baumann, Baumann & Mandel (1971) and they named the genus *Beneckeia*. Therefore, literature published between 1971 and the 1980s often refers to Vp and Vv as *Beneckeia parahaemolyticus*. Subsequent taxonomic revisions have placed this organism in the *Vibrio* genus and in 1979, the pathogen was officially named *Vibrio vulnificus* (Daniels, 2011).

Three different clinical syndromes have been documented associated with Vv: wound infections, primary septicaemia and gastroenteritis (Daniels, 2011). Primary septicaemia and gastroenteritis are both associated with eating oysters (Bachman *et al.*, 1983). The incubation for Vv period is short, averaging 26 hours (Oliver, 2015). Vv cells that survive the acidity of the upper gastrointestinal tract can penetrate the intestinal wall (most likely in the ileum) to enter the bloodstream and manifest as primary septicaemia (Horseman & Surani, 2011). Symptoms of primary septicaemia include fever (94%), chills (86%), nausea (60%), abdominal pain (44%), hypotension (43%), and the development of secondary skin lesions (69%), which typically develop on the extremities (Oliver, 2015). Almost one third of patients are in septic shock at hospital admission and the characteristic skin lesions appear within 24 hours of symptom onset (Bross *et al.*, 2007). Cases of primary septicaemia require intensive care and rapid antibiotic treatment (Daniels, 2011). The median time until death is two days after symptom onset. Necrotic skin lesions may require debridement (removal of dead tissue) or amputation (Stavric & Buchanan, 1997).

Vv septicaemia is most common in patients with suppressed immune systems, especially alcohol-induced liver disease or chronic Hepatitis B or C (both of which can also cause liver disease) (Bross *et al.*, 2007). Data from the USA found that 97% of patients with primary septicaemia had some chronic disease, including liver disease (80%), alcoholism (65%), diabetes (35%), malignancy (17%) and renal disease (7%) (Strom & Parajype, 2000; Bross *et al.*, 2007). Liver disease makes people particularly susceptible because, in addition to immune system dysfunction, they have high concentrations of iron in their serum and Vv requires iron for survival and growth (Daniels, 2011; Oliver, 2015). Hlady, Mullen & Hopkin (1993) estimated that adults with liver disease and who eat oysters are 80 times more likely to contract Vv than those without liver disease. Further, where the source of Vv is raw oysters, 74% of patients having liver disease become mortalities - only 26% survive. Among people without liver disease the outcomes are reversed (Scallan *et al.*, 2011).

In addition to having underlying medical conditions, most septicaemia cases are males and people over the age of 40 years (Oliver, 2015). There are several possible reasons for this: people over the age of 40 are more likely to have developed underlying health conditions, males are more likely to work in the seafood industry, and oestrogen has a protective role against Vv endotoxin. Experiments with simulated stomach and intestinal conditions have demonstrated that antacids increase the survival of Vv, elevating

the risk of infection for people consuming such medications (Koo *et al.*, 2000a, 2000b; Koo *et al.*, 2001). Vv has only caused sporadic cases. There has not been a single Vv outbreak (which means two or more cases linked to a specific event) reported.

A recent review of described Vv as the “single most fatal foodborne pathogen in the USA, and possibly the world” (Oliver, 2015). Approximately half the number of people with Vv primary septicaemia will die (Daniels, 2011). Ingestion syndromes account for 58% of reported cases, but 80% of the fatalities. The main source of Vv ingestion infections is raw oysters with 90% of patients eating them within the week before the illness. The following case exemplifies a typical Vv case who had consumed oysters.

In 1992, the Florida State Department notified CDC that a person had died while on vacation in Florida. He was a 40-year-old man with Hepatitis C who was being evaluated for a liver transplant. On the 23<sup>rd</sup> July, he consumed two dozen oysters at a local restaurant as part of his evening meal. Four days later, on the 27<sup>th</sup> July, he presented at a local emergency room in hypotensive shock with nausea, vomiting and diarrhoea, and blistering painful wounds covered both legs. He died within 24 hours despite aggressive antimicrobial therapy and admission to the Intensive Care Unit. The hospital laboratory identified *Vibrio vulnificus* in a blood specimen drawn from the patient. This scenario is typical of the mortalities related to oyster-borne (Whitham, 1994).

## **4.2 Science Calculates the Vibrios**

Pacino was the first to see a *Vibrio* bacterium with his own eyes, albeit with the aid of a microscope. Since his first sighting science has evolved into numerous (some might say reductionist) disciplines, meaning no longer is it only the microbiologist who has the capacity to see *Vibrios*. Instead various other disciplines have become interested in the *Vibrios*, each developing their own methods with which to see and understand the bacterium, it's association with the oyster's intricate filter feeding system and the flow on human health effects. Since the 1970s public health scientists have increasingly focused their attention on *Vibrios* in oysters, the food most commonly implicated in foodborne vibriosis. As Michael Carolan (2004) states “method makes reality” and “through translation reality shifts”. Carolan asserts that translation must first occur in our perception of nature through phenomena, such as machines, models and computer printouts (Carolan, 2004, p.504). Therefore, what we observe is not nature itself, but nature exposed to science's questioning.

Today, *Vibrios* are 'enacted' (made visible) through several scientific disciplines, each with their own methodologies, including:

- 1) Microbiologists - who in 1971 perfected the lactose positive agar test which had the capacity to identify the presence of *Vibrio* bacteria. Since then microbiologists have honed increasingly sophisticated tools, including molecular and PCR (Polymerase Chain Reaction) analytical methods, with which to make *Vibrios* and all their genetic traits more visible.
- 2) Biologists and Marine Biologists - who study and describe the living conditions and ecology of the *Vibrio* species.

- 3) Epidemiologists - who use case definitions and statistical techniques to translate the incidence of human vibriosis. Further, epidemiology has been the most prominent and influential approach to scientising the relationship between the *Vibrio*, oyster and humans.
- 4) Environmental scientists and modellers - who use measurements, such as seawater temperature and salinity, as surrogate measures with which to portray and/or predict the environmental presence of *Vibrio* bacteria.

These scientific disciplines have focussed their attention on Vp and Vv, intent on making them visible via their reports, graphs and calculations. The following sections consider the scientific outputs due to making *Vibrios* and vibriosis visible, along with the data gaps that cause vibriosis to remain a science enigma.

#### 4.2.1 Laboratory Analytical Assays for Vp and Vv

Since Pacino's original microscopic sighting of a *Vibrio* bacterium scientists have developed multiple microbiological, biochemical, immunological and molecular analytical methods, each capable of making Vp and Vv "visible" in the laboratory. Scientific efforts have been directed towards developing better molecular-based detection methods to improve sensitivity, shorten testing time and indicate pathogenicity (Malcom *et al.*, 2015; Wang *et al.*, 2016).

The conventional method for detecting foodborne vibriosis involves isolating *Vibrio* bacteria on differential/selective agar media after broth enrichment of seafood. These methods are time consuming, generally requiring up to four to seven days to produce results. These methods are also believed to have led to an underestimation of the pathogenic Vp in seafoods. Agar culture-based techniques are still important for obtaining a bacterial isolate, thus there are also efforts to improve culturing techniques (Rosec *et al.*, 2012; Escalante-Maldonado *et al.*, 2015; Nigro and Steward, 2015).

The next generation of assay is molecular testing, using deoxyribonucleic acid (DNA) colony hybridization and PCR-based assays to target pathogenicity genes to identify and characterize foodborne vibriosis. The presence of inhibitors in seafoods and non-specific DNA products especially in multiplex PCR formats necessitate labour intensive DNA extraction and purification procedures (Bej *et al.* 1999; McCarthy & Blackstone, 2000). As a result, these molecular methods usually take three days to complete (Panicker *et al.* 2004b). Rapid and sensitive real time PCR (RT-PCR) quantitative assays were then developed for Vp and Vv; some of which could be used in the field and laboratory (Blackstone *et al.*, 2003). The introduction of real-time PCR amplification has made detection of foodborne pathogens rapid and cost-effective along with simple result analysis. The entire detection method, including sample processing, enrichment, and real-time PCR amplification of the Vp and Vv can be completed within eight hours making it a rapid single-day assay (Panicker *et al.*, 2004 a,b). A range of molecular methods are used to investigate genetic relatedness between Vp and Vv isolates (e.g. Haendiges *et al.*, 2015; Hazen *et al.*, 2015; Ludeke *et al.*, 2015; Silvester, *et al.*, 2016).

The improved sensitivity, specificity, speed and cost effectiveness of the new scientific assays means that the amount of environmental and clinical information about *Vibrios* is growing rapidly. Yet gaining formal regulatory recognition and approval for new methods is a slow process and not all new

methodologies are being used within government science programmes. The FAO have recently reviewed and evaluated the Vp and Vv methods and published general guidance on the selection of fit-for-purpose methods, with the intention that internationally comparable datasets are generated (Drake *et al* 2007; Bisha *et al*, 2012; FAO/WHO, 2016).

#### 4.2.2 Epidemiology

Epidemiology is the science which studies the interrelationships between hosts, their environments and the occurrence of disease in a human population (CDC, 2006). Therefore, epidemiological methods are designed to detect a causal association between a disease and the characteristic of the ill person and factors in their environment. Since neither populations nor environments of different times or places are identical, these epidemiological variables are studied to determine the aetiology of disease (CDC, 2006). *Surveillance*, the term epidemiologists give to their vigil over the occurrence and distribution of disease, is a continuous and systematic process consisting of four major functions: collection of relevant data; consolidation of the data into meaningful arrangements; analysis (interpretation of the data); and regular dissemination of this data.

Many countries have adopted regulations which make it mandatory to undertake epidemiological surveillance for listed diseases. However, these mandatory requirements vary from country to country, particularly for vibriosis food borne diseases. The European Centre for Disease Prevention and Control does not collect data on *Vibrio* species from European Union Member States (EC, 2001). *Vibrio* infection is not notifiable in Canada, but may be kept under surveillance in some states, for example, Alberta. Vp infection is not notifiable in New Zealand unless an outbreak is detected, while Vp is a notifiable infection in three Australian states (ESR, 2016). In the USA surveillance of Vp and Vv have slowly progressed from within some states in 1979 to national surveillance in 2007 (Sims *et al.*, 2011).

Occasionally a specific pathogenic Vp serotype becomes dominant and can spread to other regions or countries. These are called pandemic strains because of their geographic spread, but lack the characteristics of a truly pandemic microorganism which, by definition, infects a high proportion of the population (Nair *et al.*, 2007). A pandemic Vp strain, known as O3:K6 emerged in 1996 (Nair *et al.*, 2007) increasing hospitalisations from Vp infection where ever it prevailed. The scientific literature contains multiple reports of the O3:K6 clone isolated from clinical and environmental samples as the clone spread to different countries and five continents, causing sporadic disease and outbreaks (Chiou *et al.*, 2000; Vuddhakul *et al.*, 2000; Ansaruzzaman *et al.*, 2005; Rykovskaia, *et al.*, 2013). While first recognised as an outbreak of clinical cases in India 1996, O3:K6 was perhaps first isolated from a traveller returning from Indonesia to Japan in 1995 (Nair *et al.*, 2007). The O3:K6 clone emerged in Japan during 1995 and by 1998 was the dominant serotype isolated from humans (Hara-Kudo & Kumagai, 2014). The first outbreak of the O3:K6 clone in United States was reported in 1998 where the vehicle of infection was oysters (Daniels *et al.*, 2000). The O3:K6 clone was first isolated in England in 2012, from Pacific oysters and water (Powell *et al.*, 2013), but was isolated earlier from travellers returning the UK (Wagley *et al.*, 2008). The clone has now caused repeated outbreaks in Chile, where Vp was not even considered a food safety problem in 2001. Another new strain, known as Vp serotypes O4:K12 and O4:KUT, has emerged as a pandemic strain. These serotypes were first identified in the

north west Pacific waters of North America in 1988, then causing large scale Vp outbreaks in 1997 and 2004. During the summer of 2012, outbreaks of Vp infection caused by O4:K12 and O4:KUT occurred on the USA Atlantic coast and in Spain (Martinez-Urtaza, 2013).

While epidemiologists use epidemiological variables to describe an illness event once it has occurred, science is still unable to forecast which Vp and Vv bacteria will cause illness and under what circumstances. In many respects Vibrios remain a mystery, because science lacks specific knowledge about the number of Vp and Vv bacteria required to infect humans (the infective dose) and what causes Vibrios to be pathogenic to humans (USFDA, 1994). The following sections summarise the state of knowledge about Vp and Vv.

#### 4.2.3 Risk Assessments and Scientific Modelling Tools

The risk analysis/ assessment food safety regime was discussed in Section 2.2.6 and vibriosis is no stranger to this regime. While not a formal risk assessment report, in 2001 the European Commission's Scientific Committee on Veterinary Measures relating to Public Health prepared a document on *Vibrio vulnificus* and *parahaemolyticus* in raw and undercooked seafood (SCVMPH, 2001). This report was written following the European Commission's request that the Scientific Committee assess the risk to human health from Vv and Vp in raw and undercooked seafood and the appropriateness of setting food safety standards for these pathogens (EC, 2001).

Formal Vibrio risk assessment reports have been undertaken by scientists in several countries (McCoubrey, 1996; FAO/WHO, 2005; USFDA 2005; FAO/WHO, 2011). McCoubrey (1996) reported on the risk of *Vibrio vulnificus* infection following the consumption of raw commercially harvested North Island oysters from New Zealand. In 2005 FAO/WHO published the *Risk Assessment of Vibrio vulnificus in raw oysters*<sup>7</sup> and the FDA published their *Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus In Raw Oysters*. In 2011, FAO/WHO published the *Risk Assessment of Vibrio parahaemolyticus in seafood*, which included a specific Vp & raw oyster risk assessment applying the FDA's 2005 risk model to estimate the risk of illness from Vp due to the eating raw oysters in Australia, Canada, Japan and New Zealand (FAO, 2011). Much of this Vibrio risk assessment work was based on scientific evidence gathered from the USA where vibriosis illness is the most prevalent.

Tools were needed to implement the risk analysis regime, so scientists invented risk calculators (USFDA 2005; FAO/WHO, 2011). In 2005, the FDA developed supposedly predictive Vp and Vv models after undertaking the *Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus In Raw Oysters*. The European Food Safety Authority (EFSA) hosts "Vibrio Viewer", as a real-time map incorporating daily remote sensing data (e.g. water temperature, salinity) into a model to predict the environmental suitability for Vibrio species in coastal waters. The model driving the mapping software has been calibrated to the Baltic Region in Northern Europe<sup>7</sup>. However, while scientists work towards models and tools that will adequately prevent illness the international prevalence

---

<sup>7</sup> Vibrio Viewer: <https://e3geoportal.ecdc.europa.eu/SitePages/Vibrio%20Map%20Viewer.aspx>. (accessed 4<sup>th</sup> April 2018).

of vibriosis appears to be increasing (Scallan *et al.*, 2011; Baker-Austin *et al.*, 2010, 2014). Epidemiological data and environmental surveys suggest the largest risk to human health comes when shellfish are harvested from waters  $\geq 20^{\circ}\text{C}$  (Cook *et al.*, 2002). Indeed warmer temperatures appear to be the cause of Vp extending its geographical range into marine areas such as Alaska (McLaughlin *et al.*, 2005), Europe (Martinez-Urtaza *et al.*, 2013) and Chile (Gonzalez-Escalona *et al.*, 2005). Further it is forecast that environmental changes, such as climate change, will increase the prevalence of vibriosis.

#### 4.2.4 Pathogenesis Remains an Unknown

Since the first discoveries scientists have identified numerous environmental and clinical strains of Vp and Vv. For example, in 1996 373 Vp strains were isolated from Korean waters (Kim, 1999) while in Italy 726 strains of Vp were found in Adriatic seawater and shellfish sample during a two-year survey (EC, 2001) While there are multiple Vp and Vv strains, not all types are harmful to humans. Scientists are still trying to determine specifically what and where Vibrios will be pathogenic.

Vp research over the last decade has identified that the pathogenicity factors are not as well understood or as not as predictable as earlier thought and no single or suite of markers that can predict the ability of an isolate to cause disease with certainty (Jones *et al.*, 2012; Nydam *et al.*, 2014; Saito *et al.*, 2015). The search for reliable Vibrio pathogenicity markers is complicated by the finding that there are both evolutionary and ecological forces acting on Vp populations (Raghunath, 2011; Paranjpye *et al.*, 2012; Loyola *et al.*, 2015). Bacteriophages may also genetically alter Vibrios (Hurley *et al.*, 2006; Wang *et al.*, 2006). As a result, it is unlikely that there is one simple set of pathogenicity factors, and these factors will vary regionally. The best estimation for Vp dose response (infection level) comes from a model based on data from human clinical feeding trials, anchored to epidemiological data from the USA (USFDA, 2005). The model predicted a 50% probability of illness for a dose of approximately  $1 \times 10^8$  Vp cells, or between  $10^7$  and  $10^{10}$  cells when uncertainty is considered. At exposure levels of approximately  $10^4$  cells, the probability of illness is  $<0.1\%$ .

As with Vp there is also evidence of multiple Vv strains, for example, in the USA 118 strains of Vv were isolated from just three oyster samples taken from Apalachicola Bay, Florida (Buchrieser *et al.*, 1995). There is scientific evidence that Vv are genetically diverse and Vv virulence appears to be multifaceted and is not yet well understood. While there may be two specific Vv subgroups (environmental and clinical strains), at this stage of scientific knowledge it is believed Vv pathogenicity could be one of the following bacterial features: extracellular products, strains utilizing transferring-bound iron, a Tumour Necrotic Factor, specific Vv genes and the production of membrane pili (Bogard & Oliver, 2007; Horseman & Surani, 2011).

The dose of Vv required to cause gastroenteritis or septicaemia is not known. Estimates of  $10^3$  and  $10^4$  have been made for people with pre-existing health conditions which make them more susceptible to infection, but the actual dose may be lower or higher. Others have proposed that the dose may be higher (Daniels, 2011) or lower (USFDA, 2012; Oliver, 2015). The number of oysters eaten by infected cases varied from one oyster to several dozen oysters. The infective dose of Vv is not known as there have been no human volunteer studies investigating the dose-response relationship. Some experiments have

been done on mice, rats, hamsters, rabbits or guinea pigs. These animal experiments suggest that all Vv strains might be equally virulent (DePaola *et al.*, 2003). However, this assumption has been questioned as others have indicated that only a few strains of the diverse Vv are linked to human disease. Estimating the infectious dose is complicated by the presence and relative numbers of various types and strains of Vv in shellfish (and the uncertainty over their virulence), and the influence of underlying illness in patient. Furthermore, a high concentration of host serum iron is essential for the multiplication of the bacterium, which only grows at elevated iron concentrations (Wright *et al.*, 1990; EU, 2001).

The lack of scientific information about the pathogenesis factors of Vp and Vv is well recognised internationally. In 2005, the FAO and WHO undertook a full review of the published scientific literature linked to vibriosis virulence and pathogenicity and concluded that virulence appears to be multifaceted and is not well understood. Therefore, the FAO/WHO recommend a precautionary food safety response and to consider all Vp and Vv strains be considered virulent (FAO/WHO, 2005)

#### 4.2.5 Reducing and Eliminating Vibrios in the Oyster

The rate of destruction or elimination of Vibrios in oysters has public health significance, so scientists have spent significant energy on looking at ways to rid the Vibrios from oysters, both when they are living in their natural, watery marine environment and after harvest. Science has researched, or is currently exploring ways, of reducing or eliminating vibrio bacteria in oysters before they are harvested including: oyster breeding and biological controls (Harris-Young *et al.*, 1995; Faisal *et al.*, 1998; Allen & Burnett, 2008; Richards *et al.*, 2012; Brousseau *et al.*, 2014); relaying oysters to natural water bodies of high salinity (Motes & DePaola, 1996); and depurating in controlled tanks systems (Borazjani *et al.*, 2003; Ramos *et al.*, 2012; Mahmoud, 2014). However, despite such efforts scientists still do not know how to prevent bivalves naturally taking up Vibrios when they are naturally present in the water column or how to remove them from the oyster before harvest.

Further, methods have explored how to reduce or eliminate Vibrio bacteria in oysters after they have been harvested. Post-harvest washing and oyster shucking (removing the oyster from its shell) do not significantly reduce the levels of Vibrios in oysters (Cook & Ruple, 1992). The increase or decline of Vp and Vv levels in harvested oysters is related to the ambient air temperature (USFDA, 2005). Vp bacteria do not multiply when the temperature is below 10°C and when oysters are stored at refrigeration temperatures of  $\leq 7.2^{\circ}\text{C}$  the levels of Vp decrease slowly as cells die under this storage condition (USFDA, 2005). Vibrios are susceptible to freezing, but regular domestic freezing conditions cannot be relied upon to kill viable Vp and Vv bacteria from oysters (FAO/WHO, 2011). At temperatures between 15-40°C Vp growth can be very rapid, with a generation time as short as 8-9 minutes in the laboratory under optimal conditions (37°C). On the other hand, Vv is capable of multiplying in oysters at temperatures above 13°C, confirming the importance of post-harvest storage times and low storage temperatures (Cook, 1994; 1997).

Vibrios are readily destroyed by cooking even when the oysters are highly contaminated (Codex, 2010). Vv is more sensitive to heat than other Vibrio species and other foodborne pathogens. Vv ( $4.3 \times 10^3$

CFU/g) in naturally contaminated shellfish was reduced to non-detectable levels by exposing oysters to a temperature of 50°C for 10 minutes (Cook & Rupple, 1992). *Vibrios* are also sensitive to low pH so acidic marinades or sauces may affect them. Marinating half-shell oysters (*C. virginica*) in lemon juice or white vinegar for 30 minutes reduced the concentration of naturally present Vv by 3.4 and 2.5 log<sub>10</sub> MPN/g, respectively (Borazjani *et al.*, 2003). While there was some belief that “hot sauces”, such as Tabasco sauce or horseradish-based seafood cocktail sauce, killed Vv scientific investigations measured no significant reduction in the concentration of Vv inside the meat of raw oysters treated with sauce (10 minutes) compared with control oysters to which no sauce was added (Sun & Oliver, 1995). While Tabasco sauce significantly reduces the concentration of Vv on the surface of the oysters, the *Vibrios* inside the oyster tissues remain protected, viable and able to cause vibriosis.

Science has identified four post-harvest processes (PHP) capable of reducing *Vibrio* levels to non-detectable levels (defined as <30 per gram). These processes are cool pasteurization, cryogenic individual quick freezing with extended storage, high hydrostatic pressure (HHP) processing (Berlin *et al.*, 1999) and low-dose gamma irradiation (Ama, Hamdy & Toledo, 1994). Cool pasteurization is a mild thermal treatment of oysters in the shell, followed by a rapid cooling. HHP is a method of inactivating microorganisms in half-shell and shucked oysters by subjecting them to very high pressure (35,000-40,000 psi) for 3 to 5 minutes (USFDA, 2011). HPP inactivates Vp and Vv by damaging the cell membrane, cell wall and degrading cellular proteins (Wang *et al.*, 2013). *Vibrio* spp. are among the most radiation-sensitive bacteria. Irradiation involves exposing oysters to ionising energy, either gamma rays, machine-generated electrons or X-rays. An ionising irradiation dose of 1.0 kGy reduced Vv artificially bioaccumulated in whole shell oysters from 10<sup>7</sup> MPN/g to non-detectable levels and had the same effect on naturally present Vv (10<sup>3</sup> MPN/g) (Andrews *et al.*, 2003). Each of these processes have been rigorously tested and is now an FDA-approved control process for *Vibrio* spp.

In summary, Vp and Vv have the capacity to increase in oysters after the oysters come out of the water. While some storage methods, such as chilling and freezing, will reduce the *Vibrio* levels they will not eliminate them. However, scientists have identified post-harvest treatments which have since been rigorously tested, then validated by FDA regulators as capable of reducing Vp and Vv levels to below the level of detection in oysters (defined by FDA as <30 *Vibrios*/gram). Therefore, science has provided food technologies with which to eradicate vibriosis.

#### 4.2.6 Looking to the Future - Climate Forecasting

Climate related changes may impact all three elements of the epidemiologic triad (host, agent and environment) (Tirado, *et al.*, 2010). Climatic factors can affect the sources and modes of transmission; the growth and survival of pathogens in the environment and the microbial ecology; and the food matrix, amongst other things. It is possible that *Vibrios* will become more prevalent around the world due to various transport pathways and climate change.

Due to the relationship between temperature and the environmental presence of *Vibrios* there is concern about the potential effects of climate change. Climate change has been linked to both rising ambient and seawater temperature, along with changing weather patterns. Changing weather has been linked

to sea level elevation, heavy precipitation, flooding, and changes in water salinity which may all have an impact on water microflora, including aquatic human pathogens such as pathogenic Vibrios (Tirado, *et al.*, 2010). Ocean warming causes acidification and changes in ocean salinity and the biochemical properties of water, in turn affecting microflora, fisheries distribution, fish metabolic rates, along with persistence and patterns of pathogenic vibrio occurrence Vibrios (Marques, 2010; Vezzulli *et al.*, 2016).

There are also concerns in Europe and other parts of the world that the increasing numbers of Vibrio illnesses may be linked to rising temperatures of the oceans (Gonzalez-Escalona *et al.*, 2005; McLaughlin *et al.*, 2005; Paz *et al.*, 2007. Baker-Austin *et al.*, 2010; Sims, 2011). Importantly, Vezzulli *et al.* (2016) found a positive correlation between human *Vibrio* spp. infections reported during the period 1973-2011 in Northern Europe and the USA Atlantic coast, and *Vibrio* spp. abundance. This correlation was particularly evident during heat waves. They also found that the highest number of reported *Vibrio* spp. infections were correlated with the presence of the *Vibrio* species, *cholerae*, *parahaemolyticus* and *vulnificus* in the phytoplankton samples. This work demonstrates a link between increased *Vibrio* spp. concentration in seawater due to result of ocean warming and increased incidence of human *Vibrio* spp. infections. The strong La Nina events over continental USA during 1998/99 resulted in higher than usual concentrations of Vv in oysters taken from the Gulf Coast (Cook *et al.*, 2002). The 2004-5 Chilean Vp outbreak, causing over 10,000 cases, was of epidemic proportions (Fuenzalida *et al.*, 2006). This large outbreak was associated with the reversal of the reversal of the Humboldt Current during the El-Nino Southern Oscillation (Gonzalez-Escalona *et al.*, 2005).

### **4.3 Synopsis of the Vibriosis story**

Vp and Vv belong to the wider family of Vibrio organisms inhabiting the marine environment. Their presence in the marine ecosystem is a natural phenomenon, unrelated to human pollution sources. Both Vp and Vv are linked to foodborne illnesses in at least 21 different countries, including New Zealand and it is predicted that the problem will spread and increase. Vp usually causes mild gastroenteritis outbreaks throughout the general population, whereas Vv usually only affects individuals who are immunocompromised, but in this subpopulation the morbidity and mortality are more severe with up to 50% fatality rates.

The highest risk of vibriosis in the USA is associated with raw oyster eating, thereby causing adverse effects on both human health and the seafood trading business. As a result, there are international efforts by scientists, food safety authorities, industry and others to better understand Vibrio's relationship with the biophysical (natural) and human environments. However, to date vibrios remains an enigma. While science has an understanding about Vibrio's life cycle, there remains significant data gaps about the environmental and evolutionary factors that cause vibrios to become pathogenic. Further, epidemiologists lack understanding about which Vp strains and the ingested dose that cause human foodborne vibriosis. As a result, it is not yet possible to provide a predictive and preventative public health programme based on shellfish harvesting practices. None the less while science fails to fully understand how to control Vibrios in their natural environment (and in raw oysters), the food scientists

have identified several fail proof post-harvest technologies, for example oyster pasteurization, that can eliminate vibriosis.

The literature used to underpin this chapter highlights that the scientific process of gaining knowledge has been used to understand the biophysical attributes of Vibrios and vibriosis. This literature highlights that while biophysical knowledge gaps remain, the scientists have used their traditional black box tools to measure how Vibrios relate to the marine environment, oysters and humans. The biophysical scientists offer simple vibriosis solutions, such as post-harvest oyster treatments. Yet, the current literature does not explain the complex vibriosis relationships between the biophysical scientists, governments, boardrooms, funding agencies and public policy decisions.

The following chapters will zoom in more closely on the USA, exploring the multi-layered science relationships and why vibriosis remains a food safety issue. By taking an ANT view of the multiple relationships it is possible important conceptual and empirical vibriosis information will be exposed.

## CHAPTER 5: THE INTERSTATE SHELLFISH SANITATION CONFERENCE FRAMES THE 'PROBLEM'

In this chapter I examine the documentary evidence and my own professional experience in the context of the United States' oyster economies, including the use of my 2013-14 field notes recorded during the observations and participation with key informants and ISSC participants. I describe these economies and the part expected of and played by the Interstate Shellfish Sanitation Conference (ISSC) in managing food safety within them. I examine the ISSC to uncover the oyster food safety assemblage that has emerged in the USA and develop a schematic model of how science is supposed to play a central role. In the second part of the chapter I use interview material to deconstruct this model and identify the complex relations at work in the messy lived world of vibriosis management. I draw on material from interviews with key informants and ISSC participants to question how the vibriosis assemblage is pulled together, their relationships with science and the practices that materialise from them.

### ***5.1 Oyster Economies in the USA***

The USA has an estimated human population of 326 million and consumption surveys suggest as many as 13% of the population are estimated to eat raw oysters (FDA, 2010). Numbers are higher in the coastal states of Texas, California, Florida and Louisiana, where between 16-19.5% of adults over the age of 18 have been estimated to eat raw oysters regularly (ORC Macro, 2004). Therefore, it is estimated that between 42 million and 65 million people in the USA regularly eat raw oysters. Not surprisingly, the oyster industry is significant; in 2012 aquaculture alone produced nearly sixteen million kilograms of oysters valued at US\$136 million, while in 2014 oysters were harvested from wild and aquaculture coastal sites in 23 of the 50 US states. Further, the domestic oyster supply (wild and aquaculture) is supplemented with imports as the USA is the leading global importer of seafood. In 2012 an additional nine million kilos of oysters were imported worth US\$52 million ([www.fisheries.noaa.gov](http://www.fisheries.noaa.gov) Accessed 27<sup>th</sup> March 2018). Yet the USA's valuable food industry is not the only oyster economy. Additionally, science, food safety and regulatory economies exist because the oyster, particularly when eaten raw, is the seafood most commonly associated with foodborne vibriosis.

The country has the highest number of the world's reported Vv cases, with Florida contributing to over 40% of the USA's total. Most cases of Vv are associated with oysters harvested from the USA Gulf Coast, though the infection rate is still only 0.5 cases per one million persons. Infections generally occur between April and November which accounts for 72% of the cases related to ingestion infections. This marked seasonality gives the key period for intervention. Indeed, epidemiologists believe if Americans with liver disease and other serious pre-existing conditions were prevented from eating raw oysters harvested during the warm summer months, 65% of ingestion and 75% of the USA fatalities could be avoided. Geographical features also affect the disease incidence, as exemplified from studies in Chesapeake Bay where Wright and Hill (1996) showed that the level of Vv in seawater and oysters is

comparable to those that have been reported in the Gulf of Mexico, but for some reason there are few Vv cases linked to oysters from the Chesapeake water body.

Unlike Vv cases which are linked to Gulf Coast oysters, the Vp hotspots are linked to the Pacific Northwest particularly Puget Sound, and the Atlantic states. In 1997, there was a multi-state Vp outbreak associated with oysters harvested from California, Oregon, Washington and British Columbia in Canada. The largest USA Vp outbreak to date was in 1998, associated with oysters from Galveston Bay, Texas with over 400 cases reported.

There is evidence that climatic events can affect *Vibrio* concentrations in oysters. The strong La Nina events over continental USA during 1998/99 have been linked to higher than usual concentrations of Vv in oysters harvested from the Gulf Coast (Cook *et al.*, 2002). It is not only Vv levels that are rising due to climate change; during the last 15 years, there has been a significant shift from sporadic (single) cases of Vp infection towards large outbreaks attributed to the consumption of oysters harvested from northern waters, which in turn has been linked to higher mean water temperatures (McLaughlin *et al.*, 2005; Drake *et al.*, 2007). For example, an outbreak caused by oysters harvested from Alaskan waters, has been linked to the progressive warming of seawater at the oyster farm between 1997 and 2004 (McLaughlin *et al.*, 2005).

In any case, the incidence of foodborne Vp infections is increasing in the USA. The 2010 incidence of USA laboratory confirmed *Vibrio* infections was significantly higher than 2006-2008 (39% increase), and in 2009, the rates of human *Vibrio* infection were substantially higher than compared to 1998-98 (Sims *et al.*, 2011). The USA Communicable Disease Centre (CDC) estimates that there are now 35,000 domestically acquired food borne Vp cases and 100 Vv cases per year (Scallan *et al.*, 2011; Newton *et al.*, 2014). However, it is important to stress that most people do not suffer any adverse effects after consuming oysters. Even in the groups recorded as having the highest risk of contracting vibriosis (defined as oyster eating & liver-diseased USA Floridians) more than 99.9% do not get sick (CDC, 1993; Hlady *et al.*, 1993). However, no matter how the vibriosis risk is calculated it remains that some raw oyster eaters will suffer, and it behoves a food safety authority to consider what might be done. The following section discusses who this authority is in the USA.

## **5.2 The Interstate Shellfish Sanitation Conference**

As with all food products the USA has established governance systems to deal with oyster food safety risks. However, unlike most other countries the USA's national food safety agency, the U.S. Food and Drug Administration (FDA), does not have the national responsibility for formulating oyster food safety policy. Instead the food safety regulations for bivalve molluscan shellfish (including oysters) are established by a co-operative organisation comprising the shellfish industry, scientists, state and federal regulators.

The USA oyster food safety co-operative has a long and proud history. This successful regime harks back to the late 1900s when the newly opened USA railroads delivered oysters to inland cities such as Chicago. Wealthy consumers, appreciating the specialty of oysters, were prepared to pay well for the

privilege of eating them, but unfortunately, the oysters served at civic receptions caused several large typhoid outbreaks. The wealthy and ill oyster eaters quickly notified the press and politicians, resulting in the USA Surgeon General prohibiting the inland trade of oysters. Suffering economically due to the trade ban the oyster industry approached the government requesting a way to reopen trade, while also assuring public food safety. In response, the 1925 USA government brought together stakeholders, including industry representatives, the Public Health Service, Bureau of Fisheries, State and municipal authorities and State conservation commissions. Industry, scientists and governance authorities worked together to define the problem, determine preventative measures and formulate policies that could be implemented by all to reduce the illness problems (Ref: Original notes from the 1925 meetings). This collaborative work resulted in the country's first oyster food safety regulatory controls and the USA is internationally recognised as one of the first countries to use scientific principles to underpin a regulatory shellfish sanitation regime (Hackney & Pierson, 1994).

Today this co-operative philosophy has prevailed within the ISSC, the USA's designated authority empowered to define 'normal' oyster food safety protection, determine the food safety rules and govern deviance from these national regulations. The ISSC states its main objective is fostering and improving shellfish sanitation through interstate cooperation and through uniformity of state shellfish programmes ([www.issc.org](http://www.issc.org)). Further, the ISSC defines its responsibilities as:

- Adopting sound, uniform, shellfish sanitation methods, accepted by participating shellfish control authorities and documented in an operations manual known as *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish* (NSSP Guide);
- Promoting mutual respect and trust among shellfish control authorities, the shellfish industry, and consumers of shellfish; and
- Providing a forum for shellfish regulators, the shellfish industry and academic community to resolve major issues concerning shellfish sanitation.

The ISSC membership has not changed since the first 1925 gathering and remains a working assemblage of industry representatives, the FDA (previously known as the Public Health Service), Bureau of Fisheries, State and municipal authorities and State conservation commissions.

### 5.2.1 The ISSC Participants

This diverse group of ISSC professionals, who come together because of their common interest in oysters (and other bivalve shellfish species), all play a part in the conference although some members such as the FDA have a higher profile.

*Food and Drug Administration* - The FDA is an important member. Having signed up to ISSC membership the FDA agreed to refrain from formulating unilateral shellfish food safety policies and to instead comply with the conference's co-operative policy protocols. In a specific 1985 MOU with the ISSC the FDA agreed to take on three ISSC roles:

- the FDA's federal food safety representative;

- FDA officers are tasked with ensuring state and industry compliance with the ISSC regulations (NSSP Guide);
- the ISSC's official science provider.

Further, the 1985 ISSC/FDA MOU recognizes the FDA as the agency responsible for providing the ISSC with scientific research, training and technical assistance. In return the FDA pledges to make every effort to maintain a current scientific basis for the NSSP guidelines and standards (1985 ISSC/FDA MOU).

FDA scientists first began describing the Vibrios in the 1970s and since then have continued professional endeavours to solve vibriosis (FAO, 2005; USFDA, 2005; FAO, 2011). Today they are recognised as international leaders in Vibrio research (FAO, 2011), applying a multi-disciplinary focus to vibriosis and using modern food safety tools, such as the risk assessment framework and modelling tools, recommended by international food safety authorities (FAO, 2005; USFDA, 2005; FAO, 2011). Indeed, the United States was the first country to apply the risk analysis model recommended by FAO/WHO to Vibrios when producing their 2005 *Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus In Raw Oysters*. FDA scientists also took the lead roles in the FAO international oyster Vp and Vv risk assessments (FAO, 2005; USFDA, 2005; FAO, 2011).

Further, FDA scientists were the first to build a 'Vibrio risk calculator', a model which made assumptions about bacterial growth rates under a variety of environmental conditions. Four factors were used to model exposure: level of pathogenic Vibrios in seafood at harvest; effect of post-harvest handling and processing; ability of the organism to multiply to an infective dose; and number of pathogenic Vibrios consumed. Unfortunately, it was ultimately found that that Risk Calculator was not predicting, nor preventing the number of vibriosis cases, resulting in the scientists' agreement that further work needed to be done on the algorithms. These new algorithms have yet to be designed. However, FDA scientists continue to offer ISSC technical options to deal with vibriosis. Based on CDC's data about the increasing Vp burden the FDA drafted new proposals for the 2013 ISSC meeting, including Proposal 13-204 requesting that Vv and Vp be treated the same for policy purposes and that all harvested shellfish be cooled to 50°F within one hour of harvest. The FDA used pre-conference forums to promote this proposal, but it was ultimately rejected by the conference.

A timeline of the FDA's significant actions associated with Vibriosis and which are discussed in this report can be found in Appendix II.

*Center for Science in the Public Interest (CSPI)* - While not an official ISSC member, a USA lobby group, officially known as the Center for Science in the Public Interest (CSPI) has been an active conference participant since the 1990s. The CSPI has a national role to educate the public, advocate government policies that are consistent with scientific evidence on health and environmental issues, and counter industry's powerful influence on public opinion and public policies. Such lobbyists represent the views of different sectors or interests in respect of regulation, and their presence at the ISSC recognises the asymmetrical knowledge and associated power relations of what would otherwise be a market-framed configuration. The CSPI lobbyists have the potential to be change the ISSC policies.

CSPI has been particularly vocal about the incidence of vibriosis associated with Vv (though not Vp) and the need to eliminate the problem. In association with their goal CSPI have written numerous critical

papers about both the FDA and the ISSC, for example, *Death of the Half Shell* (CSPI, 2001) and have twice formally petitioned the FDA for stiffer raw oyster food regulations. They were also instrumental in leading conference debates about Vv, often sponsoring Vv victims and family members to attend and tell their sad stories to the ISSC forum.

### 5.2.2 How the ISSC Co-operates

The *ISSC Constitution, By-Laws and Proceedings (Updated May 28, 2017)* outlines the organization's operational procedures. The ISSC has an Executive Board comprised of: six representatives from producing state shellfish control agencies, three representatives from non-producing state shellfish control agencies, six industry representatives, one member each from the USFDA and the National Marine Fisheries Service and the U.S. Environmental Protection Agency. The Board appoints committees to deal with shellfish food safety topics, for example, the Vibrio management, Vp illness guidance and Vv illness review committees.

The ISSC meets biennially, attended by representatives of state shellfish control agencies from both shellfish producing and non-producing states, federal agencies, industry, and academic institutions. The ISSC assemblage uses prescribed procedures to ensure adequate process before arriving at their decisions and formalising the regulations ([www.issc.org](http://www.issc.org)). The ISSC agenda focuses on shellfish sanitation, with formal and specific agenda items known as proposals. Proposals are submitted to the conference, strongly debated and voted upon. The conference uses 'adversary procedures' to debate proposals (Weinberg, 1972), using *Robert's Rules of Order* to manage the process, unless specific rules are established by the Conference. In other words, straw policies are tabled at the biennial meeting and the opposing views of both scientists and non-scientists heard before the ISSC voting members make their decisions. Fostering the co-operative relationship, no single ISSC member has elevated agency with everyone having an equal debating voice. However, the adversarial process means it can take many years before a formal decision is made to change the NSSP guide.

While the conference has broad geographical and professional attendance along with egalitarian debates, there is ultimately narrow control of oyster food safety with the regulations determined by a small group of regulatory gatekeepers. This is because the ISSC constitution only allows a few to have formal voting rights (each coastal producing state has one vote, while inland state members each have 0.5 vote).

### 5.2.3 The ISSC's Vibriosis Food Safety Work

Vv was the first Vibrio pathogen to come to the ISSC's official attention in 1987, after the FDA's South East regional officers found an association between human mortality and morbidity, Vv bacteria and the eating of Gulf Coast oysters. As a result, the FDA and ISSC hosted a 1988 Vv workshop with the aim of gathering the scientific information with which to make food safety management decisions. The ISSC conference received the first formal Vv food safety proposal at their 1994 conference, while the first Vp proposal was not tabled until 1999. A second Vv workshop was held in 1994 to reassess the information, while the first FDA/ISSC Vp workshop was convened in 2017.

The three Vibrio workshop agendas (see Table 1), illustrate the shifting governmentalities underpinning the food safety regime centred on the ISSC.

Table 1: Agendas of FDA/ISSC Vibrio workshops

1988 Vv WORKSHOP	1994 Vv WORKSHOP	2017 Vp WORKSHOP
Epidemiology Ecology Analytical Methods	Epidemiology Risk Factors Pathogenicity Analytical methods Ecology Time/temperature requirements Oyster purification Consumer education Retail food requirements	Epidemiology Pathogenic strains Risk Assessment Risk Management of Environment Science research of Vp survival

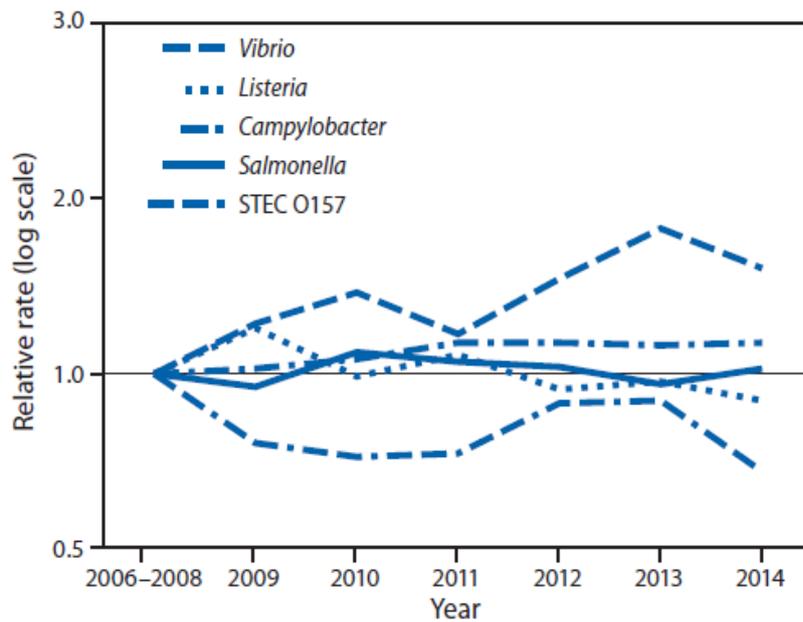
Ref: ISSC Proceedings from 1988, 1994 and 2017 workshops.

In 1988 the workshop focus was on making Vv visible through the scientific methods of epidemiology, ecology and microbiology. By the 1994 workshop risk factors featured on the agenda, identifying the medical factors that made oyster eaters more likely to contract Vv. In other words, concerns had shifted from beyond scientific measurements to a recognition of the part played by social factors, albeit reduced to human traits as an object for diagnosis alongside the ecological conditions that might constitute a problem. By 2017, the food safety question had been thoroughly reinterpreted as a risk assessment problem, with the social extended in the range of risk factors identified, but at the same time reduced from a set of concerns to a series of risk calculations. Science had once again reasserted its dominance in framing the ‘problem’

Both Vv and Vp have remained important conference agenda items, with significant ISSC energies used to consider the scientific information about both pathogens and discussion on appropriate management interventions. These management discussions were converted into various mandated regulations including: education of shellfish consumers and the industry; time temperature controls; compulsory warning tags on shellfish products; post- harvest processing (PHP); mandatory Vv and Vp management plans; principles of Good Harvesting Practices and HACCP; epidemiology recording systems; and risk reduction metrology. See Appendix III for the full timeline on the various ISSC Vv and Vp actions.

However, despite the FDA’s scientists and the ISSCs best efforts in 2013-2014 CDC formally advised both the FDA and the ISSC that the vibriosis problem was increasing, particularly when compared to other food pathogens, providing Figure 2 to support their concerns (webinar 23<sup>rd</sup> April 2014; Crim *et al.*, 2014).

Figure 2: Incidence of *Vibrio* foodborne illness compared with other foodborne pathogens for the period 2006-2014.



CDC reported that *Vp* is “now the most commonly reported species causing vibriosis in the USA with an estimated 45,000 infections occurring annually.” (FDA/CDC webinar January 8<sup>th</sup>, 2013). In 2014 there were 605 *Vp* cases and one death and 124 *Vv* cases of illness with 18 deaths, giving the USA the highest national foodborne *Vp* and *Vv* illness rates. CDC’s research suggested that not only were the vibriosis cases increasing, but new *Vp* strains were appearing with increased virulence. Therefore, in CDC’s mind, more stringent prevention measures were needed to target foodborne transmission routes.

Based on the ISSC’s constitution and arrangements with the FDA’s science group the conference is presumed to use science as the social practice with which to mechanistically and quantitatively measure food safety effects. However, if the ISSC’s measure of food safety success is reducing or eliminating of oyster associated vibriosis cases, CDC’s statistics suggest the ISSC is not achieving its goal. This research project next probes into the reasons for this situation, endeavouring to determine and analyse the ISSC relationship with vibriosis.

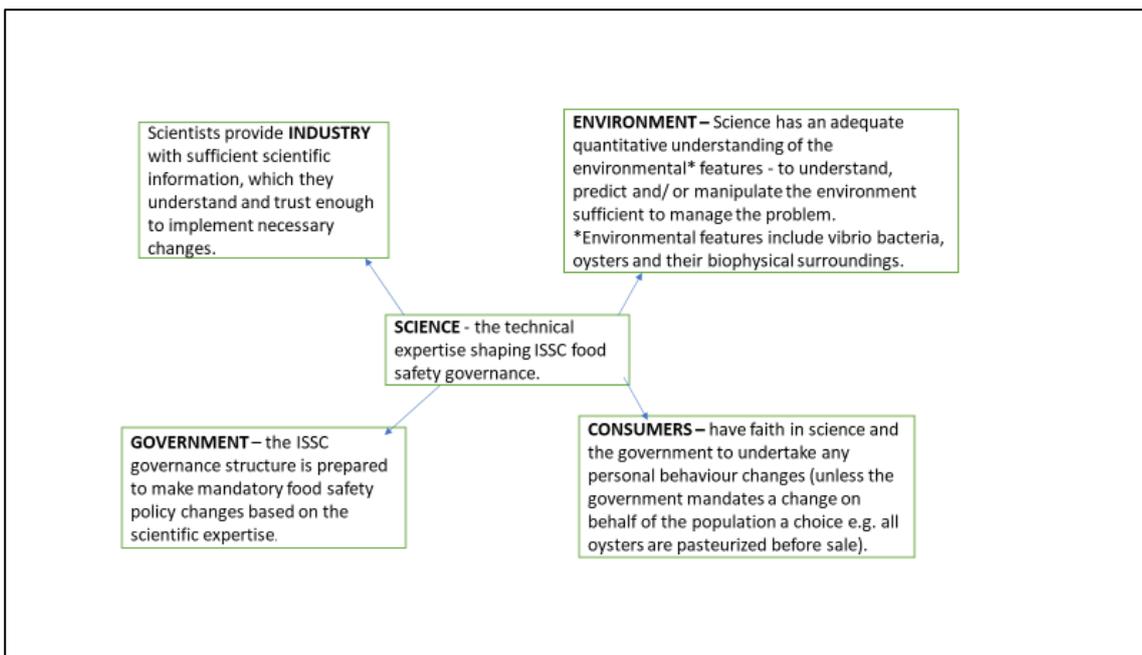
#### 5.2.4 Opening the Lid on the Black Box of Vibriosis

The ISSC is a unique temporal and spatial assemblage with which to consider the agency and translation process associated with the *Vibrio* microbes along with the socio-political, scientific and material characters. In short, the ISSC claims to bear a standardised, science-centred regime for dealing with food safety no matter how complex the food safety matter, where and how the problem arises, or the matters of concern at stake. The ISSC process assumes any food safety problem can be identified, measured, assessed and controlled by scientific expertise. As such it is presumed that science can be used equally to address problems caused by unhygienic human practices and those emanating from the natural marine environment, such as *Vibriosis* or marine biotoxins. Risk is calibrated to minimise harm. In turn, there is a ‘scientific’ application of governance, within which policy makers make informed

science-based, risk-calculated decisions on behalf of the wider public for whom they have designated social responsibility.

How then might we understand the ISSC’s food safety governmental regime and its underpinning governmentality? This analytical question invites us to understand the ISSC’s food safety regime in terms of four questions: How does it operate? What does it make visible? What technologies of control does it mobilise? What expertise shapes its operation? Analysis of my experience in dealing with the ISSC procedures along with the observation recorded in field notes during 2013-14 confirmed that science is very much at the core to any answer to each of these questions. Such analysis led me to design Figure 3 which lays out the role that science is given, and adopts for itself, the role of being the heart of the ISSC and the regime of vibriosis food safety it articulates. It portrays each of the actors involved as discrete, predictable and calculable, with food safety concerns expressed very much as matters of fact with linear causes that might be addressed through scientific solutions. At the core and centre of the standardized ISSC model lies *science* and the *scientist*, and more recently the use of mechanistic, science-based quantitative risk assessment.

Figure 3: ISSC’s scientised decision-making framework.



The actors in this model are given little agency, and there is little understanding of practice or relationality. *Vibrio bacteria* are cast as the “free spirit” actor, roaming the marine world, without boundaries, other than their own personal environmental limits such as water temperature. The Vibrios have a symbiotic relationship with marine ecology and adverse effects on humans are purely coincidental. *Oysters* are the innocent agent, transferring Vibrios to humans. Humans are divided into discrete categories. *Industry* are those who make a living dealing with oysters by farming, harvesting, and selling and are assumed to be driven by profit motives and market signals set by consumer desires. *Consumers* operate with pre-formed desires to eat oysters, although they are subject to manipulation by oyster sellers and *regulators*, a group empowered by society to deal with risks that society (unconceptualized) wants eliminated or managed. Some conception of society and the politics that

underpins its defining relations is allowed for by the presence of lobbyists, such as *USA Consumer Advocate* (The Center for Science in the Public Interest).

However, without much scratching it soon becomes apparent that vibriosis is about more than humans. For a start it includes the non-human marine actors such as seawater, *Vibrio* bacteria and the oyster. As discussed in Chapter 3 it is for this reason that the Actor-Network Theory (ANT) framework, which considers non-human and human actors, is used to explore more and the following section starts this process.

### 5.2.5 An Alternative Way to Expose the Black Box's Contents

As discussed earlier the term 'black box' is a term used to make opaque the inner complexities of a situation, with the Merriam Webster dictionary further describing it as anything that has mysterious or unknown internal functions or mechanisms. ANT provides a framework which considers the relationships between actors, which can be both things and concepts. It offers the capacity to "open the black box" of *Vibrio* science by tracing the relationships between governments, technologies, knowledge texts, money and people (Latour, 1988; Cressman, 2009). By exploring the black boxes of the different assemblages, it may be possible to identify the variety and association of social aspects and technical elements and how they interact as a whole (Cressman, 2009).

Chapter 3 described the method of application but to reiterate a total of 73 state and federal regulators, scientists, and consumer and industry representatives were interviewed during the period February – November 2014. All 73 interviewees are key informants who are active within the ISSC food safety assemblage, including those who commission and compile the official science reports used for policy input and those who make America's vibriosis food safety regulations. The purpose of the semi-structured interview was to gain a better understanding about the ISSC actors, the role of science within the conference and why vibriosis persists among oyster eaters

The semi-structured interviews used five questions to focus attention on three themes:

- i) the nature and extent of the vibriosis problem;
- ii) use of science to address the problem and the factors hindering its ability to eradicate vibriosis amongst raw oyster eaters; and
- iii) the role of the federal government's food safety authority.

The questions were designed to yield specific answers that could be coded to provide results for analysis. They were also used to elicit and frame a wider conversation, with participants invited to range widely in their answers across the fields of *Vibrios* and science, along with its funding, its implementation and its relations with policy-makers, industry and consumers. Questions drove the discussion towards the politics of science and in a sense the politics can also be described as the assemblage and how the human actors perceive their interactions with the assemblage.

The interviews yielded a rich dataset of responses and a set of perspectives on how the group frames vibriosis. In association these perspectives provide a more detailed understanding of the vibriosis

assemblage and the relational and agential nodes that shape this ever-evolving assemblage. The themes that emerged are next discussed.

### 5.3 The Making of the ‘Vibriosis Problem’

The research aimed to ascertain how the ISSC members perceived Vp and Vv associated illness. Specifically, did they perceive both, one or neither Vibrio pathogens to be a problem and if so what the actual problem was. This section describes and analyses the interviewees responses to such questioning.

The interviewees were asked directly if Vibrios (Vp and Vv) represent a food safety problem and their responses are listed in Table 2.

Table 2: Responses to Vp and Vv being a significant food safety problem

VIBRIO SPECIES	NUMBER OF RESPONSES	NUMBER OF OCCUPATIONAL RESPONSES
<i>Vibrio parahaemolyticus</i>	Yes = 54 (74%) No = 17 (23%) Don't Know = 2 (3%)	21StateReg, 16Ind, 9FedReg, 7Sc and 1 CSPI 7Ind, 6StateReg,3Sc 1FedReg 2StateReg
<i>Vibrio vulnificus</i>	Yes= 31 (42%) No= 34 (46%) Don't Know = 8 (11%)	12StateReg, 7Ind, 3Sc, 1 FedReg, 1CSPI 13StateReg, 11Ind, 7FedReg, 3SC 5 Ind, 3StateReg

Key to Table: CSPI = Center for Science in the Public Interest, FedReg = Federal Regulator, Ind = Industry, Sc = Scientist, StateReg = State Regulator.

The responses confirm that there is a lack of consensus as to whether vibriosis is a food safety problem and how that problem should be understood. There is also disagreement whether both Vp and Vv should be treated the same. The diversity of response captured in the numbers demonstrates that the starting question is deceptively simple. Yet such statistics disguise significant complexity in the responses; from understandings of what is meant by a food safety problem to differing assessments of the food safety risk they pose, and differing considerations with respect to the two vibrios. Further analysis of the responses identifies that there is a wide diversity in how people relate to vibriosis and food safety generally. While it might be predicted that the various professional groups would trend in their views, for example, industry downplaying significance of vibriosis and regulators expressing alarm at illnesses, the actual responses showed differently. Twenty of the 24 industry interviewees thought that vibriosis in one form or the other is a problem, while nine of the federal regulators did not consider vibriosis to be a food safety problem of significance.

Most respondents had firm ideas about the relevancy of Vp and Vv. However, it became obvious most nest vibriosis within the context of food safety and their personal opinions then relate to this wider topic. There are layers of consideration at work in the responses, from the nature of the discursive framing

(regulatory, ethical, extent and nature of harm, and perceptions of capacity to overcome risks) as well as assessment of levels of incidence and threat. The interviewee's own interests, expertise and responsibilities also appear to influence the material factors considered to be problematic.

'Food safety' is couched differently by the group, with emerging themes of foodborne illness, trade impacts, geographical and environmental context. In other words, there are different views on what food safety means to the interviewees, the attributes considered important, and how they measure and describe it. Food safety is identified as an important actor, but there are different reasons given for its inherent value. For four federal regulators 'food safety' underpins their job and "*We should do everything that is reasonably possible to prevent illness.*" (FedReg:3/4/14). Others (32%) relate food safety to foodborne illness, whereas others are more concerned with the linkages to trade; "*It is an economic issue. Industry needs to ensure confidence remains in their product.*" (StateReg:2/4/014). Moreover, foodborne illness and trade can be further contextualized.

The majority refer to vibriosis illness, yet they form different views on what this means. Some make comparisons between vibriosis and other foodborne pathogens: "*Because Vibrios cause the same illness burden as Salmonella*" (Sc:13/3/14) and "*The numbers nothing like norovirus.*" (FedReg:15/4/14). Others use illness numbers to determine their view "*Any sickness related to food is a food safety issue.*" (Ind:19/6/14) to "*The numbers are so low it is not worth talking about.*" (Ind:23/6/14), while others compare the symptom severity of Vp and Vv to formulate their decision: "*Although Vp makes you wish you were dead it doesn't actually kill you.*" (StateReg:28/4/14) and "*Vv is a problem due to the severity of the illness, but not Vp as it is so mild.*" (Sc:3/4/14). Rather than symptoms others consider illness outbreaks (more than one person associated with an event) to be more problematic compared to single cases. ("*Vp is a problem because there have been a number of outbreaks.*" FedReg:24/3/14).

There is lack of consensus as to what constitutes a 'food safety' issue. Twenty respondents (7StateReg, 6 FedReg 4Ind, 3Sc) believe Vv is not a food safety problem. In their minds it is a "personal health issue", brought about by the oyster eater's own health status, thus describing Vv as *just like an allergen* (Ind:23/10/14) and "*Vv only affects those in the active stage of dying.*" (FedReg:5/6/14).

On the other hand, rather than a food safety problem seven people (4Ind, 2StateReg, Sc 1) define it as a trade problem, claiming, "*It is not a food safety problem; but a trade problem since the 2013 outbreaks. Therefore, we need to do something to protect our industry.*" (State Reg:2/4/14). Within the trade context they expressed concerns about loss of trade reputation: "*Problem is when it is published in the newspaper and causes adverse publicity.*" Ind:4/4/14) or as ... *an economic issue. Industry need to ensure confidence remains in their product* (StateReg:2/4/14) and "*Vibriosis affects industry profitability.*" (Ind: 27/3/14).

Yet trade issues are not the only economic impact mentioned. Other respondents (3 FedReg, 3 StateReg, 2Ind, 2Sc) describe the 'problem' in human health costs citing "*Vibriosis is the Number 1 cause of seafood illness and Number 1 cause of death*" (Sc:15/4/14). Seven respondents (3FedReg, 2StateReg, 2Sc) were concerned primarily about the health care costs, echoing the findings of a prominent USA human health study which calculated the morbidity and mortality health care costs and

loss of productivity for Vv seafood associated cases to be US\$233 million and for Vp US\$20.63 million (Ralston, 2011).

Some 'measure' the 'problem' through scientific measurements, such as CDC's disease statistics or the ISSC's risk calculator. Interestingly, all nine scientists use such numeracy to formulate and describe their opinion. This does not mean all nine scientists came to the same decision, simply that they referred to specific CDC or FDA metrics to underpin their decision. Rather than numeracy others use social concepts to determine their stance; *"If everyone ate oysters the same as they do bread, there would be a huge outcry due to the rate of illness. But because illness is only associated with oyster lovers, a luxury food so no one cares."* (StateReg:28/4/14).

Others relate vibriosis with their own sense of place in the natural world. Some of those who do not consider Vp or Vv to be a problem came to this decision because it did not affect them personally because of where they lived; *"It is not a problem for us in California as we got rid of the problem."* (StateReg:7/4/14). Ten respondents (5StateReg, 3Ind, 2FedReg), who did not know whether Vv or Vp is a problem, explained this is because they have no direct experience with the illness in their region, again highlighting the geographical differences in vibriosis prevalence. The 'naturalness' of Vibrio bacteria was used to contextualize responses: *"We don't stop people swimming or boating yet they can pick up Vibrio bacteria in these environments. Vibrios are just part of life if you want to eat raw protein."* (Ind:4/8/14). Rather than being problematic, in contrast one scientist considered vibriosis to be a positive 'thing', because it is like a canary in a coalmine: *"Both Vp and Vv disease are good for society as it brings people's attention to their wider environment and should focus their attention on global warming."* (Sc:27/6/14).

As the above shows there are multiple ways to frame the topic with which to consider vibriosis. Not only that, each topic has been interpreted both for and against vibriosis being problematic. For instance, some interpret the disease numbers as high and therefore problematic, others interpret the same data as non-consequential. Some consider that issues outside of their region to be 'not in their backyard' and of no relevance, while others take a whole of industry view.

The interviews provide valuable information on how the 73 interviewees perceive and relate to vibriosis. Many consider the human and social consequences such as human health and industry economics; others perceive the problem as technical, a numerical dataset to be interpreted and addressed; while yet others consider their relationship with nature. Some consider the problem by looking backwards to determine trends, others focus on the present and individuals project to the future scenario. All these associations are valid and highlight the complex discursive, progressing from subject to subject. Moreover, such discursive conversations provide evidence of the multiple actors, human and non-human which form the ISSC assemblage.

## 5.4 Confronting ‘The Problem’

Having identified that many ISSC members perceive vibriosis to be problematic, albeit for various reasons, the semi-structured interviews explored the ISSC members views on what should be actions should be taken and what ‘successful’ mitigation of the problem might look like.

Respondents were asked what mitigation steps would be required to determine that vibriosis had been adequately dealt with by society. All the interviewees’ ideas on successful solutions came across as well considered but again they offered diverse responses as to how to tackle the problem. Table 3 summarises the range of responses.

Table 3: Summary of responses regarding appropriate vibriosis risk management steps

ACTION	NUMBER OF RESPONSES**	NUMBER OF OCCUPATIONAL RESPONSES
Best Practical Means implemented	n = 25	14StateReg, 4FedReg, 4Ind, 3Sc
Different approach to Vv and Vp risk management policies	n = 23	11StateReg, 8FedReg, 4Ind
Educate consumers on risks of eating raw oysters and no further action	n = 19	6StateReg, 5Ind, 4FedReg, 4Sc
Downward trend in case numbers	n = 15	5StateReg, 5Ind, 2FedReg, 2Sc,1CSPI
No Further Action	n = 14	6Ind, 5StateReg, 2FedReg, 1Ind
Have a % reduction goal	n = 13	FedReg, 4StateReg, 6 Ind, 1Sc
Predictive environmental program in	n = 5	StateReg, 1Ind, 1Sc
Warning labels and No further action	n = 4	2Sc, 1FedReg,1StateReg
100% illness elimination	n = 3	1FedREg, 1StateReg, 1Ind
Implement California’s Vv policy which bans the summer sale of Gulf Coast oyster)	n = 1	1Ind
Delivering what by finding out what society wants	n =1	1Sc
States to set their own level of illness	n =1	1Sc
Risk to be the same as for any other raw food	n = 1	1FedReg

\*\* Note some respondents provided multiple options.

Only three respondents defined success as the elimination of vibriosis, with the most common response suggesting the way to manage the disease is through industry ‘best practice’ management. Respondents did not elaborate on specifically what ‘best practice’ includes, though most referred to post-harvest temperature control on the understanding that bacterial growth stops once oysters are in a cold environment.

Table 3 illustrations diversity of opinion on how to solve the problem and what should be measured to validate that success has been achieved. This diversity means that even when ‘the problem’ is perceived

in a similar way, the respondents propose different actions on how to manage the situation. The diverse opinions mean there will be no agreement as to when 'the problem' is solved. This lack of consensus is complicated further by differences in perception related to the dissimilar threats posed by Vp and Vv, with 31% considering a need for different management strategies for the two pathogens.

## ***5.5 Accounting for Vibriosis***

So, when it comes to framing and addressing the matters of fact and concern associated with foodborne vibriosis, what is the role of science? (the part it is playing, is seen to be playing, and might come to play). I explored this question explicitly with my research participants, asking them to express their opinions as to the reason/s for the oyster associated vibriosis prevalence and then directly asked if more science is necessary to solve the level of illness. The responses to these two questions dominated the interview, not only in the discussion time but also in providing the richest and most diverse information. In fact, the interviewees often returned to these questions throughout the later interview conversation. The full interview information was analysed and coded to identify the reasons proposed for the ISSC's inability to reduce the level of illness. Science was not the primary reason given, so a thematic list of reasons was compiled from the answers to the specific science questions and from the general interview conversation. This list comprised both matters of fact and concern as narrated by the interviewees.

Table 4 presents a summary of the responses provided as to why vibriosis remains a persistent food safety topic. The left column provides a summary of the responses given to the two specific science questions, while the right-hand column summarises the full information set from the full interview conversation. The difference in response numbers between the two columns is significant because while the theme responses remain the same, the respondent further identified themes as the semi-structured interview conversation moved forward and expanded. During the latter part of the conversation the respondents would remember information they had earlier wanted to express say or instead provided a more expansive example of their experience with the topic.

Significantly it also confirms the value of a semi-structured interview process when facilitated by a technical specialist with expertise in the topic of interest who can actively engage in conversation with the participants.

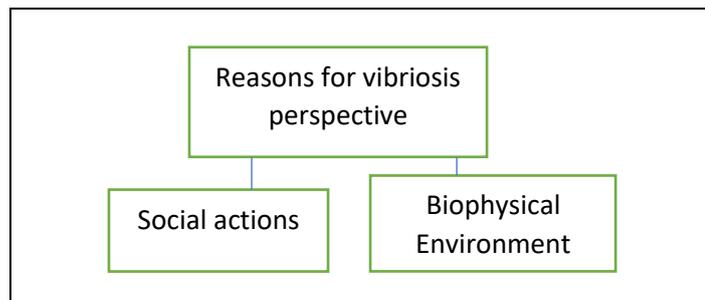
The seven reasons nominated and discussed by the interviewees can be categorised into two dimensions of social action and natural environmental causes (See Figure 4).

Table 4: Reasons provided by interviewees for persistent vibriosis amongst raw oyster eaters

REASONS AND RESPONSE NUMBERS FOR PERSISTENT VIBRIOSIS ASSOCIATED WITH DIRECT QUESTIONS**		REASONS AND RESPONSE NUMBERS FOR PERSISTENT VIBRIOSIS PROVIDED DURING WIDER INTERVIEW CONVERSATION**	
Metrology	n = 38 (52%)	Oyster eating culture	n = 55 (75%)
Natural Environment	n = 35 (48%)	Public Policy	n = 47 (64%)
Oyster eating culture	n = 35 (48%)	Metrology	n = 38 (52%)
Public Policy	n = 25 (34%)	Natural Environment	n = 35 (48%)
Politics	n = 9 (12%)	Industry Practices	n = 33 (45%)
Industry practices	n = 8 (11%)	Science Practice	n = 32 (44%)
Science practice	n = 7 (9%)	Politics	n = 14 (19%)

\*\*Note many interviewees identified more than one reason for Vibriosis persistence.

Figure 4: Reasons provided by interviewees for persistence of vibriosis



However, within these two dimensions there are multiple sub-stories including scientific practices, public policy and political ideologies, industry procedures, culinary practices along with the ‘knock and pluck’ of the oceanic tides. The interviews highlight that it is not just the science black box that requires unpacking, there are several other unidentified black boxes such as the ISSC, the natural environment and cultural mores that lead to making social and political decisions. The following sections will more fully discuss the role of science, along with the other factors interviewees believe are responsible for vibriosis amongst raw oyster eaters.

### 5.5.1 Science in Practice

Analysis of the interview material considered the respondents’ perception about the weighting, performance and agency of science within the ISSC vibriosis assemblage. The interviews sought opinions as to whether more science, for example more research and scientific publications or increased environmental analyses, would be useful. The interviews produced some surprising results.

*Is more science the answer?*

No = 38 (52%)

Yes = 30 (41%)

Don’t Know = 5 (6.8%)

Most (52%) respondents do not think lack of science is the reason that the incidence of vibriosis linked to raw oyster consumption has not been reduced. Interestingly even 80% (7 of 9) of the scientists do not believe more science would solve the situation. They explain “*Honestly No. Even as a scientist who wants to know more about Vibrios there is already enough understanding about the problem.*” (Sc:7/8/14) and “*It is not lack of science. We already have three good methods to get rid of the problem (PHP, irradiation and timely refrigeration).*” (Sc:5/4/14). The three scientists who thought more science was necessary were those employed by private agencies (outside of the FDA). Only one scientist thought the primary problem was inadequate science, but also acknowledged that human eating patterns were involved.

Those who did not consider more science is required to solve chronic vibriosis explained their stance, offering various reasons why science has not been a more effective intervention. Generally, they considered social factors are blocking scientific solutions, providing several common themes as shown in Table 5.

Table 5: Interviewees expressed common themes blocking scientific solutions

THEME	ILLUSTRATIVE QUOTES
Cultural behaviour	<p><i>“It is not lack of science. It is a cultural thing, resistance to any change.”</i> (Ind:10/11/14).</p> <p><i>“It isn’t lack of science that is the problem. It is simply not culturally acceptable to use PHP (Post-harvest Process).”</i> (FedReg:18/2/14).</p>
Lack of public concern	<p><i>“Lack of science is not the problem. It is because the public do not perceive this to be a big problem.”</i> (Sc:23/4/14).</p> <p><i>“Lack of acceptance by consumers that there is a problem.”</i> (FedReg:15/4/14).</p>
Lack of Science application in Public Policy	<p><i>“Scientists have provided Vibrio solutions; stop summer harvesting, shuck, PHP or immediately cooling after harvesting, but there is no co-operation from industry and no political will in the states”.</i> (Sc:3/4/14).</p> <p><i>“Science has not failed; it is the application of science”.</i> (FedReg:3/4/14).</p>
Politics	<p><i>“It is not science. It is political. Vibrios are a non-issue.”</i> (StateReg:22/4/14).</p> <p><i>“Lack of political will is the problem.”</i> (FedReg:24/11/4).</p>
Lack of belief in science	<p><i>“The evidence is there, but the people do not believe the science.”</i> (FedReg:24/3/14).</p>
Use of science as an excuse	<p><i>“Science does not give a definitive answer. So, everyone is using the science to dance around, but not having the hard debates about the moral issues.”</i> (Sc:3/4/14).</p> <p><i>“Lack of science is not the problem. Ignoring the current science and hiding behind it are instead the problem.”</i> (FedReg:10/3/14).</p>
Lack of education	<p><i>“No. I do not think lack of science is the problem. We are not making enough of an effort to warn people.”</i> (FedReg:27/3/14).</p>
Changing Demographics	<p><i>“General health of the population is changing and the aging population means more in the ‘at-risk’ group.”</i> (Sc:23/4/14).</p> <p><i>“Development of the coastline means more people are exposed to oysters.”</i> (Sc:2/7/14).</p>

While most scientists do not consider lack of science to be the fundamental reason for the persistence of vibriosis in the USA, they did admit to institutional frailties. Firstly, there are many things they still do not understand about Vibrios, including how the organism behaves in the natural environment, and perhaps even more importantly, the many physiological factors that lead to vibriosis. Second, the politics of science was discussed. The FDA is the official science agency responsible for reporting to the ISSC, yet scientists from private agencies believe if they received funding there would be better research. It seems that there is little collaboration between the government and private institutions undertaking Vibrio research. At least three of the private scientists, who have each been working on Vibrios for more than 30 years, have concerns about the lack of innovative research projects. Thirdly, the FDA scientists acknowledged their important role in the public policy process, recognizing the need for effective communication if they are to convince other stakeholders to use science-based food safety solutions. Table 6 illustrates quotes about the weakness of institutional science provided by federal and private enterprise scientists.

Table 6: Interviewee quotes about the weakness of institutional science

THEME	ILLUSTRATIVE QUOTES
Inadequate funding	<i>"There is a lack of capacity. To find out more serotypes would take a large amount of money."</i> (Sc:18/2/17)
Institutional Science	<i>"Small players find it hard to get funding. Funding system is either an 'in or out camp'."</i> (Sc:15/4/14). <i>"Problems between FDA, NHI (National Health Institute) and NSF (National Science Fund) as there is debate about environmental science and food safety split. Hard to get a new approach on the table if you are not in the club. Innovation goes by the wayside."</i> (Sc:27/6/14).
Lack of scientific ingenuity	<i>"Lack of ingenuity. We are seeing the same thing over and over. Tend to forget the science of 20-30 years ago. Need for more collaborative science."</i> (Sc:15/4/14)
Lack of scientific knowledge about Vibrios	<i>"There are so many things we don't know."</i> (Sc:3/4/14). <i>"Science is grasping for answers. Our tools are not precise enough."</i> (Sc:23/4/14).
Inability to translate science to public policy	<i>"We (scientists) have done a terrible job of keeping our stakeholders informed. We need to translate science better."</i> (Sc:18/2/14). <i>"Science is only going to drive the policy if policy understands the science."</i> (Sc:7/8/14).

However, it was not only scientists who identified scientific knowledge gaps about Vibrios as being problematic. Eight others (7StateReg, 1In) also consider this gap a concern stating, *"Scientific uncertainty makes industry sceptical."* (StateReg:28/4/14). In their defence the scientists noted the challenges they face: *"Hard to keep up with the science as the targets keep moving. The scientists and states understand this situation, but industry do not."* (Sc:3/4/14).

Four people (2StateReg, 2In) want the scientists to understand the necessity of providing the oyster industry with applicable and practical science options, stating:

- *“Science’s best ideas may not be practical. Science is not everything if you don’t have a viable business.”* (StatReg:9/6/17)
- *“Industry is innovative. We just need methods that don’t require a PhD person to operate.”* (Ind:18/6/14).

Specifically, several of the interviewees mentioned FDA’s 2013 proposal for icing of oysters within an hour of harvesting and their icing demonstration on a single-man boat docked in the marina at their Alabama science laboratory. They considered this an example of FDA science team not understanding ‘real world activities: Industry, state and federal regulators expressed concern about the practicalities of immediate cooling, particularly when hauling large oyster harvests onto open deck barges in oceanic waters: *“In theory the cooling option is great, but in practice impractical. We collect 1,000 bushels<sup>8</sup> in one tidal cycle of six hours. We are not convinced that this science would make a difference.”* (Ind:9/4/14).

There is a minor conversation thread from scientists that more scientific capacity may increase knowledge about Vibrio bacteria, perhaps even plugging information gaps about how to control vibrio bacteria in the natural marine environment and/or vibrios pathogenic effects on humans. However, there is consensus by the ISSC members interviewed that science has already provided post-harvest technologies capable of destroying vibrios in oysters which could eliminate vibriosis amongst raw oyster eaters.

### 5.5.2 Metrics at Work

Measurements are taken at multiple points in the vibriosis food safety chain. Vibrio assays of seawater, sediments and oysters are only the beginning, expanding to ever-widening environmental and clinical situations. Some measurements are within the ambit of the ISSC regulatory programme. Others, such as a patient’s clinical vibriosis diagnosis, operate outside the ISSC’s influence. Certain environmental and clinical metrics aim to describe the present situation; other metrics, such as modelling and risk calculators, attempt to predict the future. While there are diverse vibriosis metrics they share a common goal - to describe the situation by numbers. In other words, metrics attempt to capture and solidify, stabilize and frame the vibriosis picture so that the now ‘visible’ situation can be dealt to. However, it does not matter if the metrics are within ISSC’s control or wild and on the loose in the wider world, they do not remain stable and the ‘picture’ is never in full focus.

When the interviewees were asked to explain the ‘lack of vibriosis reduction’ this concept was contested, with more than 50% disagreeing there was no reduction. Indeed, 14 (19%) respondents started their narrative disagreeing with this suggestion. No matter whether this opinion was introduced first up, or further into the conversation, all use the same basis for reasoning to claim illness numbers are reducing

---

<sup>8</sup> A **bushel of oysters** is a USA industry measurement. It routinely contains weights between 45 and 60 pounds (20 - 27 kgs) and contains between 100 and 150 oysters.

rather than increasing. They claim scientific measurement and calculations are causing a distorted and magnified picture, creating the wrong perception that illness numbers are increasing. In their opinion the vibriosis case numbers are decreasing. They consider modern science, with its capacity to quickly and accurately identify microbes and vibriosis illness, is making the problem more visible. Not only does science make vibriosis more visible, the interviewees also believe this enhanced visibility captures the public's attention leading to the false assumption of an escalating USA problem. Table 7 lists the metrology and calculation factors cited.

Table 7: Metrics which explain the increased incidence of vibriosis

MEASUREMENT	ILLUSTRATIVE QUOTES
Better medical diagnosis	<i>"The actual illness numbers are going down. It is just better medical diagnosis now."</i> (StateReg:24/4/14)
Better microbiological analysis	<i>"The detection methods since the late 1970s have improved and by the late 1980s got good. I believe that the increased figures since the 1990s are due to better detection."</i> (Sc:18/2/14)
Incorrect relative statistics	<i>"Numbers do not reflect the risk. Way higher oyster consumption now. My gut is in the last five years the popularity of oysters has rocketed. In the 1990s there were maybe half a dozen types of raw oysters, now there are hundreds of them."</i> (Sc:24/3/14)
Changing demographics	<i>"The general health of the population is changing. The aging population means more in the "at-risk" group."</i> (Sc:10/4/14).
Changing public perception	<i>"Although scientists identified USA Vibrios in the 1970s they were not more widely recognized until the 1980-90s."</i> (Sc:10/3/14)
Changing epi definitions	<i>"CDC needs to change their definition of what is an illness (Vp). Expanding definition by CDC has diluted Vp."</i> (StateReg: 9/4/14)

Interviewees identify that now, compared to previous years, many more raw oysters are now eaten per head of population. So, they argue the actual risk of illness per oyster serving is dropping and the correct 'relative measurement' has not been applied. Others claim it is a demographic artefact; an aging population means a larger percentage of the populace are likely suffering pre-disposing health factors, thus increasing the epidemiology statistics.

Many do not believe the official CDC epidemiology data, portrayed by the comment *"CDC collects the epi data, but we don't have faith in the way CDC does this."* (StateReg:9/4/14), while others point out how quickly the visibility of vibriosis changes by adjusting the case definitions. On the other hand, not all respondents agree that measurement is making vibriosis more visible. Instead, three (4%) consider the current epidemiological systems underestimate the size of the problem, stating that: *"Vp is not a pathogen that is routinely tested for so definitely under-reporting in epidemiology."* (Sc:10/4/14). Reference was made to the lack of available industry production data, a metrics gap making it difficult to determine if the vibriosis rates are indeed dropping or increasing: *"Until lately there hasn't been a reason to understand production and consumption patterns, but we are beginning to do a study on that now."* (Ind:10/4/14).

The metrics associated with the ISSC's own vibriosis goals highlight how quickly a problem can be evoked or eroded. In 2000, ISSC agreed to reduce the number of epidemiologically confirmed Vv cases (linked to raw oyster eating) by 40% within five years and 60% within seven years. All agreed success would be measured over the core states of Alabama, California, Florida, Georgia, Louisiana, South Carolina and Texas. However, in 2003 California decided to ban the sale of Gulf Coast oysters and in 2005 Hurricane Katrina destroyed many of the Gulf oyster beds. Both these factors meant a significant change to the baseline for measuring the 40-60% reduction. Even with these changes, which should have by themselves reduced the Vv illness incidence, the reduction goals were not achieved. In response, the 2009 ISSC simply adopted a new statistical method with which to measure Vv illness, namely a 'risk per serving' of shellfish. The 'risk per serving' was introduced because some ISSC members argued traditional epidemiology statistics were "evoking" an inaccurate picture, asserting increased oyster consumption meant the risk of vibriosis amongst oyster consumers was decreasing. Such proponents offered Virginia's oyster production statistics as an example, claiming the state produced 4.8 million half shell oysters in 2007 and 28.1 million in 2012. So, the rationale was best risk could be reflected by exposure to oyster eating (or the consumption risk). As a result, the Vv risk calculator was requested by the Gulf Coast oyster industry and ISSC regulators after the failure of the 60% illness rate reduction and rejection of FDA's unilateral attempt to mandate PHP. Collaborative studies between FDA, ISSC and states were used to establish relationships between water temperature and harvest levels of Vp and Vv.

The ISSC regulations prescribe different regulatory responses for sporadic (single) and outbreak (multiple) vibriosis cases. Prior to 2013 ISSC defined a Vp outbreak as "two (2) or more persons, not from the same household, becoming ill from shellfish from the same harvest area within a seven (7) day period." At the 2013 ISSC meeting the Vp definition was redefined to "shellfish harvested within ten (10) days of each other from the same growing area are implicated in an illness outbreak involving three (3) or more persons". Such definition changes amend the picture. Further, it is opined that the ISSC's prescriptive outbreak metrics do not show the real scene. For example, six persons suffering Vp after eating oysters at a common restaurant table may tell a different story than six Vp cases who ate oysters at six different venues. Cross-contamination and/or temperature abuse of shellfish at the restaurant may be the cause of the restaurant cases, while high environmental Vibrio levels at the time of harvest the cause of the six cases who purchased their oysters from separate vendors.

Likewise, the national epidemiology measurements are not stable. Over time official surveillance of Vp and Vv case numbers has progressed from some states to national surveillance. Between 1979 and 1988 Vv was only a reportable disease in a few states such as Florida. In 1987 four states along the Gulf Coast (Alabama, Florida Louisiana and Texas) proposed a regional Vv surveillance system, initiated in 1988. One year later it was decided to include all Vibrio species in this surveillance system. Shortly after Mississippi became the fifth state to join the Gulf Coast surveillance system. CDC has been keeping foodborne outbreak information since 1973 and different surveillance systems introduced later, such as the 1988 'Cholera and Other Vibrio Illness Surveillance System' (COVIS) and the 1996 'Foodborne Diseases Active Surveillance Network' (FoodNet). In 2007, human vibriosis became a notifiable disease in the USA. Even so within the USA there remains a diversity of surveillance systems

with a need to develop an easily deployed visualization and analysis approach that can combine diverse data sources in an interactive manner (Sims *et al.*, 2011).

During the interviews the FDA's Vibrio Risk Calculator, came under repeated criticism with more than 25% of interviewees making adverse comments. FDA scientists developed this model following the ISSC's request for an official system to calculate the regional vibriosis risk per oyster serving. FDA scientists initially gave ISSC assurances that using the Risk Calculator would predict the number of Vibrio illnesses in any given season and in any place around the world. They claimed the calculator could effectively be used to develop time and temperature controls for each state, thereby reducing the 'risk per oyster serving' to acceptable levels and providing unprecedented flexibility to states in selecting fit for purpose controls to match industry practices. There were ultimately problems with the calculator's algorithms leading other ISSC stakeholders to consider the calculator to be flawed government scientific advice: "*Modelled science is a problem. FDA are mandating something that has not been fully proven.*" (StateReg:6/4/14).

Even FDA staff acknowledged concerns: "*People cannot get their head around complex modelled science*". Five scientists admitted to specific modelling problems, stating a single USA computer model is unsuitable for the diverse nation, such as "*Science models based on the Gulf Coast and other areas have different temperature salinity matrix*" (Sc:3/4/14) and "*Illness cases in Canada and Maine did not show a relationship to water temperature*" (Sc:6/11/14). Such perceptions meant an erosion in the trust of the FDA's science. This is evidenced by 19 respondents participating in the interviews, who claim they have lost faith in science and the FDA because of their Risk Calculator model which has not delivered definitive solutions.

### 5.5.3 Cultures of Oyster Eating

Most interviewees consider raw oyster eating is the nub of the vibriosis food safety issue. Eleven people (15%) started their conversation by claiming, for example, that vibriosis *is a behavioural issue not a science problem* (Sc:13/3/14). The oyster eater's relationship with the oyster is important, including the embodied cultural desires for raw oysters in relation to the increased access to the product. Of themselves oysters are not the cause of vibriosis; they are simply the vehicle delivering Vibrio bacteria to the oyster eater. Never the less, the oyster is pivotal to vibriosis. Oysters are eaten not just for their flavour but for their links to social status and their supposed linkage to sexual prowess. Interviewees point to the traditional and contemporary practices of raw oyster eating, with increased access such as the many contemporary high-end restaurant and bar facilities serving only raw oysters (Prasad *et al.*, 1996; Colagar, Marzony & Chiachi, 2009; Kurlansky, 2012; Coomes, 2014). The interviews confirm many of today's oyster eaters have a long-term relationship with raw oysters, while for others the relationship is more recent as oysters become more accessible and/or nouveaux trends have led to dietary changes.

Nearly one quarter (7StateReg, 5Ind, 3Sc) of the interviewees state that there is increasing oyster availability due to increasing aquaculture production and wider seasonal availability. Alongside this increased availability there are changing eating practices. Many oyster eaters traditionally ate them

cooked or only ate oysters raw during the cold winter months, but this is no longer always the case: *“Wild clumped oysters always used to be roasted. But now aquaculture and single oysters are all eaten raw.”* (StateReg:9/6/14). *“I don’t remember many oysters previously being eaten over summer.”* (StateReg:22/4/14). In many USA states, for example North and South Carolina, it was traditional to roast oysters, but respondents explained that this traditional cooking method is also fading - younger consumers want to eat their oysters raw (State Regs:28/4/14; 9/6/14).

The interviewees assert raw oyster eating is on the rise, and available market trend information seems to support their viewpoint (Flattery, 2003; FDA, 2010). Consumers now want year-round access to oysters in their supermarkets, restaurants and bars, with an industry informant (4/8/13) observing *“It used to be that people only ate oysters in the month with a ‘R’ in them. Now days the average American has no idea of seasonality. They expect oysters to be in the supermarket all of the time ‘because I should eat shellfish’.”* Some interviewees claim the retail trade is fostering new forms of demand and attaching new provenance values to oysters: *“Restaurants are the problem. They want the product. People want summer product and are willing to take the risk.”* (Ind:18/6/14) and *“In the 1990s there were maybe half a dozen types of raw oysters, now there are hundreds of them marketed in bars and restaurants.”* (Ind:4/8/14).

Scientists describe archetypal raw oyster eaters as *“The bulk of cases are old men eating raw oysters all of their life.”* (Sc:21/4/14) and *“Old gentlemen are the problem, but how do we change their behaviour?”* (Sc:13/3/14). However, 12 others (6Ind, 5StateReg, 1Sc) believe this is no longer the only demographic eating oysters: *“It is fashionable to eat raw oysters.”* (Ind:18/6/14), *“Boutique oysters are a growing trend.”* (StateReg:27/3/14) *“There is a new paradigm of 20-year olds eating oysters.”* (StateReg:9/6/14). *“It is fashionable to eat raw oysters.”* (Ind:18/6/14).

For some, the raw oyster is a food they have grown up with: *“It is my cultural right to dig them up, open and eat at the beach with a beer in my hand. People in the South know about Vibrios, but we have the right to choose.”* (FedReg:18/3/14) and *“It is culturally acceptable to eat raw oysters in the South and there is a public outcry for raw oysters.”* (StateReg:6/4/14).

Raw oysters may be desirable, but it seems that oysters that have been treated (PHP) to remove viable Vibrios are not. Six people (1FedReg, 3StateReg, 1Sc, 1Ind) specifically mention their personal aversion to eating PHP oysters. The main reasons given are as follows:

Cultural Reasons – *“As a consumer of product growing up in the rural South I would not want PHP product. It is a perception issue – there is a flavour difference. It is my cultural right to eat raw oysters.”* (FedReg:18/2/14).

Oyster are dead after treatment – *“People don’t want a processed oyster. They want it to be alive.”* (StateReg:9/6/14). *“One of the downsides of PHP is that it fails to keep the oyster alive.”* (StateReg:28/4/14).

Taste difference – *“I can taste the difference in a PHP treated oyster, and I can tell you it is not the same. What remains is like taking the fizz out of a soft drink.”* (StateReg:23/10/14).

Market demand for PHP oysters depends on the consumers' relationship with treated oysters, specifically whether they prefer, or dislike PHP oysters compared to raw oysters. Several studies have considered the consumer reactions to PHP oysters (Hanson *et al.*, 2003; Posadas and Posadas, 2004; Otwell *et al.*, 2010). These studies found consumers' choices depend on: whether consumers are concerned about safety; whether changes in the sensory characteristics are acceptable or possibly even preferred, and; whether there is a willingness to pay for any extra processing step. Morgan, Martin, and Huth (2009) conducted a web-based contingent behaviour study to examine the effect of information on oyster demand and they concluded that consumers would not respond favourably to processed oysters and that charging a price premium due to the processing step would have a significant effect on reducing demand. They also identified that even when fully educated about the potential *Vibrio* health risks associated with raw oysters, consumers still did not change their behaviour and exhibited optimistic bias.

The ISSC have arranged (and funded) many education programmes for both oyster eaters and medical practitioners. These programmes aimed to enhance the awareness of the vibriosis risks when eating raw oysters, particularly when the consumer suffers a pre-disposing illness which further increases the risk of vibriosis ([www.issc.org](http://www.issc.org)). Knowledge about the potential and actual health risks associated with eating raw oysters is not new information. Traditional practices around safe oyster eating started well before science became the dominant social practice underpinning food safety (Mossel, *et al.*, 1995; Meyer-Rochow, Benno, 2009). There is also evidence that many raw oyster eaters understand the risk they are exposing themselves to. An ISSC report, *Raw Oyster Consumption Follow-Up Survey; 2004 Technical Report* (ORC Macro, 2004), identified at least 43% of their respondents had heard that people with liver disease may get extremely ill from eating raw oysters yet had taken no steps to stop eating raw oysters. The raw oyster cements strong relationships with those who eat them, so strong that even when understanding the health risks associated with raw oysters they will still do so. As one *Vibrio* scientist said, "*I am never going to stop eating raw oysters.*" (Sc:8/2/14).

Further, other food safety references (Klontz, *et al.*, 1991; and Klontz, *et al.*, 1995) go so far as to say that raw oyster eaters in the USA are 'natural risk takers' who often partake in other unhealthy practices, such as smoking and drinking alcohol excessively. Examples of such informed risk-taking behaviour were provided during the interviews: "*One Alabama case suffered from Vv, recovered and then went and ate more raw oysters and died.*" (StateReg:18/9/14) and "*Certain people should not eat oysters. My wife has had two kidney transplants, but she still eats raw oysters.*" (StateReg:13/8/14) and lastly, "*Wilbur told me of a 70-year-old lady who wanted oysters. He refused to sell them to her as her husband was ill. She bought them from another operator, and he died of vibriosis.*" (StateReg:28/4/14).

During the interviews, the respondents frequently expressed their opinion about the ethical issues around the individual's choice to eat raw oysters. Eleven (15%) (3Sc, 3FedReg, 3StateReg, 2In) were prompt in expressing their subjective view, using the term "risk-taker" to this group of consumers: "*There is a culture of risk-taking in oyster consumption*" (FedReg:10/3/14); and "*Education has not worked. People know that they are at-risk. Shellfish are tagged with warnings, but people still go ahead and eat them.*" (Sc:28/4/14). Indeed, the perception of 'risk taking' perception goes further with eleven (15%) (5FedReg, 4StateReg, 2Ind) interviewees expressing criticism about such eating behaviour, especially for those consumers who will potentially suffer from Vv effects, exemplified by the following comment:

*Behaviour is the first problem. Vv victims have a pattern of risk taking. When we look at the cases there is a pattern of choices. They have abused themselves. This is the final nail in their coffin. (FedReg:6/6/14).*

It was interesting to note that the stakeholder group most scathing and moralistic in their opinion about raw oyster eating were federal regulators. Indeed, five of the nine federal regulators felt no further action should be taken to prevent Vv illness, with some suggesting that the pre-existing health status of some oyster eaters the reason for not trying: “*Cancer treatment cases have made exceptionally bad choices in eating raw oysters. It is their poor choices that is the problem.*” (FedReg:24/3/14). However, the CPSI considers the problem more complex:

*Problem is that oysters sell as a desirable product. We don't tell people that they are likely to kill or maim them. People do not understand the risk or know that they are 'at-risk', particularly in the inland states. It is a moral issue – we should not be counting the number of bodies in the morgue to see if the food police are doing a good job. (11/4/14).*

As with Question 1, which considered whether Vp and Vv are food safety problems, 10 respondents (13.6%) again commented that Vv is a “personal health issue” affecting only those individuals who are prone to suffer ill effects: “*It is a personal health issue. People who should not eat raw oysters still do. A portion of the population who are eating raw oysters is a personal illness problem not a public health problem and is like smoking.*” (FedReg:6/6/14). Furthermore, the interviews make it clear that people have differing opinions about when society should regulate food safety and when people should be entitled to make their own food choices. This topic will be discussed more in Section 5.5.5.

#### 5.5.4 Oyster Economies in Practice

The USA oyster industry has a long history in most coastal regions. Oysters were traditionally harvested from wild oyster reefs but as these resources became depleted subtidal and intertidal oyster farming became the more common source. Today the oyster industry is one of value, for example, in Virginia state alone the oyster harvest increased from 24,000 bushels in 2003 to an estimated 659,000 bushels in 2015 (Presentation by Keith Skiles, ISSC Vp workshop 2017). Despite increasing local production imports are still required to satisfy the market demand and in 2015 6,746 metric tons of oysters were imported (<http://www.st.nmfs.noaa.gov/Assets/commercial/trade/Trade2015.pdf> of oysters).

My 2013-14 field visits to the Atlantic, Gulf and Pacific Coasts identified that the USA's domestic industry is not homogeneous, operating differently in each coastal region. These differences are not only caused by geographical features such as climate and hydrographics, but also by the local oyster species, the type of industry and local social mores. For example, in the South the hot, low-salinity water of the Gulf Coast contains wild resources of *Crassostrea virginica* (American oysters). These resources are often harvested by independent operators who tong (dredge by hand) a small number of sacks per day, sold locally to cover their weekly living expenses. In contrast, operators on the Pacific Coast are more likely to be large sophisticated aquaculture (farming) companies with significant daily harvests of *Crassostrea virginica* and *Crassostrea gigas* (Pacific oysters) processed and sold nationally and internationally. The

long USA Atlantic Coast has its own diverse geography, creating different biophysical regions and industry operations.

The oyster industry is also an integral member of the co-operative ISSC. Attention was given to how the ISSC members perceived this dual role and whether industry is considered to have a conflict of interest. Just under half (45.2%) of those interviewed considered that the oyster industry is part of the problem. However, no one single industrial reason was provided as the root cause of vibriosis. Instead various combinations were provided as depicted in Table 8.

Table 8: Interviewees reasoning on the oyster industrial reasons for persistent vibriosis

Reasons	Illustrative Quotes
<u>Traditional industry</u>	<p><i>"It is the culture of shellfish industry and harvesters. They are not amenable to change. Not the most educated of audience."</i> (StateReg:21/4/14).</p> <p><i>The oyster industry is the tobacco industry of the food side"</i> (FedReg: 6/6/14).</p>
<u>New industry practices</u>	<p><i>"Since the 1990s summer harvesting has been the problem."</i> (FedReg:10/3/14).</p> <p><i>"Triploids, single racks, bamboo wild oysters are a problem. There needs to be control on farm harvests, only harvesting when the water covers them."</i> (Sc:7/8/14).</p>
<u>Market demands</u>	<p><i>"The problem is demand related. As long as people buy raw oysters there will be a problem."</i> (StateReg:9/6/14).</p> <p><i>"It used to be that people only ate oysters in the months with "R" in them. Nowadays the average American has no idea of seasonality. They expect oysters to be in the supermarket all the time because I should eat shellfish."</i> (Ind:18/6/14).</p>
<u>Increased oyster production</u>	<p><i>"One farmer has an increase 300-400% of half shell production over the last decade. 4.8 million in 2007, 28.1 million in 2012."</i> (Sc:23/4/14).</p>
<u>Lack of industry acceptance</u>	<p><i>"I have been in business since 1977 and have never had a problem."</i> (Ind:5/8.14).</p> <p><i>"Culture of oyster industry and dealers. Industry see raw oysters as a cultural value that has inherent value and must be protected."</i> (FedReg:10/3/14).</p>
<u>Industry economics and politics</u>	<p><i>"There is a strong industry lobby and the purse strings will always be the important part."</i> (FedReg:10/3/14).</p>

Eleven (15%) people firmly believe that industry's decision to start summer harvesting is the direct cause of increased vibriosis, *Since the 1990s summer harvesting has been a problem.* (Sc 2/7/14). An oyster industry person acknowledged summer harvesting might be problematic, stating *"I tried to get ISSC to advocate on summer controls (April to September) as the quality is not there. There needs to be controls on farm harvests, only harvesting when the water covers them."* (Ind:4/8/14). Oyster harvesters have little control over the number of Vibrio bacteria in oysters at the time of harvest, though it is recognised

during the warmer months the oysters will contain greater numbers. As explained in Chapter 4 the amount of post-harvest bacterial growth depends on the oysters' storage temperature.

Four persons (5.4%) (2FedReg, 1In, 1Sc) stated that the oyster industry uses politics to effectively protect their economic interests. Indeed, some industry members have used their advocacy rights. This includes the Gulf Coast oyster industry who petitioned politicians in response to the FDA's 2009 decision that all summer harvested Gulf Coast oysters must be PHP treated. One family, who had harvested and sold Gulf Coast oysters for several generations, saw the FDA's unilateral move as an affront to their traditional way of making a livelihood. Having perceived the FDA's move as political, they decided to confront the policy decision by using their own local and federal politicians. A senior family member first approached their local State Governor, who realizing the industry implications for the Southern states, took the industry crusade to Federal Congress which ultimately led to the FDA's PHP policy being blocked. Personal communication with the Southern family member who instigated the political intervention led me to understand this was his proudest achievement in a long oyster career. However, he also sadly acknowledged that a combination of other environmental and business factors meant that his family oyster business may not survive for many more generations.

In 2012, a feasibility and economic report was prepared by Research Triangle Park and peer assessed by the Government Accountability Office for the ISSC (DiStefano, *et al.*, 2011) The report considered the costs of PHP, including the cost of land purchases, new construction, insurance costs for plant expansions and equipment, transportation of shellfish to treatment facilities and industry's financing opportunities. The report concluded that if the PHP requirements were imposed, some oyster operations would be able to install PHP equipment or use some central PHP facilities (if they were constructed), and some opportunities were available for industry to obtain financing. However, it also concluded that the PHP requirements would likely cause the closure of a significant number of oyster processors in the summer. The report estimated that approximately 40% of Gulf oyster processors would become unprofitable and would close, especially in the context of rising costs and uncertainty associated with the Gulf oil spill and fresh water diversions in 2010; historic flooding of the Mississippi River in the spring of 2011; and the red tide along the Texas coast in the fall of 2011. CPSI's response (11/4/14) to this report was scathing "*A man's job is worth 30 lives!*" (referring to the number of Vv deaths per year).

It would be a mistake however to assume that industry or consumers are only represented by singular or self-interested voices. As a concerned industry member commented, "*The immune-compromised are doing to die anyway, but we (industry) shouldn't be the trigger than makes them die. We shouldn't be their executioner.*" (Ind:25/6/14). The oyster industry has not ignored the scientific information. In fact, several companies have voluntarily implemented PHP technologies. Such industry decisions provide consumers with a choice between raw oysters and those treated to be *Vibrio* free.

Food safety problems are not unique to oysters with rising problems caused by other food products, for example, fresh produce contaminated with *E. coli*. The interviewees made comparisons between the oyster industry and other food industries experiencing food safety issues: "*Industry resistant to change their business procedures. They don't want to change, but the milk industry was made to change.*"

(StateReg:28/4/14) and a pro-change industry member, who has invested heavily in PHP technology stated:

*Vibriosis problem is because of resistance by industry to implement changes to take care of the problem. Industry blocking and taking political action to stop change. Interesting to compare oyster industry with other industries e.g. almond industry who had allergen problems. The almond industry decided to form their own standard. We need to do something. (Ind:10/11/14).*

Vibriosis has caused adverse economic consequences for some, yet there have been economic benefits for others, including the science industry. Three scientists acknowledge this stating: *“If there were no illnesses I would be out of a job.”* (Sc:13/4/14); *“Anytime there are adverse conditions scientists try to “make honey” (money).”* (FedReg:10/3/14) and *“Scientists will research as long as there is money.”* (Sc:15/4/14).

### 5.5.5 Public Policy and Politics in Practice

Interview participants often discussed topics that can be described as ‘public policy’ and ‘politics’. Public policy has been defined as the role of public authorities within central and local government responsible for managing issues that involve a strong element of public good (Nowotny, 1990). Public good describes the issues that are of interest to or affect society. Historically and internationally governments have been expected to protect its citizens, their health and their property (Nowotny, 1993; Cockerill, *et al.* 2017) and it is the role of governments to define ‘normal’ for topics, including food safety, and then to govern deviance (Foucault, 2007). On the other hand, politics is described as the activities, actions, and policies that are used to gain and hold power in a government or to influence a government ([www.merriam-webster.com/dictionary](http://www.merriam-webster.com/dictionary)).

During the interviews twenty-four (32%) of the interview respondents spoke of public policy matters with 11 (15%) people listing this topic at the start of their response. However, no one considered public policy to be the single reason for vibriosis. During the public policy and political discussions common themes emerged: the role of both the FDA and the ISSC and that there is contest between those for and against more food safety policy.

### The Role of the FDA

As described in Section 5.2.1 the FDA (originally known as the U.S. Public Health Service) has been involved in oyster food safety from the very beginning. Based on the historical evidence it could be claimed that the administration has failed to reduce or eliminate vibriosis even though their scientists and public policy officers have endeavoured to do so. Given their performance the interviewees were asked if in today’s changing world if the FDA still had a vibriosis food safety role. Overwhelmingly, they answered ‘yes’ (96%) with only three people against the administration’s involvement with the ISSC *“Absolutely FDA have a role. Role should be to translate science to the states and aid in writing state management plans. States need all the latest science to make risk assumptions.”* (StateReg:28/4/14). While the importance of the FDA’s scientific role is recognised there are views on how this might be

better translated within the ISSC assemblage, with respondents stating: “*FDA need to drive the technical science. They should be at the forefront of pushing the science.*” (StateReg:2/4/14). “*FDA’s role should be a national science clearing house. FDA should galvanize people and deal with fundamental science problems.*” (Sc:27/6/14).

Further the interview conversations provided valuable insights about the ISSC members’ relationship with the FDA. The following themes emerged:

### 1) Changing Governmentality

The interviews suggest that over time the FDA’s ideology has changed, particularly *FDA’s changing public health stance*. (StateReg:9/6/14). Long term ISSC members provided their observations, including an FDA regulator with 40 years’ service in the US Public Health Service: “*Politically since Reagan there has been a drum beat ‘government is the problem’. There is lack of trust by people and this lack of trust has permeated even the ISSC. There is the perception now that the FDA is not necessary.*” (FedReg:10/3/14). Another long-term state regulator with a senior role within the ISSC stated:

*I have watched FDA evolve over 25 years. In old days FDA was a public health agency and I used to complain that they did not pay enough attention to outside issues. Now with political environment FDA has inability to establish their own agenda. FDA staff no longer have same public health motivation. How FDA acts is a landscape of our society. FDA has become political e.g. CSPI leant on FDA. FDA used to be able to focus more on public health issues rather than being driven by other agencies (9/6/14).*

Others commented that the USA government (and therefore the FDA) no longer perceives its role to be one of devising population strategies to deal with health matters, instead believing individuals should take more responsibility for their own health. Further, according to the interview narratives, the government of the day tends to favour free market capitalism, support private industry and is reducing the role of government in many areas. It was recognised by federal and state regulators, and the CSPI that the FDA is obliged to respond to political pressures: *There are different political agendas and directors are politically appointed. Problems are perpetuated by politics.* (StateReg:28/4/14); “*FDA is a bad position to be in as everything is political. Top dogs have to deal with Congress and there is so much other stuff to deal with.*” (Ind:27/3/14).

It is not the intention of this research to review the changing ideology of the FDA. However, it is recognised that since the 1990s there has been a universal trend for governments to move from traditional public health concepts to the ‘new public health’. New public health focuses on the individual’s responsibility for good health rather than the traditional concepts of population-based strategies (Salmon, 1989; Petersen, 1997). Many reasons have been put forward for this new governmentality, including the decrease in contagious disease outbreaks and the subsequent increased in lifestyle diseases such as diabetes and heart disease; neoliberalism and economics (Starr, 1978; Salmon, 1989; Hooghe & Marks, 2003).

## 2) Food Safety Risks Throughout the Food Chain

Interviewees recognise that the scope of the FDA's food safety role extends beyond oysters but believe that there should be a food safety policy linkages and risk equity between the wider food supply and oysters. For example, *FDA should pay attention and when they look at the big picture should realize that there are small Vibrio numbers (of illnesses).* (Ind:11/8/14) and *"FDA should compare the risks with other food products which is not done in ISSC process."* (StateReg:12/11/14). Six respondents (8.2%) (4StateReg, 2Ind) specifically feel the FDA is responsible for establishing the acceptable food safety risks for USA citizens, stating *"They need to determine the acceptable risk. We need a hard number to work towards."* (StateReg:28/4/14) and *"FDA should compare the risks with other food products which is not done in ISSC process."* (StateReg:12/11/14).

## 3) FDA Relationship Issues

Interestingly the question about the FDA's role seemed to provide a platform for the interviewees to vent frustrations about the general FDA's systems. In categorising the narratives three common themes emerged: the FDA's relationship with ISSC members; FDA's public policy and political activities; and the FDA's scientific role.

The most frequent criticism was the FDA's inability to work collaboratively with ISSC stakeholders. 30 (41%) (14StateReg, 10Ind, 4Sc, 2FedReg) expressed their concerns about the lack of FDA collaboration and communication with other ISSC stakeholders. Examples of such comments from the various professional groups are listed in Table 9.

Such relationships concerns were not just expressed by those external to FDA; criticism was voiced by FDA about lack of collaboration between the FDA organisational silos:

*FDA should be managing technical exchange of information. Large amounts of money are spent at CFSAN (FDA's Policy Office) but what are what are we doing for the money? There are two parallel lines in FDA (CFSAN and ORA) with no reason to intersect. There is no culture to exchange information. It is "them and us", then when we go to ISSC it is "them, and us and them". There is no accountability at CFSAN. We do not do a good job at explaining and then stick to it. We never know if someone is going to drop in from above in FDA and change the policy. Perhaps CFSAN needs to operate more like a private company with regards QA (Quality Assurance). We need to explain science to local FDA specialists. People have lost confidence in us.* (FedReg:18/2/14).

Table 9: Stakeholder comments on relationship issues with the FDA

STAKEHOLDER GROUP	ILLUSTRATIVE QUOTES
State Regulators	<p><i>FDA is needed as there should be a certain amount of uniformity between states. A few FDA people are making decisions behind the wall. They need to speak to us as we have no idea what they are thinking. We have a certain level of distrust. (StateReg:28/04/14)</i></p> <p><i>FDA is trying to support states but comes up with conflicting regulations. They spend time fighting with us, rather than being constructive. They come up with regulations and then fold. They are extraordinarily heavy handed. We have been put off doing research as never know to interpret and manage FDA's reactions. There is no support or leadership. They all act out of fear. (StateReg:5/6/14).</i></p>
Other science agencies	<p><i>"FDA should work with other science agencies to provide ISSC with the data on which to make decisions." (Sc:15/4/14).</i></p>
Industry members	<p><i>"FDA has become ineffective in working with industry. They make unilateral decisions. Limiting harvests and temperatures is not going to sort the problems." (Ind:23/6/14).</i></p> <p><i>"FDA have a role to enforce policy across state lines, but they need to work more with industry." (Ind:4/8/14).</i></p>
FDA making unilateral decisions	<p><i>"New personnel are making unilateral decisions. Get your ducks in a row before coming out strong or you lose your reputation. At least consult." (StateReg:5/6/14).</i></p>

During this research evidence was identified that the FDA's communication with others can be very slow. For example, in June 1998 the CSPI formally petitioned the FDA for a regulatory standard requiring non-detectable Vv levels in oysters intended for raw consumption and harvested from waters to which deaths or illnesses from Vv contaminated shellfish have been traced. Four years later in 2002 CSPI receive a reply, in which the official FDA response was the best course of action was to work with the ISSC who had adopted a control strategy for Vv in July 2001.

Again, in February 2012 the CSPI formally petitioned the Commissioner of the FDA to *take regulatory action to issue and enforce a performance standard of non-detectable as determined by the best available method of detection for Vibrio vulnificus in molluscan shellfish intended for raw or processed raw consumption* (CSPI, 2012). This petition was based on CSPI's opinion that Vv warranted FDA action because *"Death occurs in at least half of the Vv cases, and when death does not occur, infection may impact a survivor's future quality of life due to disfiguring skin debridement or amputation"* (CSPI, 2012). More than four years later, in November 2016 the FDA finally responded to CSPI's 2012 petition. Once again, the FDA declined the petition on the basis that working co-operatively with the ISSC and industry to implement appropriate controls was considered the most effective control mechanism. This response was of course after the 2011 decisions by Congress which meant that the FDA was no longer able to work effectively outside of the ISSC. However, that the FDA's delayed response to the 1998 and 2012 petitions is not abnormal; under USA law the FDA have up to five years to respond to any petition, a

legal provision and an administrative loophole that the FDA chooses to use when dealing with their stakeholder.

Further to the science issues identified in Section 5.6.1, seventeen interviewees (23%) (4FedReg, 6State Reg, 4Ind, 3Sc) had some criticism of the FDA science system because, in their opinion, the science is not always valid, and the agency is ineffective in convincing others about their research. Such criticisms include:

Ineffective science - *FDA are a regulatory agency trying to control something that they do not understand. Industry gets more and more imposed on them just because no one knows what to do. There is need for better co-ordination with CDC. FDA needs to provide sound science. Current FDA science is embarrassing and not practical e.g. icing studies, the whole thing was hurried and weird. If you are going to come up with draconian rules, you better do your homework first. When you back down you look even more stupid. Improve your game. FDA coming up with threats and not having science makes the agency look weak and incompetent. You must do your homework. FDA worked everyone into a tizzy and then backed down. We don't take you seriously.* (StateReg:9/4/14).

Impractical Science - *"FDA's science needs to be practical – a boat tied to a wharf in Alabama is not the same as real harvesting."* (StateReg:9/6/14).

*"FDA should remain involved and listen. Best ideas may not always be practical. FDA should be a participant, providing supportive science. Science is not everything. If you don't have a viable business this is useless."* (Ind:10/4/14).

Inability to perceive regional differences - *"FDA's role is to co-ordinate and interface regions and synthesize science information. They need to recognize regional differences."* (StateReg:30/6/14).

Moreover, 19% of interviewees (9StateRegs, 3Ind) expressed concern about their wider relationships with the FDA, such as the following examples:

Fear – *"We are put off doing our own research as we are unsure of how to interpret the results and unsure of how to manage FDA's reaction e.g. methods development. Who owns the data, and who would release? We were denied data from FDA that our States had collected."* (StateReg:5/6/14.)

Loss of faith – *"We are losing faith in the FDA's science. They are shrieking 'the world is ending' which is over the top."* (StateReg:24/4/14).

Lack of trust – *"FDA is too disconnected from policy to make decisions. We have no trust in them."* (StateReg:28/4/14).

Lack of belief in FDA – *"We don't believe FDA's extrapolation of CDC data. FDA keep changing their policies. We are thoroughly disgusted with FDA as they are lumping all Vibrios together and not representing the data correctly."* (StateReg:2/4/14).

FDA staff themselves recognised this loss of faith:

*FDA should be leading the charge. We should be identifying the things, based on best science modelling to convince the states. We try to do this with ISSC. Our credibility as an agency is not what it used to be. Mike Taylor did this. Now every time we do something people dismiss it and “we can’t do that” “CDC stuff is not right. How do you convince them? Best approach is little steps rather than giant leaps. Thought our cool down proposal, with other things would have been a good thing. People did not want it. (Sc: 18/2/14).*

#### 4) FDA Cannot Please Everyone

It emerges from interviews that it is impossible for the FDA to please everyone on food safety matters. On the one hand the FDA is criticised for not taking decision leadership action regards vibriosis:

- *“FDA should be leading the charge.” (FedReg:10/3/14)*
- *“There is lack of leadership within the FDA.” (StateReg:5/6/14)*
- *“Public health food safety ought to mandate PHP. Industry see raw oysters as a cultural value that has inherent value and ought to be around. The Gulf Coast industry has significant political power which means that legally FDA has now been taken out of the picture. Institutionally now FDA only have a role working with ISSC.” (FedReg:10/3/14).*

On the other hand, fifteen people (20%) (6FedReg, 3 StateReg, 4Ind, 1Sc and 1CSPI) criticised FDA’s ability to effectively participate in the ISSC co-operative policy process. The FDA’s unilateral Vv policy action in 2009 was often cited as an example of such uncooperative behaviour: *“It was a single person’s idea to mandate PHP. Commissioner’s study showed that PHP was not affordable, so FDA dropped this policy.” (FedReg:24/03/14).*

### The Role of the ISSC

The interviewees provided their views on the work of the ISSC members, including that of formulating and enforcing policies. But more important the interviews exposed the on-going contest about when food safety policies are necessary.

#### 1) The public policy contest - debate about need for vibriosis food safety policies

Access to the ISSC’s records confirm the lack of agreement about the role and need for vibriosis public policy. The interviews, and the ISSC records highlight the diversity of opinions about the perceived severity of the vibriosis problem and how it should be managed, if at all. The documents highlight the vociferous vibriosis debates starting with Vv in 1987, extending to Vp in 1999 and which remain unresolved to date ([www.issc.org](http://www.issc.org)). These disparate opinions cannot be neatly divided along professional divisions, such as industry versus regulators. Even within each professional category (industry, regulators and scientists) there is obvious dissension. The historical ISSC documents also identify differing opinions between the USA’s regions, for example, ISSC members linked to the Gulf of Mexico harvesting waters relate differently to the Vibrio issues compared to those from the Pacific and Atlantic coasts.

Some argue that vibriosis, particularly when caused by Vv, is not an illness that ISSC should be tasked with addressing. According to eight members (4StateReg, 2FedReg, 2Ind) vibriosis should not be on

ISSC's agenda at all *"ISSC should not have taken ownership of the (Vibrio) problem."* (StateReg:30/6/17) while another claims the ISSC is now *on auto-pilot. There is lack of agreement that Vp and Vv illness are a problem and what the problem is.* (StateReg:3/7/14). A few (2StateReg, 1FedReg) claim there is *"No dedication by ISSC to solve the problem."* (FedReg:24/3/14). Five federal regulators went so far as to say that public policy is unnecessary to protect those suffering Vv health consequences given their pre -health status: *"A Vv policy was established to save some 30 people, many of whom were going to die of their illness anyway"* (FedReg:9/4/14); and *"For people who are impacted with significant health issues they are dying – Vv is what shortens an active stage of dying"* (FedReg:27/3/14).

On the other hand, CSPI has vociferously advocated for policies to address the incidence of Vv (interestingly they have not advocated similarly for Vp). The CSPI lobbied the ISSC (and the FDA) hard until 2009. During this research project research, I interviewed CSPI for three hours at their Washington DC office (11/4/14) during which time they confirmed their stance, describing the oyster industry as *the tobacco industry of the food side because industry sells oysters as a desirable product, but don't tell people it is likely to kill them.* and *"A responsible industry would care about product and would treat during the at-risk season, have testing controls and regulated harvest controls. Some would lose their business, but small boat operators would find other jobs."*

An important theme that emerges is the divergent view as to when food safety regulations are necessary. The interviews indicate two sides in the governance debate; the rights of individuals versus government control of the population. On the one hand respondents voiced that even when in their mind consumers made "stupid" personal decisions, that this was their prerogative and that personal choice was imperative. The following quotes illustrate the two camps.

#### Freedom of Choice

- *"It is my right to eat oysters. People in the South know about Vibrios, but we have the right to choose."* (Sc:8/2/14)
- *"Option is to say people cannot eat raw shellfish. My opinion is that the illness outcomes do not warrant that level of big brother. Personal choice is important. I eat unpasteurised raw cheese and cider".* (StateReg:2/4/14)
- *"There is a personal level of responsibility. It is a personal health choice..... I don't think that the government needs to be responsible for all."* (FedReg:27/3/14)

In contrast, others expressed concern about the lack of regulation.

#### Need for Regulation

- *"Unless we stop people eating raw oysters we will not eliminate illness. It is no different to smoking".* (State Reg:6/4/17).
- *"Because we are allowing people to eat raw, whole animals when the only control is to cook or PHP. Allowing people to eat raw oysters will always cause illness – a live animal that is an organism that concentrates pathogens."* (Fed Reg:9/4/14).

Others felt that regulations mandating oyster treatments would not solve the problem: *“Even if we mandated PHP we would only battle an underground network such as is available for turtle, racoon and game bush meat. There is a culture involved that we cannot change.”* (FedReg:5/6/14).

## 2) ISSC Procedures

Several interviewees believe that it is the ISSC’s institutional procedures that ensures persistent vibriosis. Fourteen (5StateReg, 4FedReg, 3Ind, 1Sc, 1CSPI) consider the co-operative model especially problematic, because the *“FDA is just a single voice within ISSC. There is no ability to make unilateral decisions. I don’t think a co-operative programme makes any sense.”* (Sc: 3/4/14) and

*The ISSC model is the problem. Prior to this we had the Public Health Service. We provided workshops and science to the states (1950-1980s) and let states get on with it. The introduction of the ISSC system means we cannot vote unilaterally. We need to do ‘PR’ (public relations) which introduces politics. ISSC was introduced then states became responsible as FDA not capable of ensuring that states were implementing the program uniformly.* (FedReg:10/3/14).

Further ten interviewees (3FedReg, 2StateReg, 3Ind, 1Sc and 1CSPI) refer to the ISSC’s procedures which do not allow agenda items to progress, stating *“The adversarial nature of ISSC is the problem.”* (StateReg:24/3/14) and *“The ISSC is dysfunctional. The inland states have less votes than the coastal states.”* (StateReg:28/4/14).

## 3) Dealing with Deviance

It might be assumed that once the internal ISSC policy debates have occurred and the voting process completed that this secures national regulatory safety autonomy. However, this research identifies that this is not the case and this autonomy is regularly tested. Two well documented and publicised cases of contest include the state of California and the FDA versus the ISSC. First up, the state of California who in April 2003, decided to break with the co-operative ISSC tradition and go it alone. Having assessed their state Vv epidemiological records they passed a state regulation restricting the sale of raw oysters, harvested from the Gulf of Mexico from 1<sup>st</sup> April to the 31<sup>st</sup> October each year. The alternative was to post harvest treat the oysters reducing the Vv to non-detectable levels (Vugia *et al.*, 2013).

There were consequences for California’s unilateral decision to formulate independent state shellfish food safety regulations. First up, California was shunned by the ISSC. In 2003, the ISSC Executive Board determined that California should lose all ISSC voting rights until they aligned their state policies with those of the ISSC. It was further resolved by the Executive Board that the FDA be requested to use whatever means possible to compel California to follow the national rules agreed by ISSC. Second, a policy review (Vugia *et al.*, 2013) concluded that California’s 2003 regulation led to significant reductions in reported raw oyster associated *Vibrio vulnificus* cases and deaths. Their conclusion was reached because the annual number of illnesses and deaths, in situations where raw oysters were the sole exposure, were 0-6 cases and 0-5 deaths per year during 1991-2002. After the regulation was implemented, during the period 2003-2010, the illnesses and deaths dropped to 0 ( $p = 0.0005$  for both). In other states the median annual numbers of similar cases and deaths increased slightly after 2002.

California's single-minded action and the consequences were noted by interviewees with comments such as *"I agree with California's policy stance. Though rules cost money."* (StateReg:28/4/14) and

*California is paying the price for their policy decision – they can no longer contribute to ISSC. This is not healthy to anyone. It is unfair that a regulatory body is excluded to decisions made on public health grounds. The decision was made by other public health agencies and not solely by California's shellfish control authority.* (StateReg:10/4/14).

The FDA provides the second example, when as mentioned in Section 5.5.4, in 2009 the administration decided to formulate their own national oyster food safety policy. Having reviewed the previous 10 years of ISSC regulatory policies aimed at reducing the Vv illness linked to oyster consumption the FDA concluded none had worked. It also determined that there was an unacceptable Vv illness risk linked to eating raw oysters harvested from the Gulf States (Alabama, Florida, Louisiana, Mississippi and Texas) during the summer months (April through to October). As a result, the FDA took the unilateral policy decision of amending the *Seafood HACCP Regulation*, 21 CFR Parts 123 and 140, thus making post-harvest processing mandatory for all Gulf Coast oysters harvested during the summer months. In using this legislation rather than the NSSP Guide, the FDA acted outside of the ISSC. Following industry objections and political intervention *the FDA's post-harvest treatment policy was scuttled (by Congress), and since the FDA have reverted to their role as one of the ISSC's co-operative members.* (FedReg:24/11/14).

Not only did Congress scuttle the FDA's policy, they erected further hurdles by amending the *FDA Food Safety Modernization Act* (US national food safety legislation) to protect the oyster industry. Specifically, on January 4, 2011 Public Law III-353, *Section 114 Requirement for Guidance Relating to Post Harvest Processing of Oysters* was added to the Act. This amendment mandates that when any future oyster post-harvest processing regulations are proposed, including federal or ISSC regulation or suggested amendments, the Secretary must immediately advise Congress committees. The promulgation and process requirements of Section 114 effectively stops ISSC or the FDA's ability to request or mandate PHP shellfish food safety measures.

Fourteen (19.1%) of the interviewed acknowledged the power of politics, with two persons (2.7%) considering politics to be the primary problem. This group considered politics an important factor in deciding who and what economies should be protected in US society. Statements were made about political power; *"Congress will always decide"* (Ind:23/6/14) and *"The politicians have taken policy control away from the FDA"* (FedReg:24/11/14). Referral was made to the use of such powers by oyster businesses, including: *"Politics. Industry is politically connected. The last bastion is the harvester/farmer. Politicians are very protective. It is hard to go before a judge and say that industry is to be penalized so that one alcoholic can be saved.* (FedReg:9/4/14) and *"The industry's holdup is the problem. Industry have a grip on the regulatory folk. They use politics, Congressional caucus and US congress to give industry the upper hand."* (FedReg:24/3/14).

While the cases of California and the FDA provide significant examples of contest within the ISSC there is also a quieter, more insidious contest against the ISSC's regulatory dominance. During my 2013-14

tenure with the FDA regional field visits recorded the different regional practices used by state and federal regulatory officials. Such differences include various *Vibrio* management plans activated on differing environmental triggers. Such diversity is to be expected given the USA's climatic and epidemiological differences. However, it was noted that there were also different techniques in interpreting and implementing the NSSP legislative by the state and federal officers. I also observed and participated in the regional association meetings: the Gulf and South Atlantic States Shellfish Conference, the Pacific Rim Shellfish Sanitation Conference and the Northeast Shellfish Sanitation Conference. These regional forums bring together local industry, regulators and scientists to discuss food safety matters. The 2013-14 meeting agendas and presentations revealed that each region had a different *Vibrio* focus brought about by their specific regional climate, hydrographical features, shellfish industry practices and vibriosis epidemiological patterns. During the semi-structured interviews six people (2FedReg, 2StateReg, 2Ind) referred to the problem of forming policies for their large, diverse country: "*One policy does not fit all of the US*" (StateReg:9/6/14) and "*There are 100% operational differences between States*" (Ind:27/3/14).

Ten interviewees (5StateReg, 4Ind, 1FedReg) consider the ISSC food safety rules are not adequately and equally implemented throughout the USA states. They claim *Lack of enforcement*. (FedReg:3/4/14) and "*It is the Stockholm Syndrome of the regulators. The regulators are not following up on non-compliance as they should be.*" (Ind:27/3/14). Others blame the oyster harvesting and processing industry: "*Lot of industry non-compliance but we can solve that. We need to drive compliance up in a nutshell.*" (FedReg:3/4/14). Specific points in the food chain and implementation of the wider food safety regulations were discussed, with seven (9.5%) (4StatReg, 3Ind) believing that vibriosis illness is exacerbated along the post-harvest food chain. Some blame the retail chain, citing: *Lack of control at the retail level* (Ind:11/8/14); "*Retailers and restaurants I deal with know nothing about Vibrios*" (Ind:23/10/14) while others list fault with consumers: "*People place uncooked food in the trunks of their cars without adequate cooling.*" (FedReg:2/6/14).

### 5.5.6 Natural Biophysical Environment

Last, but far from least, my participants pointed to the significance of the natural environment in the mix of factors that bring about the vibrio problem. Across the different types of members of the ISSC, my participants made comments such as "*Vibrios are a 'natural occurrence' and we can't stop it.*" (StateReg: 30/6/14); and "*Vibrios are naturally occurring. It is hard to change nature*" (Sc:21/4/14). The point is also made by 15 (6StateReg, 5FedReg, 2Ind, 1CSPI and 1Sc) that freshly harvested oysters come naturally contaminated with sufficient *Vibrios* to cause illness: "*They are naturally occurring. The only way to stop illness is to stop harvesting.*" (StateReg: 22/4/14) and "*Vibrio strains contain an infective dose straight out of the water.*" (FedReg:9/3/14). In all, thirty-five ISSC members (47.9%) consider biophysical forces to be central to the incidence of vibriosis. While no one considers the natural environment to be the sole reason for the continued incidence of the disease eleven (15%) people started speaking about the environmental issues before moving to other causes. Respondents saw four areas of concern: the marine environment causing infections; regional concerns; constantly changing

environments; and the lack of understanding about the relationship between Vibrios and the environment.

The relationship between physical geography and Vibrios is highlighted (n=20 27%) as the Vv and Vp incidence varies in the different coastal regions, with Vp outbreaks more commonly caused by oysters harvested from the northern Atlantic states while Vv is linked with Gulf of Mexico. The following quotations summarise these viewpoints: “*There are geographical differences. In New Hampshire, we have high Vp numbers in the water, but no illnesses.*” (StateReg:22/8/14) and “*There are regional differences with regards the number of pathogenic Vibrio strains.*” (Sc:7/4/14).

Respondents also remarked on the inherent instability of Nature resulting in on-going environmental changes making it difficult for science to focus on a stationary and stable problem. Some respondents alluded to microscopic changes with Vibrio bacteria constantly evolving into new serotypes and strains: “*Vibrios are living organisms that are constantly changing, and we don’t understand the situation.*” (Sc:23/4/14). Others recognised larger environmental changes, such as climate change, which is constantly affecting the vibriosis risk profile: “*The climate is warmer geographically and seasonally.*” (FedReg;10/3/14) and “*No denying climate change in Alaska over the last 30 years.*” (StateReg:24/4/17). “*The changing climate – is it a problem? We don’t know.*” (Sc:15/4/14). One scientist expressed the view that increasing vibriosis is a symptom of larger environmental problems:

*Vibriosis brings attention to the changing environment. Nature is beating us. Uncertainly in nature is not new. The way the globe is changing climate was seen in the NE Atlantic last year. NE had their warmest set of records in 2012-13. US is extremely dumb in terms of their climate year. Congress is not in touch with reality which affects policies.* (Sc:27/6/14).

Science lacks understanding about the environment and vibrio bacteria meaning that scientists find Vibrios unpredictable and therefore difficult to manage. Expressions of unpredictability included statements such as “*When and where it (vibriosis) will rear its head? It is extremely hard to regulate with blinkers on*” (Ind:27/3/14) and

*We don’t know why the problem exists: whether it is caused by biosecurity or climate. There are many things we don’t understand: seasonality, ecology, and proliferation of biotypes (which makes them hazardous or not hazardous) in areas not very far apart.* (Sc10/4/14).

Even so eleven people (6Sc, 3StateReg, 2Ind) consider environmental changes will eventually increase the vibriosis burden. As one scientist predicted on the 15/4/14:

*Things in the environment are changing. Changing dynamics. Global warming. Ocean upwellings are higher on the West Coast but may develop on the East Coast with changing weather patterns. There will be larger environmental problems. It is going to get worse, not better.*

Figure 4 differentiates the causes of vibriosis into two silos – social action and the biophysical environment. However, the information gathered during this research suggests that it is not so easy to draw a line between nature and culture when it comes to Vibrios even if, as with most other microbial illness caused by oyster eating, vibriosis is not associated with human pollution. Instead Vibrios live

naturally in the marine environment, largely unaffected by anthropogenic influences (Veenstra, *et al.*, 1994; DePaola *et al.*, 1994; FAO, 2011; Martinez-Urtaza *et al.*, 2013). Nonetheless, while they may well be a 'natural' bacteria they interact with human practices from farming to eating, and they have profound social consequences.

Further there are other illustrations which highlight the tangled relationships. For example, natural evolutionary processes caused Vp bacteria to morph into a new serotype known as O4:K12, first identified in 1980 on the northern USA Pacific coast where it caused human illnesses (Abbott *et al.*, 1989). The Pacific coast might have remained O4:K12's ecological niche but ships also have a marine relationship, collecting and discharging ballast water at different ports of call. The first European illnesses of O4:K12 occurred in 2012, aboard a passenger ship after seawater was used to make ice and then used to cool (and contaminate) the luncheon buffet. In 2013, the first O4:K12 illnesses caused by USA eastern seaboard oysters occurred (Martinez-Urtaza *et al.*, 2013). Subsequent investigations suggest O4:K12 was transferred from the Pacific to the Atlantic oceans after moving Pacific coast oyster stock to the Atlantic oyster farms (Newton, *et al.*, 2014). Therefore, human activities were involved in spreading the naturally occurring vibrio bacteria, contributing to the level of illness.

## **5.6 The Continuous Cycle and How to Break Away**

When embarking on the exercise of asking ISSC stakeholders five questions the aim was to find out more about the prominent vibriosis actors (Vibrio bacteria, oysters, industry, regulators, scientists and consumers) and their relationships. However, the interview conversations provided a much richer and detailed story, extending the number of actors and exposing the multiple assemblages. What emerges is a tangled picture; one that STS would describe as more "complicated, messy and happenstance" (Le Heron, Le Heron & Lewis, 2013) than traditional black-boxed science would have us believe.

Actor-network theory considers that the answer necessary to address 'the' vibriosis problem will depend significantly on how it is conceptualised and framed. This chapter demonstrates that the ISSC delegates frame vibriosis in multiple ways (ethically, economically, epidemiologically, regionally and socially). As post-structuralist forms of critique would expect they select, emphasise or omit to make salient certain aspects of a perceived reality, while obscuring others to promote a definition or interpretation of an issue (Entman, 1993; Shah, 2002). The ISSC's work on vibriosis clearly illustrates that framing involves identifying who is (or is not) affected by a given problem as well as who is responsible for its resolution (Saguy, 2008). For example, the NSSP defines what vibriosis situations (outbreaks of a specific case numbers over a specific time) are worthy of regulatory action and determines that the state shellfish authority is responsible for controlling the situation. It also illustrates how framing involves moral judgements (Entman, 1993) with the potential to reconfigure the distribution of tangible benefits or losses to groups (Kwan, 2009), especially when policy makers use the frame when making decisions (Siegal, 1998). For example, Congress has determined that the annual vibriosis mortality rate associated with raw oyster consumption is currently not high enough to warrant the introduction of mandatory oyster pasteurisation (DiStefano *et al.*, 2011; Public Law III-353, 2011).

These insights immediately challenge any sense that 'the' vibriosis problem is singular or stable and thereby destabilises the standard approach of instrumental and solutionist science, where a problem is specified, a set of data, experiments are collected, and interventions tested to develop a response. Again, the ISSC illustrates this point and the consequences that flow from it. As the answers to my questions reveal, the ISSC cannot agree on whether vibriosis is a matter of concern, and even when it is, how this might or ought to be configured into a problem. Different members of the ISSC frame the nature and extent of the vibriosis problem differently, an insight that confirms observations from the grey literature and my wider USA field observations.

In many senses, the interviewees recognise that attempting to place a problem framework around the science-policy-economy assemblage of vibriosis-oyster-human relations fails to stabilise these relations. The Vibrio situation is complex as there is no common view as to the scope of the problem, made even more complex by the diversity of opinions as to when, what and where any solutions should be applied to the vibriosis assemblage. The framework is not solid or fixed making it almost impossible for any actor, including science, to stabilise a situation that does not have a concrete focus point.

The interviewees offered up multiple reasons for the persistence of vibriosis amongst raw oyster eaters, including what they perceived to be the matters of fact and concern. These reasons include biophysical (natural) forces, dietary choices, oyster industry practices, public policy and political decisions. Surprisingly, they did not immediately lapse into a solutionist discourse centred on more science, even though many of Vibrio's biophysical features and their relationship with human illness are not fully understood. They agree that neither vibrio bacteria, or the environments in which they live, stand still long enough for science to form a stable relationship which allows them to know and conquer Vibrios in their natural marine environment. On the other hand, they acknowledge that science has done its job by offering up technologies with which to render harvested oysters safe. There is still work for science to do, but the answer to the persistence of the disease lies elsewhere - in the realm of why the preventative food safety option science offers is not universally applied. That is, post-harvest treatments of oysters strip them of the cultural and natural qualities that make them desirable (naturalness, taste, vitality, and meaning), or at least in the view of their eaters. They are no longer raw.

The potential for the ISSC to act in this space is restricted by its relational configuration. They must act in relation to the oyster, the vibrio, oyster eaters, gatherers/farmers and the FDA, even given their expressed concerns about the co-operative relationship with the FDA. Further the FDA must abide by the decisions of Congress and interviewees suggest that over time the government social weightings and ideologies have changed. The FDA's work is in this way contingent, not just on the economy, value choices and food safety decisions of individuals, but the ways these topics are translated into and through national politics. This can involve making difficult choices between protecting individuals and addressing wider questions to do with property rights, economy, and culture.

Many interviewees believe that changing biophysical and social factors will increase the prevalence of vibriosis and sharpen the challenge of making these choices. They predict a combination of environmental changes will lead to an increased threat, while others point to the threats that may emerge from human demographics and social changes, such as the ageing population that puts more eaters at

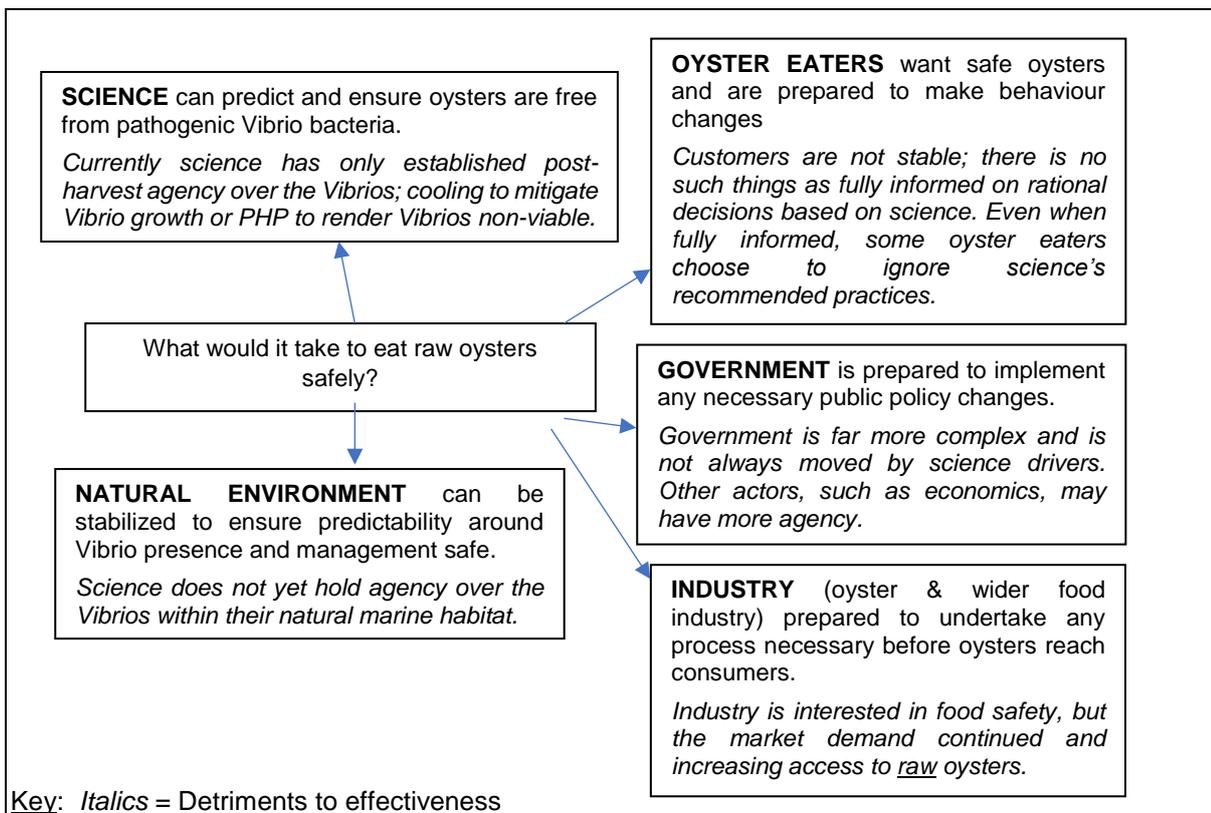
risk and increased coastal development that may affect oyster-vibrio relations through increased oyster consumption.

Yet, even with the potential for an increased USA illness burden the ISSC remains locked into their current problem-solving cycle. Since the first 1988 Vv science workshop, the ISSC group has continued to use the same conference procedures to deal with science's offerings. By repeating the same science/policy cycle every two years the conference outcomes will likely remain the same.

Chapter 4 focused on the science used to biometrically describe the Vibriosis 'problem'. However, by taking an ANT focus on the ISSC it is revealed that that vibriosis is not a singular problem. This chapter reveals much about the constellations of relationality which frame and underpin vibriosis through the work of the ISSC (including the nature of that work itself). Science is just one actor relating to a wider constellation. Not only that, 'science' is more complex than a simple black box containing value-free, ethically neutral and repeatable laboratory methods.

The vibriosis food safety issues are multiple and complex, involving social, including moral, attributes. Science might offer simple solution, such as oyster pasteurization, but that does not mean the ultimate answer. In this situation Latour would ask what is required to eat raw oyster safely, with Figure 5 depicting the answers and associated detriments.

Figure 5: Modelled factors which ensure raw oysters are safe to eat



There is potential in using ANT concepts to further explore these relational constellations and in doing so there is also the possibility of exposing a new way forward. The following chapter will explore some of this potential.

## CHAPTER 6: REFRAMING THE PROBLEM

Using ANT's notions of relational agency, this chapter analyses the insights from the interviews and other sources. It uses the information to explore how science is being mobilized to confront the vibrio; whether these interventions are proving effective, useful or otherwise; and what might be done to enhance the effectiveness of the science itself and its translation into policy. This case study exposes the complexity of contemporary food safety matters and social opinions that must be considered by scientists and those using science to interpret what to do on behalf of today's consumers.

### **6.1 Will the Real Actors Please Stand Up?**

Read through an ANT lens, Chapters 4 and 5 suggest that the relationship between science and vibriosis food safety involves multiple human and non-human actors. Some ANT authors use the term *primary actor* to describe those pivotal actors who are the network builders, frame the problems that animate the network or lead the identification of the relevant actors involved (Macome, 2008; Cressman, 2009). For example, in Callon's famous 1986 scallop study the primary actors were the three marine biologists who proposed to design the conservation strategy for St Brieuc Bay and who then went about engaging with the other human and non-human actors to enact the strategy. In this research, it is clear that the scientists and regulators of the ISSC are primary actors, but so too are the industry actors and consumer advocates who also make up the ISSC, as well as vibrio bacteria, oysters, and oyster eaters. Each of these individual actors are trying to animate the network for their own purposes. It is also clear that these actors act in relation to each other and diverse other human and non-human actors. The federal food safety regime assembled around vibriosis in the USA is not simply a set of instrumental transactions among FDA scientists and the ISSC voting members. Rather it is assembled around all these actors, each of whom become present at debating tables prefigured by their own internal and external relationships with the other human and non-human actors.

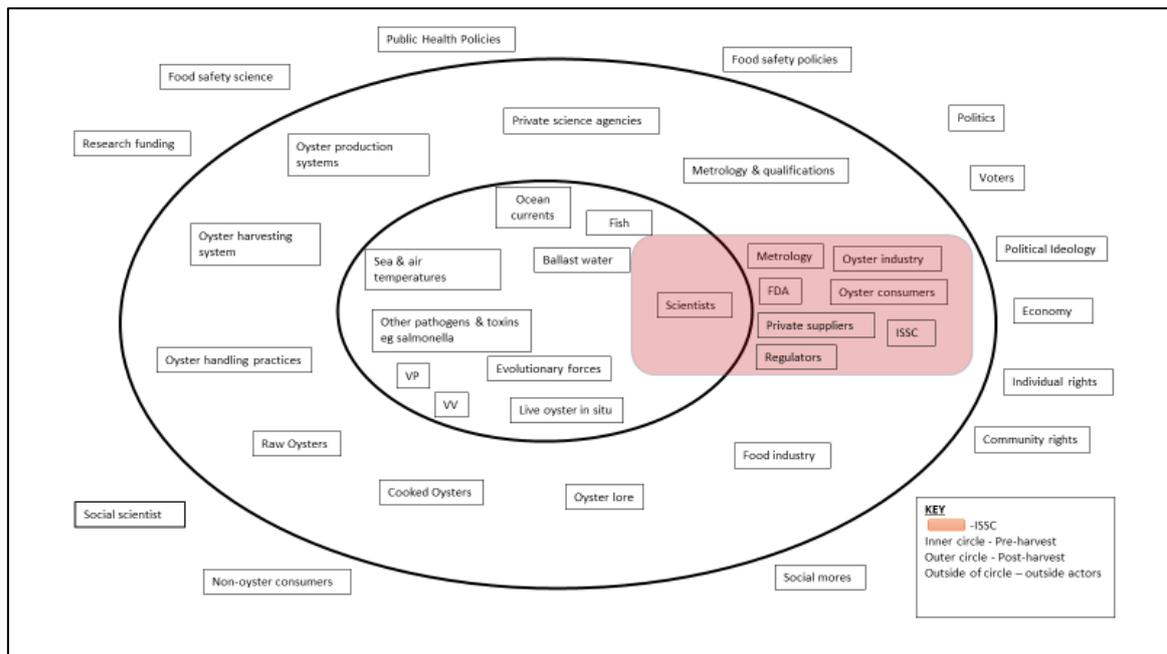
This relational agency is recognised implicitly by the ISSC participants, but it is not conceptualised as relational agency. Everything from consumer desire and behaviour, 'industry perspective', vibrio behaviour, policy as a practice and the oyster itself is considered prior or external to the pivotal relationship between the scientist and the regulator. Traditionally, it is perceived that the epidemiological triangle of host, disease and the environment, is a set of discrete, independent and preformed actors. However, this research suggests that not only are there more actors (the measures and devices used by scientists, the rules made by regulators, and the taste makers that shape eaters, as well as many other physical objects, happenings, events, signs and utterances), but the agency that these multiple actors generate is relational. The interviewees offered up diverse accounts of the relational agency at work in vibriosis food safety.

Many of the actors revealed through the interviews with ISSC members do not appear or are backgrounded in human-centric scientific and policy accounts. Their agency is disguised and under-recognised in the standardised ISSC schematic in Figure 3. The relationality of that agency does not

appear. The biophysical scientific literature clearly reveals that *Vibrio* bacteria, oysters and physical environments (from shifting temperatures and ocean currents caused by altering energy balances and diverse human action) are all at work in shaping oyster food safety, as are oyster production systems and ISSC protocols. However, this is not carried into either scientific analysis or policy thinking as recognition of specific and uncertain agency or as relational agency. These physically identifiable non-human actors are reduced to largely inert biological problems to be overcome. Other, less material actors, such as desires (for raw oyster eating), science knowledge gaps, or the ignorance produced by dominant methodologies and knowledge bases that close out other ways of knowing (Kleinman & Suryanarayanan, 2013) are not registered at all.

Figure 5 portrays the extensive list of actors spoken about during the interviews. The figure avoids any sense hierarchy of actors, but for visual purposes assembles them into groups: those in the marine environment prior to commercial oyster harvesting; actors involved after harvesting; those involved in the ISSC assemblage (see below); and the wider group of food safety actors, who while supposedly operating independently are also acting on and through the ISSC. In any case, Figure 6 highlights a diversity of otherwise hidden human and non-human actors, including the marine environment, the ISSC, the industrial procedures for growing, harvesting, processing and distributing oysters, and the analytical procedures and the metrological/calculations which make *Vibrio* bacteria visible.

Figure 6: List of actors identified during the semi-structured interviews



At first it seems the wide group of actors can be divided into those originating from the natural biophysical environment and those coming from the social environment. Though such a clean, dualistic division is not possible as it soon becomes obvious that everything relates to everything else, with culture, society and nature are in a perpetual state of becoming (Latour, 1992, p.281). Climate change provides such an example. There is consensus that climate change effects the natural environment, leading to different

Vibrio behaviour, but it is possible that such effects are caused by human activities which provoke and/or escalate climate change.

None of the actors are static or permanent. They are all (human and non-human) morphing into new forms in relation to others. These processes of change include species evolution; environmental changes over space and time; population demographics; political philosophies; consumer appetites and dietary patterns; accepted cultural norms; economics; unintended public policy consequences; public policy implementation lags; lack of policy implementation; industrial processes; measurement systems; and human perceptions of trust and belief. Likewise, science as an actor is not stable. It is constantly changing with new problems to address, challenges to its findings (which are, of course, almost always incomplete), and new analytical protocols, metrology systems, laboratory facilities and institutional agendas. As Latour (1988) originally argued, science itself is an assemblage of diverse assumptions, methods, hypotheses, emphases, and perspectives.

Participants in the ISSC confirm that the relationship between science and the other actors (human and non-human) with the vibriosis problem is complicated and messy, and that agency is always relational. Science is often overwhelmed by the other actors and their relationships. It is unable to comprehend all it needs to understand to account for or subdue the agency of other actors and science's knowledge gaps create opportunities for other actors to exert agency. It is simply ill-equipped to account for many of the relationships at work, especially those between oyster eaters and oysters that are mediated by culturally framed desire, as well as those between industry actors, politicians and vibrios which are mediated by accumulation imperatives. Scientists place research information on tables in the form of calculations, reports, new technologies, and risk assessments. They even seek to convince other actors directly, but their work in all its forms encounters others and becomes agentic through relationships that are diverse, complicated and messy.

While scientists have been locked into a long-term relation by the 1985 FDA/ISSC MOU that commits the FDA to providing the ISSC with scientific support, it would be wrong to see science here as a singular actor or positioned, as per Figure 2 (Section 5.2.4), as the central driver of the ISSC's food safety decisions and the primary actor within the vibriosis story. Rather, science itself is unstable and fractured. Within the ISSC science is made up of microbiologists, biologists, marine biologists, epidemiologists, environmental scientists and systems modellers all from different institutions with different backgrounds, theories, working practices, and project interests. They go to work on environmental factors that are messy and only weakly understood. Even before the challenge of translating this messiness into predictive science models, they must establish ways of bringing their diverse lenses, interests and concerns into focus to explore the relationships between environments, vibrios, oysters, human actions (producing, processing, transporting, storing and eating), And then there are knowledge gaps amidst the biological and other instabilities in the actions of specific actors and their inter-relationships. Despite best intentions and concerted efforts to build multi and interdisciplinary initiatives and knowledge, science is fractured and must be assembled and reassembled actively within the ISSC.

As described in Chapter 2, these multiple actors form relationships, otherwise known as networks or more broadly and evocatively as assemblages. According to Dewsbury (2011, p. 149) assemblages

explain the world. They develop and frame the 'who', 'what' and 'how' of situations and the coming together of the heterogeneous relations that make up these relationships. The concept allows researchers to focus on the complexity and indeterminacy of social realities established by these relations (Lewis & Rosin, 2013). The following section will explore what I have loosely understood thus far as the vibriosis food safety 'regime', as an assemblage. For this research, the term assemblage refers to a configuration of actors, ideas, interests, objects, practices, and relations that is fundamentally unstable but assembled and held together to do particular work in the world. It may take any provisionally structured format. Further, as Dewbury (2011, p.150) interprets the assemblage is something that is always in the making and encountered as situated in text, perception, imagination and experience.

## **6.2 The ISSC as Assemblage**

The ISSC is tasked with dealing with USA oyster food safety matters. To do so, it must assemble and lock into place (interesse) a diverse set of professional members (federal and state regulators, oyster industry representatives and regulatory and research scientists). This diverse group arrives at the ISSC with their own diverse and contradictory matters of concern, predefined agendas, established relationships, knowledge bases and political interests. From this diversity the ISSC is expected to deal with multiple matters of fact and concern centred on the action of vibrios and oysters in relation to their environments and oyster eaters, as well as the direct interests of the actors at the ISSC table. Not only that, but they must deal with all those human-human and human-nonhuman relations that represent. From this complexity the ISSC is expected to shape the myriad of relations legitimately and effectively, as well as handling food safety in a way that yields a set of accepted understandings and related practices that can be applied to a diversity of biophysical environments and cultural and economic situations. As Chapter 5 demonstrates, holding these relations together and meeting these expectations is no easy task, even before recognising that the key determinants are widely contested.

Science, despite its own internal fractures, is asked to hold this assemblage together by making sense of and framing and governing the myriad of relations. Despite some unease at its capabilities in this regard all those interviewed in the ISSC turned to the authority of science as a way of explaining how the ISSC worked. All oyster food safety issues are turned over to scientists, whether the cause originates from human/social or natural derived sources of chemical or microbiological contamination. Scientists are expected to take an objective stance and adopt scientific methods in all matters, and to identify causal relationships, measure and document the facts of the matter, and propose potential solutions. Using the terminology of the risk assessment regime, the scientist measures the hazard and the exposure and characterizes the risk.

Scientists have been locked into the vibriosis story by the 1985 FDA/ISSC MOU agreeing the FDA will provide the ISSC with scientific support. It is through its scientists and the regulatory compliance officers that the FDA is bound into the ISSC (Section 5.2.1) and through which its wider food safety policy roles are brought to bear through it, and in turn informed and shaped by it. Science binds the actors in the ISSC into relationships with USA Congress and other government agencies. The FDA's own scientists, research scientists of multiple disciplines, seafood scientists, and scientists whose work focuses

specifically on Vibrios are bound together through commitments to and reliance on science, the scientific method and scientific practice.

Within the FDA itself science attempts to frame relations among experts and matters of fact and concern to do with general food safety policy, oyster safety policy and regulatory compliance. Science informs the dominant governmentality and mediates relations across these divisions through the technologies of control associated with it. The *2011 FDA Food Safety Modernization Act*, for example, shifted many of the responsibilities for food safety from government funded controls to individual food industry operators. While reframing the work of science and locking it more firmly into risk management regimes, this shift in the key framing of science-policy-action relations does not disturb the centrality of science in assembling the FDA as it acts within the ISSC or the wider ISSC assemblage itself. Science remains the body of knowledge and practice charged with bridging the world of policy, regulation, science and 'external' action and articulating the different action, structures, functions and processes involved in the work of the ISSC.

The ISSC is bound not just internally but also to external actors. Its food safety agenda is always developed in relation to the larger USA food safety arena. Each year, for example, people die from tetrodotoxin poisoning after eating puffer fish or become ill after sewage discharges pollute the marine environment. The ISSC must compete for attention in the policy fields of the FDA and wider public perceptions of priority food safety problems. As one interviewed federal regulator points out:

*To be fair to CFSAN (FDA) in the last decade there has been a steady incoming tide of new food safety problems which has taken attention away from shellfish. Food production has changed while FDA struggles to keep experts. There is uncertainty as to what we can accomplish due to budgets and lack of subject managers. (24/3/14).*

Sustaining long-term science capability in shellfish research, including oyster/vibriosis scientists, relies on the FDA's commitments to fund it and its own abilities to sustain public interest in shellfish food safety. Scientists again must work hard to hold the ISSC together in terms of its external relations as well as internally, and they again rely on established science practice to do so. Much depends not just on how they engage with the vibriosis as a pathogen and an object of their science, but on how they engage with oyster eater and in turn the oyster as a cultural actor.

The oyster is far more than a simple conveyance shifting the *Vibrio* bacteria from the marine environment into the human alimentary canal. Rather, the oyster, particularly the raw oyster, is a cultural actor that embodies a whole host of nature-cultural meanings and performs in meaningful ways in diverse socio-cultural settings. Jonathan, Swift an Irish essayist, novelist, & satirist (1667 – 1745), famously stated "*He was a bold man that first ate an oyster.*" Yet, it does not take much scratching to find many such bold actors consuming this small, sessile, snotty-looking animal. The oyster was introduced in Chapter 1, but to reiterate the raw oyster is desired because of its: taste; history and linkages to sexual prowess and bravery; desirability as a celebratory festive food; cultural power; and a fashion statement when sold in raw bars and upmarket restaurants. These attributes have enabled oysters to develop a personality or 'social face', perform culturally and do performative work (Appadurai, 2011). Indeed, they

are routinely personalized with individualized names such as Blue Point and Bluff Oysters and provenance stories link them to specific terroir (growing regions).

Science has offered oyster eaters solutions to render oysters safe, technologies such as pasteurization kill both the vibrios and the oyster itself. Some scientist and policy interviewees believe that there is an ethical responsibility to use such technologies to eliminate vibriosis, yet they tend to miss the importance of the oyster as a cultural as well as a biological actor:

*“We know how to control and kill Vibrios. Consumers know too. It is irresponsible not to keep trying to reduce the cases since we know how to. We have to keep trying to make the world a better place” (FedReg:3/4/14).*

To many oyster consumers eating a live and fresh oyster, untouched by human technology, is a deep pleasure. Counter to the views of the modernist morality of those who would have all oysters pasteurised or cooked, at least one FDA scientist personally considers this raw eating experience to be of greater cultural importance than the mandatory food safety treatments. As Latour recognises, the object (oyster or vibrio), has agency in its relations with others. This agency is wider than converting vibrios into illness. It is valued and produces value that sustains the assemblage (Pawson & Perkins, 2013). The raw oyster in relation with its eater, is a central actor in the wider vibriosis assemblage.

As my interview participants suggest, the biography of the oyster depends on complex but specific, social and political mechanisms that regulate taste, trade and desire. Relations that are intricately tied up with cultural values are more likely to be responsive to a politics of value than to manipulation by scientific knowledge, price or supply. Politics of value is one of fashion, of sumptuary law, and of taboo, which shape value, matters of concern, desire or the possibilities of consumption (Law, 1991; Latour, 1993, 1999). There is a moral economy standing behind any apparently objective economy; and one in which relations between humans and non-humans are mutually affective (Krarup & Blok, 2011).

In the background there is also a brute political economy of industry interests in maintaining this culture of oyster eating and the commodification of the values it represents. This is of course being backed by the local or state-wide politics of development concerned with investment and jobs. There is also an economy of food safety lobbying, which is at the same both moral and political. In 2009, for example, the FDA felt sufficient external pressures from the health-based food safety lobby to step outside the ISSC to formulate unilateral vibriosis oyster policies based on its own science. Yet, ultimately other pressures (by Congress) came to bear on the FDA and they were forced to drop their desired policy of PHP for summer-harvested Gulf Coast oysters. Science is always brought to bear in different ways in these struggles, but its objectivity and independence can be overwhelmed; in effect by the inherent flaws at its core identified by STS and SPS scholars alike (see Chapter 2). In such cases science is not simply competing with the agency of the Vibrio bacteria or alternative policy priorities in seeking to assemble the ISSC and mediate its relations with external assemblages (such as the FDA, the culture of oyster eating, or industry lobbies).

The research identifies that assemblages are a set of complex relationships and it is difficult to cleanly delineate them from other assemblages which are also perpetually acting. The ISSC is just one complex

assemblage, which is responsible for assembling US oyster food safety, which is in turn relating to other national and international food safety assemblages. The ISSC, a loose configuration of science-centred actors and practices, assembles science, the FDA, the oyster, the oyster industry, and oyster eater into a set of relations around food safety 'facts' and concerns. The FDA's principle aim is policy constructions of public health and food safety, oyster eaters pursue taste, desire and oyster culture, and scientists pursue science careers and knowledge. Using ANT's terminology food safety is the obligatory passage point of passage. So, is there a primary actor empowered to define the problem, the solution and the relevant actors involved? Despite the dominance of science as the primary governmental force at work, my participants confirm that the scientists are not in charge. Indeed, as Callon (1987) insists and my respondents recognise, science must enlist the of others (enrolment) and maintain the network (mobilization of allies) to secure itself within the assemblage (interessement). Neither is the FDA the primary actor, effectively directed by Congress to settle back into a cooperative role in the ISSC. Likewise, neither industry, oyster eater, nor oyster is in control; the first might at any time be regulated, the second regulated or poisoned and the latter cooked. The voter and Congress are always answerable to each other and in a material sense the ISSC. In short, not one of the significant actors acts in isolation, while the authority of the ISSC is subject to each of the other actors, in isolation or in relation.

It is difficult to capture and describe an assemblage in detail as it is never static or stable, instead constantly being reformed because culture, society and nature are constantly restructuring (Latour 1992, p. 81). Despite the organising and governmental work of science, the ISSC is continually in a state of 'becoming' and at the same time are acting with and upon other assemblages (Deleuze & Parnet, 2006). It comes into being through multiple internal and external relationships and this makes for tangled complexity. One way to sort this complexity to use the 'analytics of assemblage' by asking: how they are brought together; what practices hold them in that relation (what makes them stick together); and what effects they have or what agency is generated from the relations that are held in place (Henry & Roche, 2013). That is, what socio technical devices are at work and on what matters of concern.

### ***6.3 The Conference Agenda: Holding the ISSC Assemblage Together in a Dynamic Stability***

This account of the ISSC assemblage misses two key features: its dynamics and its socio-technical composition. As Chapter 5 suggests, the ISSC assemblage is neither static nor necessarily stable, despite the governmental work of science and scientists. Rather it is always in the process of being destabilised by the shifting relations among vibriosis, science, science funding, environmental change, the political and moral economies of the oyster, and a politics of personality among ISSC members. The ISSC is however, composed of more than these relations and the human and biological actors involved. It is also composed of socio-technical devices such as the conference agenda and ISSC procedural processes. Once an item arrives on the agenda of the annual conference it can take on an agency all of its own. For many years, for example, the conference focused on the Vv deaths linked to Gulf Coast oysters reaching a crescendo when the FDA tried to mandate PHP in certain situations and was ultimately blocked from doing so by Congress. This intervention by Congress has displaced Vv from the

centre of the agenda, and from 2014 the ISSC began to focus on the Vp illness outbreaks associated with oysters harvested from the northeast and northwest coasts.

A review of the historical ISSC minutes identifies topics rise and fall from the agenda depending on the status of relationships. The ISSC deals with all food safety matters and other infectious pathogens, such as salmonella, hepatitis A and norovirus compete for policy attention. Food processing and food labelling are also agenda items meaning the conference can become obsessively focused on items, such as, the regulated size and colour of the mandatory wording on oyster bag labels. Over time colourful personalities have commandeered the debating floor, filibustering to avoid conference decisions that would adversely impact their operations. Indeed, the ISSC agenda is constantly morphing and changing shape, reflecting the food safety concerns of the day.

The ISSC was assembled to manage food safety and interesse their members by using functions to lock them into place. These functions include the ISSC's standardised institutional procedures, the use of science to underpin the food safety regulations and the publication of the National Shellfish Sanitation Guide (NSSP) (agreed national standards). However, the research highlights that none of these functions are in themselves solid and stable. For example, the NSSP manual provides Vp and Vv epidemiological definitions which define the existence of a vibriosis problem ([www.issc.org](http://www.issc.org)). Yet the ISSC definitions and qualculation are often changed by the conference members, thus quickly redefining the problem. The metrics associated with the ISSC's own vibriosis food safety goals verify how nimbly a problem can be reframed by simple changes. While one conference might put science to work on specific projects and qualculation, such as the Vibrio risk calculator, another conference might decide that such information is unnecessary or disagree with the original qualculation process. The nature of the ISSC means that the debates about what and how the ISSC should measure will continue.

Much of the work performed in and through the ISSC is framed by a cooperative model which is used determine food safety public policy, but this does not mean 100% consensus. ISSC operates with many and shifting voices, both internally and in relation to the external world. Alongside scientists and federal and state regulators, other voices include those assembled to express individual views, notably those of industry and oyster eaters. The interview responses make it obvious that there are various views on what constitutes a public food safety issue, with further division on when the government should intervene and take away the rights of the individual. For example, California has chosen a different vibriosis food safety regime, while in 2009 the FDA attempted to deviate from the ISSC's co-operative assemblage by proposing a unilateral policy regarding vibriosis. Further, ISSC members from various regions have differing views on what constitutes a food safety problem and how to deal with Vp and Vv.

When the members of the ISSC make their food safety decisions they proclaim science is a key policy input, assembling a diverse range of scientific knowledge, and in a sense the biological and human actors whose behaviour this knowledge endeavours to interpret and confine. It legitimises itself as a 'science-based' provider of food safety solutions, following the norm for food safety governance agencies which use science to flatten space, stripping it of the politics of its production and its scalar variability. In all their official forums, the ISSC frames vibriosis using science's quantifiable, empirically produced knowledge about Vibrio bacteria and their environmental relationships. The ISSC first formally

focused on vibriosis with a 1988 science workshop, drawing together *Vibrio* experts from a range of science disciplines. This practice of science assemblage continues with the ISSC sponsoring further *Vibrio* science workshops (See Table 1, Section 5.2.3). These workshops are tasked with consolidating *Vibrio*'s science jigsaw, identifying knowledge gaps and recommending management options to the ISSC.

Yet this research makes it apparent that when ISSC members formally decide upon the oyster regulations they do not make their decisions primarily based on scientific information. The interview narratives provide a telling story; while the ISSC voting members may listen to science's narrative, with respect to regulations they often vote based on matters of social and economic concern. What point is there in mandating more science or science-based solutions when the food safety risks are clear and most actors (including eaters) are fully aware of them? Consumers still choose to eat raw oysters, and for many other actors as well, post-harvest technology is an unacceptable intervention. This culinary preference would be the case even if intervention in the population's dietary choice was considered appropriate over individual rights. On these questions, too, the ISSC is divided, and the conference actively uses science as a tool from which to hide from the contentious social issues and to pre-stabilise the divisions that would inevitable emerge.

ISSC members tend to recognise implicitly the relationality of the agency which they must deal with, but it is not unpacked to explore what it means in more fundamental terms. The relational agency at work then includes consumer desire and behaviour, 'industry perspective' (or better, its multiple and fractured forms of desire and practice), *vibrio* behaviour, policy as a practice, and the oyster itself. They all operate independently and in relation with human actors including scientists, corporate actors, food safety regulators and consumers. All are both potentially internal and external destabilisers. This relational agency both shapes and restricts the ISSC's efforts to bring science and policy into a more productive relationship to enhance food safety. To use the works of Featherstone (2011, p.141) the ISSC is a 'site of co-existence of different trajectories' where multiple heterogeneous elements are brought into a particular ordering frame with its own sets of rules and where new alliances and commitments may be formed (and broken) and new knowledge may be made.

## ***6.4 Reflections on Translation***

Vibriosis is not the first difficult food safety matter that the ISSC has had to deal with. It is worth reflecting on the differences between the typhoid situation of the 1900s and the contemporary vibriosis situation. The original USA oyster food safety assemblage came into being because of typhoid outbreaks caused by contaminated oysters. At that time typhoid and cholera were pathogens of major social concern because they caused large and contagious community outbreaks. Again, oysters were only the messenger delivering the pathogen; the real culprit was poor sanitation due to overcrowding, polluted drinking water supplies and inadequate sewage disposal. Such contagions affected everyone, rich or poor, so the public lobbied for waste water treatment systems and potable water supplies. The original oyster sanitation regulations reduced illness associated faecal pollution, no doubt assisted by engineered sanitation systems.

The differences between the vibriosis and typhoid assemblages can be portrayed by applying Callon's four 'translation' principles to impose conceptual order on this earlier food safety scene (Callon, 1987). These four principles aid in framing the problem (problematization), establishing the actor's roles (interessement), getting others involved (enrolment) and representing collectivities (mobilisation of allies).

1) *Problematization* – all parties accepted that typhoid contamination of oysters was problematic, and it was necessary to reduce microbial illness outbreaks and start interstate shellfish trade again. Currently there is no agreement on how definition of the vibriosis problem, especially for Vv.

2) *Interessement* – in the 1920s the primary actor (industry) was able to recruit others (scientists and government agencies) and have them act on the agreed problem. There is currently no significant, primary actor with sufficient force to enrol others into mandating technologies to deal with vibrios in oysters. There is evidence that "Science" as an actor is too weak to take the lead role, enabling and mobilizing other ISSC actors and external allies.

3) *Enrolment* – during typhoid contagions scientists, the industry and the regulatory agencies agreed to deal with the problem. Vibrios do not cause contagious epidemics and this may be just one reason there is no groundswell to change the current USA vibriosis shellfish food safety status.

4) *Mobilisation of allies* – the typhoid event provoked adequate community representation to resolve the problem. Studying the vibriosis assemblage presents competing 'things'. First food safety is a 'thing' of primary interest to the ISSC members. Yet even within this 'thing' there is competition as to what food safety means and to whom it should apply. Second is the 'thing' that society has for consuming raw oysters. It is the oyster's sociability with all its cultural and epicurean facets, that ensures continued access to raw oysters is a consumer matter of concern.

By considering the oyster associated typhoid outbreaks there is evidence that the four translation steps were essential (though the four steps did not need to be taken in numerical order and can even occur simultaneously). The following four sections reconsiders these translation steps and how they might be used to impose a conceptual order on the complex and situated process of vibriosis, while pondering to what would be required for different outcome to the current situation.

#### 6.4.1 Problematization: Houston, do we have a Problem?

When collective groups share and act upon a desire for stability and predictability, they develop a common worldview that scholars have deemed 'solutionism'. This research confirms that such collectivism does not exist on the vibriosis food safety issues. Further Callon states unless a shared 'problem' is agreed upon there will be little change. This research identifies that there is lack of consensus within and outside of the ISSC as to whether vibriosis is a problem. Different actors frame vibriosis in different ways, therefore the first important step of translation has not been achieved.

Aside from the ever changing ISSC definitions, which currently legally define the USA Vibrio problem, there is lack of consensus amongst the ISSC stakeholders interviewed as what the problem is. First there is lack of agreement as to the boundaries and significance of the vibriosis food safety problem, especially for *Vibrio vulnificus*. Callon (1987) would say the lack of consensus about the problem definition is itself the problem because this is the first key to translating the situation. Unless all the actors converge on and generate relational agency on a certain topic, purpose or question it will be impossible to form an effective assemblage to deal with the defined problem.

Secondly, there is opinion diversity on how to deal with the problem. This diversity is further complicated because many consider Vp and Vv should be dealt with differently. Thirdly, there is lack of agreement on acceptable solutions, which means that when ultimately some perceive the problem has been resolved others will disagree. For example, only 4% define success as the full elimination of vibriosis, while a wide range of other measures of success are tabled, including simply educating consumers with no further risk management actions (12%). Unless the conference reaches consensus on how to frame the problem the food safety actions will not change.

#### 6.4.2 Interesement: Science a Compromised Lead Actor

As the ISSC's science provider, the FDA scientists are challenged to lead the vibriosis actors by using their technical solutions. If the FDA scientists want ISSC to mandate their technical solutions, they must persuade the conference of a common issue, including the acceptance that both Vp and Vv are food safety problems that must be tackled. When undertaking actions to induce the other actors to follow the lead then anything goes, whether it be force, seduction or solicitation (Callon, 1986). In the battle to co-opt fellow ISSC members the Vibrio scientists rely on their mastery of calculations in biology and marine science, microbiology, epidemiology, environmental science and modelling to make the situation visible to others.

STS researchers have also identified that predictive models involving environmental science are especially problematic when translating a problem. (Dankert (2010) defines 'translation' as the work necessary to displace and transform a network). This is because models involve degrees of complexity which excite scientists, but others may fail to understand. Michael Carolan's 2004 research identifies that people relate to things that they can easily see. For example, when people can see litter or oils spills in the marine environment they quickly relate to that issue. Once the evidence is harder to visualise, for example, the need for scientific instruments to detect dioxin levels in shellfish, there is less trust. Further, when the problem is complex linked with multiple, complex and messy relationships, such as global warming, trust diminishes further. Carolan identified a consistent trend; trust and belief are diminished the harder it is to see a problem. Enrolment therefore represents a significant challenge.

#### 6.4.3 Enrolment

To describe enrolment is to describe the multilateral negotiations, trials of strength, strategies and tricks that accompany interesement and allow it to succeed (Bijker & Law, 1992; Dankert, 2010). This research has identified multiple areas where such negotiations are needed before USA society would

agree to mandatory oyster pasteurization. These areas include: trust and belief by the ISSC voters; social mores about eating raw oysters; oyster industry economics; control of the ever-changing evolutionary and environmental factors that cause *Vibrio* bacteria's human pathogenicity; and social agreement as to what constitutes a food safety problem.

Many of the interviewees consider scientists (and the process of science) focus on the scientifically measurable "effects" without considering the emotional and ethical "affects" on all concerned, an opinion expressed clearly by those interviewed. Given the consistency of this message, it seemed unethical to wait until the end of this research to share this information. While maintaining the individual's confidentiality this general opinion was provided to Dr Angelo DePaola, FDA's Senior Seafood Scientist. He actively listened and decided to change his interactive approach with ISSC stakeholders. As a result, in 2014 DePaola undertook field trips to the oyster producing regions with the specific aim of interacting within the physical world of shellfish harvesters and state regulators. Such interactions included expeditions on harvesting vessels, listening to criticism and to alternate practical policy initiatives posed by others. My research involved observing DePaola's interaction at meetings with regulators and the shellfish industry, including a particularly vociferous Connecticut meeting. In Connecticut, he actively listened to the harsh criticism of the FDA; answered questions, using his answers to translate scientific concepts to the harvesters; acknowledged deficiencies with FDA's 2013 policy that had suggested 'one temperature policy would fit all'. Pivotal to the DePaola's new communication strategy was an effort to provide the scientific evidence about of temperature on *Vibrio* growth, while at the same time showing empathy to the social "affects" of the proposed temperature policies. Following several of these field meetings industry themselves made changes to their harvesting systems. For example, in 2015 the main Connecticut industry naysayer, designed and engineered their own barge cooling system for use when dredge harvesting oysters.

However, it would be wrong to suggest that such changes will enrol the wider constituencies. Science is competing, or at least failing to account for the "colourful affects" of the raw oyster. The interviews highlight that the raw oyster is exciting, eliciting passion and inciting increased consumption with its promise to emotionally fulfil consumers. The power of the raw oyster is such that even those considered to have a high risk of dying from *Vv* are prepared to take the consumption gamble. Published papers have already documented this so-called risk-taking behaviour (Klontz, *et al.*, 1991 & 1995). The interview with a state regulator put this decision to take a risk into perspective: "*My wife has had two kidney transplants, but she still eats raw oysters. You can't regulate 'stupidity'*". The point here, of course, is not that the consumer is stupid but while comprehending the potential lethal health hazards she still considers eating raw oysters adds pleasure and value to her life.

Currently, within the *Vibrio* actor network the face of the raw oyster remains the dominant force and it will require something significant for this to change. In conclusion, the "face of the FDA scientist" is currently coming second to the "face of the raw oyster".

#### 6.4.4 Mobilizing Allies

The formal co-operative and democratic modus-operandi of the ISSC means that the scientists, or any other stakeholder, cannot autocratically demand actions. The majority votes rules when deciding on oyster food safety policies. The number of voting members varies between 30 – 39 members, who decide on behalf of the total US population of approximately 320 million (USA Census Bureau), of which it is considered 50 million are likely to eat raw oysters. To date science has been unable to persuade (enrol) enough ISSC members to mandate science's offered technologies for reducing or eliminating Vp and Vv in oysters.

Outside of the ISSC assemblage are all the other human and non-human actors that compete with the ISSC science/policy process. This includes the USA population and their social patterns, along with the wider biogeographical world that impacts Vibrios and oysters. As recognised assemblages are never fully closed. Messages continue to be communicated into the ISSC by other actors and there is little evidence to suggest that this wider group is dissatisfied with the current ISSC food safety policies. Up until 2009 the CSPI consumer lobby group actively participated in the ISSC vibriosis debates. The CSPI worked to convince and enrol the FDA to take unilateral action and regulate to manage the food safety risks linked to Vv, though it should be noted that they have never lobbied for Vp food safety steps. However, once the decision was made to pass over the FDA's attempt to mandate the post-harvest treatment of Gulf Coast summer harvested oysters, the CSPI reduced their participation in the conference and there was one less vocal advocate mobilising the allies to mandate stiffer Vibrio controls.

### **6.5 What Does the Reframe Identify?**

This chapter set out to explore how science is mobilized to confront vibriosis and to consider its effectiveness. The style of analysis introduced in this chapter dramatically disturbs traditional assumptions, calling into question the dominant divides between subjects and objects and ideality and materiality, and in turn the value of the scientific knowledge that is then produced. The approach highlights a new set of actors in the USA vibriosis story. As predicted the actors include various humans and non-humans; yet the complexity and diversity of the various actors was not forecast. The ISSC asks science (with its supposedly neutral, repeatable scientific assays), to frame food safety using biochemical and biophysical metrics, which will in turn provide food safety solutions. However, to date little or no regard has been given to the fact that science is also social; a relational and political process. Science is not just a simple black box of methods, but is itself is constantly forming relationships with governments, money and people. Science is just one actor or configuration of relational agency across disciplines, institutions, material relations, compromised relations with others and so on. As such a configuration it must compete with all the others, including the biophysical environment, ISSC protocols, industry operation and public policy processes. Perhaps, science's toughest contestant in the struggle over vibriosis agency is the 'social face' of the raw oyster – an intangible concept but a very real presence and the main cause of vibriosis in the USA.

Multiple actors were identified, each doing their own work, and ultimately impacting the other vibriosis actors and assemblages. Exploring these various assemblages offers a new way of understanding the spatial and temporal vibriosis relationships, while resulting in new insights. What emerges from this research is confirmation that the vibriosis story is a complex hybrid of biophysical (natural) and social actors with all the inherent attributes of a 'wicked problem' (Rittel & Webber, 1973). The vibriosis problem originates in the biophysical (natural) environment, with *Vibrio* bacteria naturally occurring in the marine ecosystem. The biophysical problem then extends into the social realm when oysters containing *Vibrios* are consumed and cause human illness. Further, nothing in the vibriosis example is stable; the biophysical world is constantly changing due to environmental and evolutionary forces while the many social factors, for example, economics, political ideologies, food safety regimes and scientific knowledge are themselves continuously morphing. Likely the most stable actor is the human raw oyster eater, a USA actor that has remained relatively unchanged spatially and temporally given the country's traditional culinary practice.

At the outset of this research the following questions were posed:

- 1) What role does science play in vibriosis food safety and what can we plausibly expect of it?
- 2) Can science provide the solution to the vibriosis associated with oyster eating?

As a food safety regulator these questions were really based on a personal quest to find out why "Why science had not yet solved vibriosis?" This judgemental question was framed because of my personal belief that institutional science, with all it encompasses (scientific method, objective measurements and peer review processes), is a powerful food safety tool. Traditionally we have expected science to find solutions by measuring and gathering the 'matters of fact'. However, this research identifies this is too great an expectation to place on science. Science is a powerful tool, but like any crafting tool the results depend on: the user, what they apply it to, how they use the tool and what they want the end-product to look like. Even then the final work results may look different to that envisioned by the crafter. In other words, the 'matters of fact' that science gathers depend very much on how and who applies the tool.

Frequently it is found that science is simply unable to provide all the matters of fact because of information gaps, especially when biophysical (natural) factors are involved. But more than that, our complex world requires that we not only consider the food safety facts: other matters of fact will compete, including economic and public health ideologies. It is wrong to believe that science can stabilize the ISSC food safety assemblage, or any other food safety assemblage, and solve any food safety problem. Technical answers do not always provide the ultimate solution because any food safety assemblage contains multiple social and moral actors who do not only relate on a technical basis. Moreover, all 'matters of fact' must compete with societies 'matters of concern', which arrive with their own powerful agency.

The 'matters of fact and concern' assemblages will vary from country to country, region to region and even between various food safety situations. This means that it is impossible for science to be deemed as the international arbiter of food safety – in designating it as such we will ultimately be disappointed. The following chapter further considers further the role of food safety science and what we can rightly expect of it, not only for vibriosis, but for all food safety matters.

## CHAPTER 7: RESEARCH CONCLUSIONS AND CONTRIBUTIONS

Vibriosis, specifically that caused by *Vibrio parahaemolyticus* and *Vibrio vulnificus*, is a microbial foodborne illness of international significance. Aside from the illness burden costs vibriosis is causing international seafood trading restrictions. As a result, food safety regulators and the seafood industry are challenged to deal with the issues. As with all other food safety matters, national and international food safety regulatory authorities claim science is used to underpin their food safety decisions. This thesis has investigated the deployment of science within the context of persistent oyster-borne vibriosis within the USA. It did this by studying the Interstate Shellfish Sanitation Conference (ISSC) and its wider relationships, exploring the role of science to determine if science should be expected to provide the vibriosis food safety solution. It found that there are multiple complex relationships.

ANT concepts were used to expose and explain these multiple relationships and the research offered up “specific surprising, so far unspoken events and situations, visible, audible, sensible.” (Mol, 2010; p.255). In using ANT to explore how the ISSC members use science and food safety policy to deal with vibriosis much more is unveiled. It becomes apparent that many of the wider assumptions about science, as expounded by national and international food safety agencies, are not what they seem. The findings in this research identify that we need to rethink how science can and should be used within the food safety paradigm.

The research identifies specific unknown qualities about the US vibriosis situation, including the moral dilemmas linked to the disease which have not been formally debated and resolved. Further it makes another four contributions to the literature and to the food safety policy realm. First, it provides the first study of the ISSC as a unique assemblage. Second it provides the first account of the ISSC and food safety as seen through the opinions of its own members. Third, it suggests that the food safety science most frequently posed to science, namely “Why has science not solved the problem?”, is the wrong question. Finally, through each of these points there is a contribution to food safety policy. In this chapter I tease out these contributions and a new way of dealing with food safety matters.

### **7.1 The ISSC as Assemblage**

Throughout the world the oyster is now one of the most ‘scientized, metrologized, qualculated and managed’ of food products. Mainstream accounts of food safety regimes present themselves as a science-policy arrangement at war with bacteria, unsafe practices and human ignorance. This research uses Actor-Network theory (ANT) to examine the ISSC assemblage, which results in a messier picture of food safety.

The decision to use the ISSC as an assemblage and the basis of the methodology for this thesis is a novel concept. The ISSC’s historical activities are well documented and the conference membership is spread both geographically and professionally. The ISSC group comprises multiple actors (both human

and non-human) and as an entity it relates to other regional, national and international actors. In summary, the ISSC brings together all the actors and relational assemblages in a defined package, thereby providing the opportunity for both a longitudinal and contemporary analysis of the USA's oyster food safety science-policy cycle.

This research benefited from privileged access to the ISSC and an opportunity to converse and interact with all its professional stakeholder groups, including all the scientists and 100% of voting members who determine the oyster food safety regulations. These conversations provided a basis for analysing the conference as an assemblage of actors, interests, protocols, regulations and science held together to try and stabilise food safety. Interpreting the ISSC as an assemblage highlights the work carried out to hold it together and regulate its relations with its constituent outsides – the stakeholder interests represented by the members of the ISSC (government, businesses, science establishments, eaters of oysters, states and so on). It also emphasises that the vibrios and oysters themselves, the food safety metrics constructed and reviewed by parties to the ISSC, the conference agenda and protocols, the venues, break out groups and lunches and so on are all part of this assemblage. This assemblage is inherently unstable but is held together by its constituent elements in relation to each other and across its boundaries to its outsides (oyster eaters, investors, politicians, climate change and so on). This insight allows us to capture the ISSC as a place-based instantiation of the 'complex and always situated processes that continuously mix together a variety of heterogeneous social and natural entities.' (Callon, 1986). At the core of this insight lie notions of multiplicity of agents, relational agency, co-constitutiveness, emergence, and the work required to hold together all the actors (human and non-human).

## ***7.2 A Multiple and Complex ISSC***

This research confirms that the ISSC is much more than its human membership. Instead there are multiple actors and multiple assemblages relating with the ISSC. The vibriosis case highlights that multiple actors are always involved in food safety situations including important non-human actors such as oysters, bacteria, environmental and evolutionary pressures, conference protocols and industry practices to name but a few.

Further the conference acts not only in relation to food safety matters, but also with other societal matters of concern and from these varying matters of relational agency emerge. Indeed, the ISSC might be considered an 'obligatory point in passage' (OPP), the funnel where the interests of actors come together to deal with food safety matters, including vibriosis. By focussing on the ISSC it becomes obvious that the conference acts as an OPP by mediating the interactions between the human and non-human actors in its network. By breaking open and exposing the complexity of the ISSC assemblage it becomes evident that there are crucial points in translation with all the other relational assemblages. There are multiple assemblages which relate to the ISSC assemblage, of which the science assemblage is only one. All these assemblages compete within and outside of the ISSC for the agency (power) associated with their own OPPs. On occasions such interrelationships aid the ISSC but on other

occasions provide hurdles or impasses to ISSC's activities. Examples of such competing assemblages include economic, political, cultural, social and biophysical assemblages.

Food safety is a topic of primary interest to the ISSC members. Yet this research finds that there are multiple ways of potentially framing a food safety problem: ethically, economically, epidemiologically, regionally and socially. Additionally, various ISSC members have different descriptors; a natural, economic, ethical and political problem. There is no consensus in the ISSC as to whether vibriosis is a food safety problem of significance. Further there is contentious debate about how to frame Vv; some consider it a food safety matter, others consider it a personal health problem. Nor is there agreement on acceptable solutions for either Vv or Vp, which means that, ultimately, when some perceive the problem has been resolved others will not agree. The ISSC continues to struggle to manage to name 'the problem', which Judt argues is a fundamental step to solving it (Judt, 2010). Further, the FDA scientists have not been able to interest (interesse), enrol and mobilize the necessary actors to persuade the ISSC to mandate scientific solutions to eliminate vibriosis.

Vibriosis, particularly Vv, polarises ISSC members into factions with differing social values. There is a viewpoint that people who choose to eat raw oysters, thereby exposing themselves to vibriosis or other oyster borne pathogens, are by nature 'risk takers'. The interviews provide evidence of subjective moral judgements about such risk-taking behaviour, intensified when the oyster eater is already suffering a pre-disposing disease, for example, liver damage caused by excess alcohol consumption. The interviews highlight an underbelly of undebated moral issues, for example, who is worthy of food safety policies, along with the rights of society versus the individual's right to choose. Many consider that the rights of the individual to make their own dietary choices is paramount, while others believe food safety regulations should be implemented to remove any risk once technology becomes available.

The various ways of measuring Vibrio bacteria, the incidence of vibriosis, the illness risk per serving of raw oysters and the desirable level of societal food safety protection, are all hotly debated measurements – by scientists as well as other ISSC members. In all, 50% of those interviewed have significant doubts about questions of metrology. These debates centre on what is measured, how it is measured, who does the measuring, the veracity of the various tallies, and that such measurements are neither fair nor objective. It becomes evident that the metrology used by the ISSC is moulded by the political and ethical ideology of the day. At the same time, improved diagnostic methods, changing metrological definitions and public attention suggest, possibly inaccurately, that vibriosis is an escalating matter of concern.

This research provides a novel commentary on how USA oyster food safety works in practice. The research identifies that the ISSC does not actually have national autonomy. Instead there are multiple external actors and assemblages who exert powerful agency on the ISSC, including. economic, political factors.

## **7.3 Expecting Too Much of Science**

Societies, particularly those involved in food safety, have come to expect much of science - the institution which uses the scientific method to find and reveal facts. Indeed, science has proved its food safety worth by identifying the causes of foodborne illness, providing a better understanding of food safety and enabling safer ways to produce and preserve food.

Over time the expectations of science have increased. Figure 3 produces a model of the vibriosis problem that locates science and the FDA scientist as the great saviour, if only all the other actors would perform as they should. This is not an idle claim. Chapter 5 confirms that scientists within the ISSC are confident that they have built a knowledge base of matters of fact that have allow them to agree protocols to tackle all oyster food safety issues - irrespective of whether the cause originates from human or natural derived sources of contamination. They have an agreed set of post-harvest technologies that will ensure oyster eaters can be provided with safe oysters. These matters of fact have been presented to the ISSC forum as objective facts in the form of figures, diagrams, epidemiology statistics, death curves and other models, and graphs. These metrics are configured into hazard identification, risk assessment measurements and risk calculator models. Science appears and performs as a set of numbers, calculations, manipulations, scenario models and assessments of risk that are presented as 'matters of fact'. However, analysis of the information in Chapters 5 and 6 identifies that science is not the central actor.

The 'solutionists' believe science has the capacity to solve all problems, not only those caused by humans but also those caused by the wider biophysical world. Many individual food safety investigators and epidemiologists consider that the answer to all foodborne illness will be found once scientists accurately portray the facts linking the human, the disease and the environment. But more than this, national and international food safety agencies such as FAO and WHO, and the world's leading trade organization the WTO have made science a political actor because they deem it to be apolitical. These authoritative organisations hold science up as an unbiased authority, founded in objective metrology, that can be used as the arbiter to neutralise the food safety and trading world. National and international food safety organisations expect that science will provide the holy grail - a set of effective global food safety standards. In their quest to find this global solution these organisations have established the risk analysis food safety regime, splicing science and functionally separating it from other social food safety activities, so that science retains its objectivity and is untainted by the politics of risk management.

Yet this thesis suggests that such grand expectations of science are flawed. These flaws play out in numerous ways through the work of the ISSC. The analysis of Chapters 5 and 6 suggest that expectations of science need to be reworked in at least four significant realms.

### **7.3.1 Nature-Culture and the Work of Science**

The development of science and the scientific method came with the early promise that nature could be conquered and controlled by humans. Vibriosis, provides just one example that this is not the case for

food safety. Vibriosis originates in the biophysical (natural) environment, with *Vibrio* bacteria naturally occurring in the marine ecosystem and unrelated to human pollution sources.

Science still does not fully understand and cannot measure the relationship between *Vibrios* and the natural marine environment. This means science remains unable to accurately define the environmental assemblage sufficient to command and control *Vibrios* in seawater and oysters. Further, science cannot yet predict when or where vibriosis will be pathogenic to humans meaning it remains impossible to establish preventative regulatory programmes based on environmental actors. This status is complicated further by the ever changing environmental and evolutionary factors that mean an all-knowing relationship is likely to be always elusive. As Latour has describes “Natural objects are naturally recalcitrant; the last thing that one scientist will say about them is that they are fully masterable. On the contrary, they always resist and make a shamble of our pretensions to control.” (Latour, 2000, p.116)

Most interviewees refer to *Vibrios* as a ‘natural’ problem, suggesting that somehow it is one outside of human reach and control and that somehow *Vibrios* are more difficult to control than other food safety pathogens. This framing is itself performative as it guides not just appropriate policy responses but attracts resourcing to environmental science and shapes public response. This prominent use of language, describing a biophysical problem as somehow ‘other’ is likely to have an impact on the policy response (Tannenbaum, 1963; Dunbar, 1995; Cockerill, *et al.*, 2003; Cockerill, *et al.*, 2017). Other researchers have identified that metaphorical frames can play an important role in reasoning and steers people’s thinking on what needs to be done in ‘natural’ situations (Thibodeau & Boroditsky, 2013). Labelling *vibrios* a ‘natural problem’ highlights the tension between biophysical processes and their effect on humans, which societies want to predict, control and/or contain. As with flooding (Cockerill, *et al.*, 2017), labelling a *vibrios* a ‘natural problem’ presupposes a bio-technological solution (Thibodeau & Boroditsky, 2013). Yet in the words of Latour (1992, p.281) “nature, society and culture and constructed simultaneously and are in a perpetual state of becoming. It is incorrect to think that social causes can explain nature, or that natural science can explain the construction of culture, as all are in a perpetual state of inter-related becoming.”

### 7.3.2 Beyond Solutionism

There are multiple reasons why science cannot yet predict and destroy pathogenic *Vibrios* in their natural marine environment. However, even though science does not yet have the knowledge to control vibriosis in their natural environment it has identified options to mitigate, even eliminate, *Vibrio* bacteria once oysters are harvested and within a human controlled environment. Scientists have determined it is possible to control *Vibrio* bacterial growth under refrigerated conditions. Alternatively, science has offered ISSC a suite of validated processes capable of destroying the *Vibrio*'s viability. By using prescriptive scientific food technologies such as high pressure, cryogenic freezing or irradiation eliminating vibriosis amongst raw oyster eaters is a real possibility. Indeed, there is food safety precedence where science and public policy have successfully solved persistent food safety problems by mandating science-based food technologies, for example, milk pasteurisation eliminating the chronic incidence of tuberculosis. Yet, these human technologies have not been accepted as appropriate to deal with the ‘naturally’ occurring *Vibrio* organisms in oysters.

The irony is that the 'scientised' oyster is rarely socially acceptable. Many oyster eaters have rejected such post-harvest technologies, instead preferring that nature remain unconquered because, in their minds, the raw oyster has valuable natural attributes they wish to retain. To many raw oyster eaters – eating an unadulterated raw oyster is an important part of the eating experience. 'Matters of fact' diverge from 'matters of concern' - some see the importance of mandating science food technologies, while oyster eaters consider the natural, unadulterated oyster is more important than a safe one. The 'face of the oyster' is in this sense a more powerful actor than the scientist – people are prepared to eat raw oysters even when there exists a food safety health risk and, in some cases, a lethal risk. Even when science has formulated a solution, this may not be an acceptable.

A theme underpinning solutionist science is the principle that individuals will maintain their bodies in ways that produces least health risk (Kahneman, 2011). Yet this is not the case for oyster eaters who continue to eat their oysters raw. This situation defies one of solutionism's principles, that is, if science provides the matters of fact about food safety then people will change their behaviour (Cockerill, *et al.*, 2017). As stated in *Everything is Obvious; how common sense fails* (Watts, 2011):

Common sense is 'common' only to the extent that two people share sufficiently similar social and cultural experiences. Common sense, in other words, depends on what sociologist Harry Collins calls collective tacit knowledge, acquired by participating in society itself. But it also means even among humans, what seems reasonable to one might seem curious, bizarre, or even repugnant to another.

### 7.3.3 Beyond Universalism

International food safety agencies and the World Trade Organization assume that the best way to flatten and homogenise global market access is to have one common international food safety standard. This research identifies factors that are likely to undermine such a goal and questions its validity. In short, not all food safety assemblages will be the same, and standards will operate differently in different assemblages to different effect. At the same time, however, the notion of assemblage and the ANT concepts of problematization, interessement, enrolment and mobilizing allies are all translatable into other settings and the insights of emergence, multiplicity, relational agency and stabilisation work are all applicable in any food safety configuration.

The ISSC has some unique features when compared with other national food safety agencies. For a start, unlike most countries operating a food safety programme the USA's national food safety authority (FDA) is not responsible for shellfish food safety. Instead the national food safety role was politically bestowed upon ISSC, a group of interested stakeholders who unilaterally decide when and how oyster eaters (and other shellfish consumers) are protected. However, this unique feature is not of significance when comparisons are made between national food safety agencies dealing with vibriosis. On further exploring the regional divisions within the USA and those of the international scene it becomes obvious that all societies have the same diverse set of human and non-human actors depicted in Figure 6. These actors can be aggregated into four principle categories: the biophysical environment, oyster industry practices, social mores and the governmentality ideology of the day. Every society, no matter whether

it is regional or national, contains these four categories, confirming our commonalities. Yet these groupings fold differently in every society because the matters of fact and the matters of concern are always different. Not only that, each of these categories and their associated actors are constantly in a state of transition.

Societies and their governments define their normal matters of fact and concern based on the values that come from stakeholders. Therefore, there is always a moral basis for society's food safety decisions. In Australia, Canada, the European Union, Japan and New Zealand the vibriosis problem is entangled in the context of specific governance, industry, and cultural features, and consequently there are different food safety assemblages.

As a federation Australia has six shellfish producing states. Each state operates their own shellfish sanitation programme while adhering to national food safety principles. Currently neither the national model or the state programmes require specific regulatory attention be given to *Vibrio* food safety risks. Until recently there were few reported cases of *Vp* or *Vv* and these cases were not specifically linked to eating raw oysters. However, in January 2016 there was a *Vp* outbreak of seven confirmed cases and a further 3 probable cases. A trace-back investigation identified a common source of oysters harvested from St Helens region, Tasmania. At the time of the St Helen's harvest there were unusually warm seawater temperatures with 4.5°C above average. Given the recent Tasmanian outbreak the Australian state and federal food safety authorities are now pondering how best to manage the vibriosis food safety risk.

Commercial shellfish harvesting occurs on both the Canadian Atlantic and Pacific Coasts. The two coasts have different ecological and oyster industry profiles, with the Atlantic Coast only linked to sporadic, occasional *Vp* cases. Prior to In 1997 there was a low incidence of *Vp* associated with British Columbia (Pacific coast) oysters. In 1997 there was an illness outbreak of 111 reported cases linked to oysters harvested from British Columbia and Washington State, USA. In the summer of 2015, Canada experienced its largest reported *Vp* outbreak with 82 cases linked to raw oyster exposure harvested from growing areas in British Columbia. During 2015 the spring and summer seawater temperature was on average 2°C higher than usual due to a strong El Nino event. To deal with these emerging vibriosis food safety issues Canada has drawn on its recognised expertise in relating science with public policy, using a multi-jurisdictional stakeholder approach that is actively engaging federal, provincial, regional authorities in partnership with the shellfish industry. A series of meetings and industry workshops led to the publication of a microbiological guideline for industry to use, which is credited as having prevented further *Vp* outbreaks to date.

The European Union is made up of multiple states with the European Food Safety Authority using science-based information to govern and formulate food safety policies ([www.efsa.eu](http://www.efsa.eu)). In 2001 the European Union commissioned a report to review the need for specific Vibriosis food safety regulations. This report concluded that the currently available epidemiological data, which identifies a low vibriosis burden, does not support setting specific standards or microbiological criteria for pathogenic *Vv* or *Vp* in seafood. To date the EFSA has maintained this stance, despite evidence of increasing *Vp* illness

linked with shellfish harvested from the Mediterranean and the Baltic Sea (Baker-Austin, 2014) and the significant vibriosis in Europe more generally (Lingren *et al.* 2012, *Science*).

The Japanese population consume a high amount of seafood in their everyday diet (Hara-Kudo, Kumai, 2014) and *Vibrio parahaemolyticus* is a significant cause of foodborne infections. Oysters are not the predominant agent; instead caused by other national seafood dishes (Kumagai, 2000). A Vp epidemic in 1997 led the Japanese Ministry of Health, Labour and Welfare to institute regulations for all seafood. These regulations require the use of disinfected or artificial seawater for processing seafood; temperature controls during seafood distribution and storage; ready-to-eat boiled seafood must comply with Vp microbe standards; and education of restaurants and consumers about the need for refrigeration.

In principle, New Zealand follows the same regulatory shellfish controls as the USA. To date there is no record of any Vp or Vv illness associated with eating seafood commercially harvested in New Zealand waters (Lake *et al.*, 2003; Thornton, *et al.*, 2002; Kirs, 2011). Despite the lack of illness in 2014 the Ministry of Primary Industries decided to formulate Vv food safety governance for oysters. When asked for the rationale underpinning this regulatory decision, MPI responded that as an exporting nation the government wanted to maintain a global image of taking a precautionary food safety approach - even when any risk was only a potential. To date MPI have not activated any regulatory response for Vp although MPI maintains environmental prevalence surveys.

Appendix IV sets out these defining features which set these national assemblages apart. Notably, at a global scale Codex concludes that it cannot set a global standard.

### 7.3.4 Beyond Political Neutrality

Science is perceived to be objective mainly because it banishes all relations other than those associated with their measurements. Science itself, through STS studies and verified with this research, understands that metrics are in fact malleable and are never apolitical. Instead they are always political and ethical. Science alone is insufficient to deal with food safety matters and is always relational. The agency or power of any actor or assemblage, including science, always comes from its relations with others such as individual actors (human or non-human) or organizations and their associated form and processes. In this research it is possible to identify the many relationships that prevent science from convincing and enrolling others. Science is compromised in many ways, from the inherent flaws in its oracular stance to specific failings in its practices. It is not all-seeing, objective and morally virtuous or particularly adept at translation or interessement. Science may not be as objective as we think and is likely more malleable than some would like to believe.

The contest within the ISSC over metrology highlights that successful science does not just mean a relationship with *Vibrio* isolations on laboratory petri dishes or graphically depicted in reports. At the same time science and scientific knowledge becomes relational only in relation to others; to be effective it must act in relation with other important actors. The information gathered during this thesis indicates that far from being detached, the science assemblage has many complex attachments to the wider vibriosis assemblage. Latour claims that science is a network with resources concentrated in a relatively

few places while that all factors that make science are agential and has much to do with contingencies of politics, simultaneously involving socio-political, scientific and material characters (Latour, 1988).

But this does not mean that the ISSC scientists have performed inadequately. In tabling their food safety matters of fact to the ISSC and the wider USA public science has undertaken its technical role. However, in the words of Law (1987, p. 113) the technical should not be privileged over the social and natural actors – none of these facts can exist independently. The science food safety assemblage, complete with its technological capacity to deal with vibriosis, is just one operating amongst multiple other powerful assemblages.

In summary, vibriosis associated with raw oyster eating can be defined as a ‘wicked problem’ – one that defies simple logic or long-term solutions; wicked because it is embedded in complex systems and can be defined in multiple ways and at the core of the matter is the relationship to human values (Rittel & Webber, 1973). While we can expect science to table its offerings in any food safety situation, we cannot plausibly expect it to unilaterally solve any problem. Often science simply does not have the capacity to do so. This deficiency might be due to lack of knowledge or alternatively because of unstable natural or social assemblages that are constantly transforming outside the reach of science and its agent, the scientist.

By using STS and ANT principles to explore vibriosis it becomes apparent that we cannot expect science to be the unbiased solver and unilateral rescuer for any food safety matter. Science does play an important part in the USA vibriosis assemblage, but it becomes clear when unpacking the issues that science is not capable of always finding solutions or dominating nature. Science does play an important part in the USA vibriosis assemblage, competing with all the others, including the biophysical environment, ISSC protocols, industry operation and public policy processes. Yet science cannot be singular or an independent problem solver. Indeed, in some situations and different dimensions of science (measures, hypothesis, political interests, personalities, accidents, etc), science may even cause new food safety problems or exacerbate one that is already present. The scientific development of the triploid oyster is one such example; while the aim was to beat nature, the methods used only enhance a human health problem (Nell, 2002). By inventing an oyster that cheats nature of the spawning cycle, this in turn means more raw oysters are eaten during the season when they are likely contaminated with pathogenic vibrios, thus escalating the food safety risks.

Science is not even the primary actor or assemblage in the USA vibriosis story. Even when science offers tangible and significant food safety options, such as the elimination of vibriosis, it does so in relation to social assemblages that shape science itself, as well as being used to block the acceptance and implementation of such offerings. Instead there are multiple assemblages that exert powerful agency on the ISSC, with the most powerful being the raw oyster.

Science is only one assemblage operating and competing in a complex world of multiple human and non-human assemblages, therefore science must work with other assemblages if change is to occur. The FDA scientists is only one professional group employed by the administration. There are other professional silos within the FDA, operating both with and externally to the ISSC. Such professionals include regulatory compliance officers, public policy analysts and those dealing with the political

appointees in Congress. This research identifies that due to conflicting social drivers these other professional groups can vote against the advice of their fellow scientists at the ISSC forum. If scientists wish to convince fellow ISSC members of the need for scientific solutions, they must first “sell” their story. Yet in pedalling their wares scientists seem to somehow tarnish one of science’s primary attributes, namely objectivity; by stepping into the ISSC arena to fight its quarter science no longer stands alone, emotionally aloof, simply tabling their supposedly objective metrics for others to make the subjective decisions.

Food safety science is more complex than simply measuring the three sides of the epidemiological triangle and science alone is not the objective, apolitical institution that FAO, WHO and WTO hold it up to be. The ‘matters of fact and concern’ assemblages vary from country to country, region to region and even between various food safety situations. This means that it is impossible for science to be deemed as the international arbiter of food safety – in designating it as such we will ultimately be disappointed. The following chapter further considers further the role of food safety science and what we can rightly expect of it, not only for vibriosis, but for all food safety matters.

#### ***7.4 From ‘Matters of Fact’ to ‘Matters of Concern’: What We Should Expect of Science***

This research confirms that science is unstable, fractured, political, multiple and messy. It is neither linear nor determined by scientific determinism and that science is a network with resources concentrated in a relatively few places. Science is agentic and wrapped up in the agency of others – it changes the worlds that it seeks to describe. These factors have as much to do with the contingencies of politics, simultaneously involving socio-political, scientific and material characters (Latour, 1988). Science (as a singular project, a collection of multiple projects, and its myriad constituent subjects and objects) must work with other assemblages if change is to be considered, and even then, there is no guarantee, with only the potential for its products to be ultimately implemented. Science is not reducible to its own best advocate, the scientist or even scientists as a group. Yet scientists and all those other actors assembled into science assemblages such as the ISSC are configurations of a host of facts and concerns.

Food safety is one theme of interest to the ISSC members, yet this topic resists ‘scientisation’. It remains uncertain, weakly bounded, unstable and subject to politics. What food safety means and to whom it should apply are irreducible to matters of fact. Matters of fact and concern are co-constitutive. Oysters, for example, have a social face and it is the oyster’s sociability, with all its cultural and epicurean facets, that keeps oyster eaters eating raw oysters. Depriving the oyster eaters of their desired food quickly becomes a consumer matter of concern. So, the ISSC must deal with a mixed assemblage of matters of fact and social concern and the following discusses how the ISSC endeavours to do so. Like Japan, New Zealand, the EU, and other nations it must deal with the playing out of a complex, shifting and context-specific assemblage of matters of fact and matters of concern.

It is not only the scientists who table matters of fact. Other ISSC actors table their own matters of fact, such as the economics of the raw oyster industry. Of course, facts are never simply facts and can never be 'facts'. Vibriosis takes us beyond the 'fact factions' because it also includes the colourful battalion of the 'matters of concern'. This is evidenced by the research interview narratives; people are concerned with matters other than scientific biophysical measurements. They also concerned, and some may say more concerned, about the cultural mores of eating raw oysters, the financial model around this culinary practice and the debate about individual versus government responsibility management of food safety risks. These other matters provoke emotions and are an important consideration within the vibriosis assemblage. Ignoring the 'matters of concern' would mean taking a blind-sided view of the whole scene, ignoring the important public concerns around the social, moral and ethical matters of eating. In practice, within the ISSC, the association of metrological objects and matters of concern risks creating "things" which organise 'publics' that are committed to addressing an issue) (Di Salvo *et al.*, 2014).

The ISSC defines itself as an assemblage that uses 'science-based' food safety solutions. Yet this research makes it transparent that when ISSC members formally decide upon the oyster regulations they do not primarily make their decisions using scientific information. Instead ISSC members use social concerns and values to select their preferred regulatory options. While presenting arguments in terms of objective, quantifiable, empirically produced knowledge the ISSC voters use science knowledge and gaps within it to develop positions with respect to the difficult political questions, such as whether Post Harvest Processing (PHP) should be used to deal with food safety and who 'deserves' government protection. As Jamieson (2000) would say the ISSC vibrio arguments are conducted in technical discourse thus pretending that differences "can be washed away by the solvent of scientific decision-making."

The raw oyster has significant agency, not only driving its culinary oyster-eating assemblage, but also its own economic and political assemblages. It is in turn a complex hybrid of biophysical (natural) and social actors, their relation and the consequences of these, including illness. Nothing in the vibriosis example is stable; the biophysical world is constantly changing due to environmental and evolutionary forces while the many social factors, for example, economics, political ideologies, food safety regimes and scientific knowledge are themselves continuously morphing. Not only that, science at play is also unstable. Likely the most stable actor is the human raw oyster eater, a USA actor that has remained relatively unchanged spatially and temporally given the country's traditional culinary practice.

Vibriosis highlights the complex issues of governance - currently if the people's health is to be fully protected all oysters would be treated, but in doing so the industry would lose their property rights to sell a product the market wants (in USA due to potential industry losses it was decided not to mandate pasteurization of oysters). Food safety is a shifting target because humans, the agent, and the environment keep shifting. In the 'old days' of contagious diseases the government set up engineering systems to protect the public, for example chlorination of drinking water supplies. Today the 'contagious' diseases have, in the main, been conquered and we are now dealing with lifestyle diseases, caused by personal choices which do not transfer person to person. Therefore governments/public are not so quick to deal with these – there is no real political reason for them to do so as illness outbreaks are much less, and it seems there is a moral dilemma about public controls versus individual rights.

## **7.5 What We Now Know**

Many national and international food safety agencies treat food safety as a problem that might be solved by understanding the discrete, independent and pre-formed epidemiological actor triad (host, disease and the environment). Further they treat science in simplistic terms, as an assemblage, as it were, of value-free, ethically neutral and repeatable laboratory methods. In this research, I replace the traditional science-based food safety triad model (patient, disease agent and the environment) with Science and Technology Studies (STS) concepts. This move represents science as immediately much more complex, more political and less stable/singular than is normally recognised. Science, and its products in the form of conferences, accepted findings and recommendations is far more open and multiple than normally understood. It is always in the making and emerging from complicated and messy relationships with governments, funding agencies, people and the natural environment. It still makes sense to talk of science and to see it as an actor in the singular, but not as a stable subject or object, but as an assemblage and a political project. As such, science is still at work in the world in a singular sense as well as in terms of its myriad constituent elements, theories, experiments, reports, scientific papers, and individual scientist actors. However, as 'Science' it is a project – unstable, but subject to on-going stabilisation by agencies such as the FDA and the Royal Society (in New Zealand), discourses of science solutionism, science as saviour, science communication and science in schools, and science-policy initiatives and conferences such as the ISSC. We should be critical of this project, sceptical of its powers, and dismissive of simplistic solutionism thinking. Just as food safety is a far more complex configuration of human and non-human actors than its metrics suggest, so too is Science.

As Mol suggests the power of this type of research is its ability to add to our repertoire of such accounts while challenging us to see reality differently. Most significantly it ensures we assemble the actors differently. In our busy lives it is easy to focus on the specific day to day activities of our professional discipline. Most food safety professionals work slavishly aiming to save lives and prevent suffering by using the same instruments, tools and paradigms provided by our forbearers. We often know that there are pitfalls with our methods, yet we are too busy doing the professional tasks required of us to think and do things differently. We become stuck in our paradigms; the practices, norms and standards that institutionalise conformity and suppress creativity (Kuhn, 1962).

Kuhn suggests paradigms only change when circumstances eventually reach a crisis and people begin to look for alternative conceptual schemes. When a successful alternative is found it becomes the paradigm for the next few generations (Kuhn, 1962). Von Schomberg (1993) confirms that history has taught us that our ethical and scientific insights have, time and again, been shown to be fallible and that those insights had to be revised in the light of new situations and problems.

By taking time to reflect we can find new ways of understanding and practicing. Such alternative options might come from a different direction than we might expect. By using ANT as a new way of framing a food safety situation we become more empowered in gaining an understanding of the multiple actors and their relationships. In doing so it is possible to better understand the continuous contest between the environmental and social factors impacting a situation. We can also come to the appreciation that

food safety solutions do not always require a scientific solution – only society can define their desired outcomes, even if it decides that rejecting science’s solution is the correct solution.

Currently food safety authorities use the risk analysis regime which purposely divides science and food safety management because science is deemed objective and apolitical. However, this thesis verifies science is not objective and apolitical - expecting it to be so is fallible. Societies are responsible for focusing science on the matters of fact and that is the first step in removing its neutrality. The vibriosis case highlights solving a food safety issue does not simply require a situational description using biophysical scientific measurements. Societal decisions are not only made on scientific ‘facts’ but on other matters of fact that affect society such as economic and political decisions. Moreover, ‘matters of concern’ are of equal importance; the moral, ethical or other matters that “involve us, touch and brush up against us, envelop us, or otherwise call on us to respond to them” (Ivakhiv (2014)). Matters of concern are equally important facts that must be considered when societies determine their acceptable level of food safety. If a binary division is made between scientific facts and other facts and concern the risk assessment will not be robust. Further the ultimate risk management decisions derived from such a risk assessment may be unacceptable to society because, as this research clearly identifies, people have differing views of acceptable food safety risks.

To pose the question “Why has science not solved vibriosis?” is not the right food safety question. Instead the question needs to be posed “What are the matters of fact and concern associated with this food safety situation?” Others have argued for a new politics of knowledge production, embedded in an active and experiential process of coming to understand both the qualities and factors of a condition (Di Silvo *et al.*, 2014). In using the ANT model to focus attention on the instabilities of both matters of fact and concern we can better understand the important political work of science. Some might suggest that this is the purview of risk management, but this thesis argues important wider matters of fact and concern fit within the ambit of scientific risk assessment. STS, including ANT concepts, use valid methods to obtain a more detailed picture than if only using biochemical assays. These social science methods must be placed alongside the biochemical assays in the scientific risk assessment step.

Ultimately, for food safety regulators, my research suggests that unless we move away from the current risk assessment model which uses only biophysical parameters to describe and measure ‘problems’ we will not make headway in understanding how best to deal with the many complicated food safety and environmental matters that we are faced with. This research highlights the usefulness of a different framework to identify the problem, set the actor’s roles, get others involved and representing collectives. In doing so it offers new ways of rethinking food safety concepts and empirical food safety governance.

It is important to recognise that any new approach still may not achieve the holy grail of unilateral food safety standards. Matters of fact and concern vary from place to place, always conspiring against unilateral standards. However, a comprehensive food safety risk assessment frame, integrating all the important matters of fact and concern into risk characterization will provide wider food safety benefits. This thesis sets the challenge of designing a new risk analysis framework and food safety regime. There will be multiple food safety benefits by taking account of all the matters of fact and concern, not least of which will be a better use of the world’s variable and valuable food resources.

## **7.6 Applying ANT Outputs**

This research might be described as active research; it did not passively explore theories or academic constructs. Instead as information became available it was applied, both in the USA and other countries.

As discussed in Section 6.4.3 during my 2013-14 research-linked discussions with ISSC stakeholders' strong themes began to emerge. All individual conversations were deemed confidential, yet it soon became evident that there were unified, major concerns about the FDA's established process for developing and implementing policy. Many stakeholders, including industry, state and federal regulators and scientists, expressed concern that the FDA did not use a consultative approach when formulating policy. It was perceived that FDA policies were drafted remotely, without any real understanding of the practical and diverse USA systems for producing and harvesting shellfish. This information was passed to the FDA's Senior Seafood Scientist who actively listened and decided to change his interactive approach with ISSC stakeholders. This included field visits to the oyster production states with a new communication strategy to validate temperature reduction as a vibriosis mitigation step, while showing empathy to the social affects of the proposed temperature polices. Following several of these field meetings industry themselves made changes to their harvesting systems. For example, in 2015 the main Connecticut industry naysayer regarding icing at the time of harvest designed and engineered their own barge cooling system for use when dredge harvesting shellfish.

This research project was instrumental in gaining an invitation to be keynote opening speaker at the 2017 *International Molluscan Shellfish Safety Conference*, convened in Galway, Ireland. The title of my presentation was "Matters of Fact versus Matters of Concern, Shellfish Food Safety in 2017" and was framed using the research findings.

Further, the knowledge has been applied in the context of New Zealand's *Vibrio* food safety issues. MPI requested three technical reports, two risk profiles on *Vibrio vulnificus* and *Vibrio parahaemolyticus* in Pacific oysters (King, McCoubrey & Cressey, 2017) and a report on NZ's oyster industry's best practical options for preventing vibriosis. (McCoubrey, 2018). ANT principles were applied to the report writing, causing MPI to review the *Vibrio* food safety issues differently and impacting their decision making.

## APPENDIX I: UAHPEC's rational for Research Ethics Approval

### Secondary data analysis

Some research studies make use of secondary data; that is, data that was originally collected for a purpose other than the current research purpose. Secondary datasets include censuses and clinical records. The same dataset can be a primary dataset to one researcher and a secondary dataset to a different researcher.

Permission of the custodian of the data is required for access to secondary data which is not publicly available and researchers considering giving access to data sets should be aware of the requirements of the Privacy Act 1993, particularly Principles 10 and 11.

Ethical approval will sometimes be required for the use of secondary data; for example, if the data identifies individuals. Ethical approval for proposed research may sometimes be required by custodians of data prior to providing access. If the personal information collected for a particular research project is to be used for statistical research purposes in a second project, and the information will not be published in a form that is likely to identify the individual concerned, no further ethical approval is required.

The University of Auckland interprets that this research project relates to the use of secondary data and that no individual will be identified in any publication resulting from this research.

## APPENDIX II: History of FDA's Principle Actions re Vp and Vv

YEAR	ACTIVITY
1980	Became a member of ISSC
1985	MOU signed to undertaken ISSC tasks, including provision of science.
1987	FDA determined an association between Vv and oysters
1988	Sponsored Vv science workshop
1994	FDA submits first formal Vv proposal to conference. FDA sponsors second Vv science workshop.
1997	FDA submits first Vp proposal to conference
1998	Received petition from CSPI for regulatory action on Vv.
2002	FDA responded to CSPI's 1998 Vv petition
2005	FDA published <i>Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus In Raw Oysters</i>
2009	Established unilateral policy to have all summer harvested oysters PHP treated. ISSC requested FDA develop Vibrio calculator.
2011	FDA received Congress verdict that that were unable to implement Vv policy. Collaborated with FAO/WHO <i>Risk Assessment of <u>Vibrio parahaemolyticus</u> in seafood (2011)</i>
2012	Received petition from CSPI for regulatory action on Vv.
2013	FDA proposal re Proposal 13-204 re quick oyster cooling submitted to ISSC
2014	FDA's Chief Seafood Scientist changed his communication strategy with ISSC stakeholders, undertaking field visits.
2016	FDA responded to CSPI's 2012 Vv petition.
2017	FDA sponsored Vp science workshop.

## APPENDIX III: History of ISSC Actions Taken in the Attempt to Reduce Vp and Vv Illness Amongst Oyster Eaters

YEAR AND ACTION	YEAR AND ACTION	YEAR AND ACTION
1987 - South-East Region of FDA identify Vv as a public health problem	1988 - ISSC and FDA sponsor Vv workshop which recommends: a) Educating public and industry. b) Collecting illness data c) Science research to determine controls.	1994 - First ISSC proposal tabled by FDA recommending: a) Time/temperature seasonal controls for Gulf oysters OR b) Shucking or cooking of Gulf oysters.  Proposal <u>not</u> accepted and referred for further deliberation.
1997 - ISSC proposal adopted <i>Interim Control Plan</i> requiring reduced time from harvest to refrigeration when Vv levels elevated.	1998 - ISSC adopted: 1) Mandatory tags and labels warning consumers 2) Consumer education. 3) Application to FDA for irradiation approval.  ISSC initiated a National Consumer Education Program to advise high-risk consumers.  ISSC requested that FDA approve irradiation as a PHP method.	1999 - ISSC appoints Vibrio Management Control Committee (VMC) to review problems. Vv and Vp sub-committees were appointed.
2000 - ISSC VMC recommends Vv controls based on FDA <i>Egg Safety Action Plan</i> . States with two or more illnesses since 1995 required to have a Vibrio plan.	2001 - ISSC accepts Vv Illness reduction goals of 40% by 2005 and 60% by 2007.  VMC Illness reduction plan included: a) Encourage PHP. b) Temperature controls. c) Science to find other PHP methods. d) FDA to target time/temperature assessment.	2003 - Modification to of formula to measure illness reduction.  VMC to produce an annual report.  California decides on unilateral Vv policy for their state. ISSC Executive Board determined that California should lose all ISSC voting rights until they aligned their state policies with those of the ISSC.
2005 - ISSC appoints committee to review and approve CDC and FDA's list of annual Vibrio illnesses.  FDA approves irradiation of shellfish for PHP.	2007 - FDA Statistician forecasts that Vv illness reduction goals will not be met.	2009 - FDA reformulated their policy change and advised ISSC that mandatory PHP would be required with effective date May 2011 for half shell oysters harvested during the summer months.  ISSC adopted a proposal to change their 60% illness reduction rate with a risk per serving goal. ISSC requested FDA to develop a Vv calculator based on the FAO/WHO Vv Risk Assessment to inform the states regarding predicted effect of time/temperature controls.

<p>2010 - FDA reformulated their policy change and advised ISSC that mandatory PHP would be required with effective date May 2011 for half shell oysters harvested during the summer months.</p> <p>ISSC adopted a proposal to change their 60% illness reduction rate with a risk per serving goal. ISSC requested FDA to develop a Vv calculator based on the FAO/WHO Vv Risk Assessment to inform the states regarding predicted effect of time/temperature controls.</p>	<p>2011 - ISSC accepted proposal establishing acceptable risk/serving standards for various times of the year based on mean monthly water temperatures.</p> <p>FDA to run a two- year cumulative risk/serving determination followed by running a three-year cumulative risk/serving determination.</p>	<p>2012 - ISSC changes Vv measure from illness reduction to risk per serving.</p>
<p>2014 ISSC agreed that annually the risk/serving be used to determine whether states have individually met the standard.</p> <p>FDA tables Proposal #13-204 which recommends cooling of oysters/clam within 50°F within one hour of harvest.</p> <p>Proposal 13-204 not accepted. Instead proposal amended to task ISSC Executive Board to seek and obtain funding for the purposes of assessing the efficacy of time temperature controls on post- harvest growth</p> <p>Proposal not accepted. Instead proposal amended to task ISSC Executive Board to seek and obtain funding for the purposes of assessing the efficacy of time temperature controls on post- harvest growth</p>		

Timeline of ISSC Vp policy actions

YEAR AND ACTION	YEAR AND ACTION	YEAR AND ACTION
<p>1999 - First ISSC <i>Vibrio parahaemolyticus</i> proposal tabled.</p>	<p>2000 - ISSC approves definitions for Vp outbreaks and Vp limits which would activate the need for a Vp management plan. Plan would start regular sampling, time/temperature control (under 10°C in under 10 hours).</p>	<p>2001 - Recommended that ISSC find funds to develop better lab methods to detect pathogenicity and contributing factors that trigger <i>tdh</i> gene.</p>
<p>2005 - FDA releases a Risk Assessment report on <i>Vibrio parahaemolyticus</i></p>	<p>2008 - Approval given to produce an education DVD providing information on the post –harvest growth of Vp. ISSC adopts guidance outline on how to prepare a state <i>Vp Control Plan</i>.</p>	<p>2014 ISSC accepted change to definition of <i>Vibrio parahaemolyticus</i> outbreak. Changed from “<u>two (2)</u> or more persons, not from the same household, becoming ill from shellfish from the same harvest area within a <u>seven (7) day period</u>” to “shellfish harvested within ten (10) days of each other from the same growing area are implicated in an illness outbreak involving three (3) or more persons”.</p>
<p>2017 – ISSC sponsors Vp workshop</p>		

## APPENDIX IV: Examples of specific national dynamics in countries dealing with vibriosis

<i>Jurisdiction</i>	<i>Defining dynamic</i>	<i>Key Feature</i>
<u>United States</u>	FDA leadership and constitutional commitments to freedom of action	The ISSC
<u>Australia</u>	<i>Distinct change in Vp epidemiology.</i> (Madigan et al., 2016)	Complex federal-state negotiations
<u>Canada</u>	<i>Best Vp science = Industry Collaboration, Innovation and Implementation.</i> (Health Canada, 2017)	Collaborative engagements
<u>European Union</u>	<i>“There is no need for specific standards to control Vibrios.”</i> (EU, 2001)	Science based policy at a distance
<u>Japan</u>	<i>Japanese people eat raw seafood ... and are frequently infected by Vp.</i> (Toyofuku, 2014)	Direct regulations to deal with a significant total dietary risk
<u>New Zealand</u>	<i>International market protection is much more important than food safety science.</i> (MPI representative, 2015)	Regulation without illness but to protect market reputation.
<u>Codex Alimentarius</u>	<i>... harvesting areas need to manage their own environmental risks.</i> (Codex, 2010).	Universal global food safety standard not possible or tenable

## REFERENCES

- Aagesen, A.M. and Häse, C.C., 2014. Seasonal effects of heat shock on bacterial populations, including artificial *Vibrio parahaemolyticus* exposure, in the Pacific oyster, *Crassostrea gigas*. *Food microbiology*, 38, pp.93-103.
- Ababouch, L., 2006. Assuring fish safety and quality in international fish trade. *Marine pollution bulletin*, 53(10), pp.561-568.
- Abrahamson, Mark. 1983. *Social Research Methods*. Prentice-Hall International Ltd. New Jersey, USA.
- Akrich, M. and Latour, B., 1992. A summary of a convenient vocabulary for the semiotics of human and nonhuman assemblies.
- Allen, S.M. and Burnett, L.E., 2008. The effects of intertidal air exposure on the respiratory physiology and the killing activity of hemocytes in the pacific oyster, *Crassostrea gigas* (Thunberg). *Journal of Experimental Marine Biology and Ecology*, 357(2), pp.165-171.
- Ama, A.A., Hamdy, M.K. and Toledo, R.T., 1994. Effect of heating, pH and thermoradiation on inactivation of *Vibrio vulnificus*. *Food Microbiology*, 11(3), pp.215-227.
- Amjadi, K. and Hussain, K., 2005. Integrating food hygiene into quantity food production systems. *Nutrition & Food Science*, 35(3), pp.169-183.
- Andersen, L.B., Danholt, P., Halskov, K., Hansen, N.B. and Lauritsen, P., 2015. Participation as a matter of concern in participatory design. *CoDesign*, 11(3-4), pp.250-261.
- Anderson, B. and McFarlane, C., 2011. Assemblage and geography. *Area*, 43(2), pp.124-127.
- Andrews, L., Jahncke, M. and Mallikarjunan, K., 2003. Low dose gamma irradiation to reduce pathogenic vibrios in live oysters (*Crassostrea virginica*). *Journal of Aquatic Food Product Technology*, 12(3), pp.71-82.
- Ansaruzzaman, M., Lucas, M., Deen, J.L., Bhuiyan, N.A., Wang, X.Y., Safa, A., Sultana, M., Chowdhury, A., Nair, G.B., Sack, D.A. and von Seidlein, L., 2005. Pandemic serovars (O3: K6 and O4: K68) of *Vibrio parahaemolyticus* associated with diarrhea in Mozambique: spread of the pandemic into the African continent. *Journal of clinical microbiology*, 43(6), pp.2559-2562.
- Antle, J.M., 1995. *Choice and efficiency in food safety policy*. American Enterprise Institute.
- ANZFA (2001) Raw commodity consumption figures. Australia New Zealand Food Authority, Canberra. (accessed:
- Appadurai, A. (ed.) 1986. *The social life of things: commodities in cultural perspective*. Cambridge: University Press
- Aston, A. 1993. Improving food hygiene - a dilemma REH1S Newsletter 2/93, 9–10. Edinburgh, , UK: Royal Environmental Health Institute of Scotland
- Atkinson, P., 1992. The ethnography of a medical setting: Reading, writing, and rhetoric. *Qualitative Health Research*, 2(4), pp.451-474.
- Bacchetti, P., 2002. Peer review of statistics in medical research: the other problem. *BMJ: British Medical Journal*, 324(7348), p.1271.
- Bachman, B., Boyd Jr, W.P., Lieb, S. and Rodrick, G.E., 1983. Marine noncholera *Vibrio* infections in Florida. *Southern medical journal*, 76(3), pp.296-299.
- Baethge, B.A. and West, B.C., 1988. *Vibrio vulnificus*: did Hippocrates describe a fatal case? *Reviews of infectious diseases*, 10(3), pp.614-615.

- Baggott, R. 1990. Looking Forward to the Past? The Politics of Public Health. *Journal of Social Policy*, 1990, 20, 2, 191-213.
- Baker, D.P., 1984. *The Library Media Program and the School*. Libraries Unlimited, Inc., PO Box 263, Littleton, CO 80160-0263.
- Baker-Austin C. 2014. Living in a *Vibrio* World: The ecology, geographical distribution and impact of climate change on pathogenic vibrios. Presentation given to South Atlantic Gulf Coast Shellfish Association, Beaufort, North Carolina.
- Baker-Austin, C., Stockley, L., Rangdale, R. and Martinez-Urtaza, J., 2010. Environmental occurrence and clinical impact of *Vibrio vulnificus* and *Vibrio parahaemolyticus*: a European perspective. *Environmental Microbiology Reports*, 2(1), pp.7-18.
- Banerjee, S.K., Pagotto, F.J. and Farber, J.M., 2007. Prevalence and molecular diversity of *Vibrio parahaemolyticus* associated with molluscs harvested in Canada. In *Sixth International Conference on Molluscan Shellfish Safety* (pp. 185-192).
- Barley, S.R., 1996. Technicians in the workplace: Ethnographic evidence for bringing work into organizational studies. *Administrative Science Quarterly*, pp.404-441.
- Barnes, B., Bloor, D. and Henry, J., 1996. Scientific knowledge: A sociological approach.
- Baross, J. and Liston, J., 1970. Occurrence of *Vibrio parahaemolyticus* and related hemolytic vibrios in marine environments of Washington State. *Applied microbiology*, 20(2), pp.179-186.
- Barnett, V. and O'Hagan, A., 1997. *Setting environmental standards: the statistical approach to handling uncertainty and variation*. CRC Press.
- Barrett, R., Kuzawa, C.W., McDade, T. and Armelagos, G.J., 1998. Emerging and re-emerging infectious diseases: the third epidemiologic transition. *Annual review of anthropology*, 27(1), pp.247-271.
- Barry, A., 2002. The anti-political economy. *Economy and society*, 31(2), pp.268-284.
- Barry, A. and Slater, D., 2002. Introduction: the technological economy. *Economy and society*, 31(2), pp.175-193.
- Bauer, A., Østensvik, Ø., Florvåg, M., Ørmen, Ø. and Rørvik, L.M., 2006. Occurrence of *Vibrio parahaemolyticus*, *V. cholerae*, and *V. vulnificus* in Norwegian Blue Mussels (*Mytilus edulis*). *Applied and environmental microbiology*, 72(4), pp.3058-3061.
- Bauman, H.E., 1995. The origin and concept of HACCP. In *HACCP in meat, poultry, and fish processing* (pp. 1-7). Springer US.
- Baumann, P., Baumann, L. and Mandel, M., 1971. Taxonomy of marine bacteria: the genus *Beneckeia*. *Journal of Bacteriology*, 107(1), pp.268-294.
- Beaz-Hidalgo, R., Balboa, S., Romalde, J. L. and Figueras, M. J. 2010, Diversity and pathogenecity of *Vibrio* species in cultured bivalve molluscs. *Environmental Microbiology Reports*, 2: 34–43. doi: 10.1111/j.1758-2229.2010.00135.
- Beck, U., 1992. *Risk society: Towards a new modernity* (Vol. 17). Sage.
- Bej, A.K., Patterson, D.P., Brasher, C.W., Vickery, M.C., Jones, D.D. and Kaysner, C.A., 1999. Detection of total and hemolysin-producing *Vibrio parahaemolyticus* in shellfish using multiplex PCR amplification of *tl*, *tdh* and *trh*. *Journal of microbiological methods*, 36(3), pp.215-225.
- Bell, B.P., Goldoft, M., Griffin, P.M., Davis, M.A., Gordon, D.C., Tarr, P.I., Bartleson, C.A., Lewis, J.H., Barrett, T.J., Wells, J.G. and Baron, R., 1994. A multistate outbreak of *Escherichia coli* O157:h7—associated bloody diarrhea and hemolytic uremic syndrome from hamburgers: the Washington experience. *Jama*, 272(17), pp.1349-1353.
- Bennet, J., 2005. The agency of assemblages and the North American blackout.

- Bergeaud-Blackler, F. and Ferretti, M.P., 2006. More politics, stronger consumers? A new division of responsibility for food in the European Union. *Appetite*, 47(2), pp.134-142.
- Berlin, D.L., Herson, D.S., Hicks, D.T. and Hoover, D.G., 1999. Response of pathogenic *Vibrio* species to high hydrostatic pressure. *Applied and Environmental Microbiology*, 65(6), pp.2776-2780.
- Bier, V.M. and Mosleh, A., 1990. The analysis of accident precursors and near misses: implications for risk assessment and risk management. *Reliability Engineering & System Safety*, 27(1), pp.91-101.
- Biesta, G., 2007. Towards the knowledge democracy? Knowledge production and the civic role of the university. *Studies in Philosophy and Education*, 26(5), pp.467-479.
- Bijker, W., Hughes, T. and Pinch, T., 1987. The social construction of technical systems. *New directions in the Sociology and History of Technology*. Cambridge, Mass.
- Bisha, B., Simonson, J., Janes, M., Bauman, K. and Goodridge, L.D., 2012. A review of the current status of cultural and rapid detection of *Vibrio parahaemolyticus*. *International journal of food science & technology*, 47(5), pp.885-899.
- Bishai, D., Ghaffar, A., Kelley, E. and Kieny, M.P., 2015. Honouring the value of people in public health: a different kind of p-value. *Bulletin of the World Health Organization*, 93(9), pp.661-662.
- Björnberg, K.A., Vahter, M., Grawé, K.P. and Berglund, M., 2005. Methyl mercury exposure in Swedish women with high fish consumption. *Science of the total environment*, 341(1), pp.45-52.
- Blackstone, G.M., Nordstrom, J.L., Vickery, M.C., Bowen, M.D., Meyer, R.F. and DePaola, A., 2003. Detection of pathogenic *Vibrio parahaemolyticus* in oyster enrichments by real time PCR. *Journal of Microbiological Methods*, 53(2), pp.149-155.
- BMRCs. Animal Products (Regulated Control Scheme—Bivalve Molluscan Shellfish) Regulations 2006. <http://www.legislation.govt.nz/regulation/public/2006/0038/latest/DLM369353.html>. Accessed 23<sup>rd</sup> March 2018.
- Bogard, R.W. and Oliver, J.D., 2007. Role of iron in human serum resistance of the clinical and environmental *Vibrio vulnificus* genotypes. *Applied and environmental microbiology*, 73(23), pp.7501-7505.
- Bolton, D.J., Meally, A., Blair, I.S., McDowell, D.A. and Cowan, C., 2008. Food safety knowledge of head chefs and catering managers in Ireland. *Food Control*, 19(3), pp.291-300.
- Borazjani, A., Andrews, L.S. and Veal, C.D., 2003. Novel nonthermal methods to reduce *Vibrio vulnificus* in raw oysters. *Journal of food safety*, 23(3), pp.179-187.
- Bowler, P.J. (1992). *The Norton History of the Environmental Sciences*. Norton & Company. United States of America.
- Braithwaite, J., Marks, D. and Taylor, N., 2014. Harnessing implementation science to improve care quality and patient safety: a systematic review of targeted literature. *International Journal for Quality in Health Care*, 26(3), pp.321-329.
- Bromley, D. A. Viewpoint on the theory and practice of giving scientific advice to the government. *Science and Public Policy*. April 1993.
- Brooks, H. 1981. Some notes on the feat and distrust of science, in A.S Markovits and K. W. Deutsch, (Eds), *Fear of Science-Trust in Science* (Cambridge, USA: Oelschlager, Gunn and Hain Publishers)
- Bross M H, Soch K, Morales R and Mitchell R B (2007) *Vibrio vulnificus* infection: Diagnosis and treatment. *American Family Physician*; 76: 539-544.
- Brousseau, D.J., Braun, P.C., Harper-Leatherman, A.S., Sullivan, E. and Baglivo, J.A., 2014. Antimicrobial activity in the pallial cavity fluids of the oyster *Crassostrea virginica* (Gmelin) from a highly impacted harbor in western Long Island Sound. *Journal of Shellfish Research*, 33(3), pp.719-725.

- Brown, J.H., Burnside, W.R., Davidson, A.D., DeLong, J.P., Dunn, W.C., Hamilton, M.J., Mercado-Silva, N., Nekola, J.C., Okie, J.G., Woodruff, W.H. and Zuo, W., 2011. Energetic limits to economic growth. *BioScience*, 61(1), pp.19-26.
- Brown, S.D., 2002. Michel Serres: Science, translation and the logic of the parasite. *Theory, culture & society*, 19(3), pp.1-27.
- Bryan, F.L., 1988. Risks of practices, procedures and processes that lead to outbreaks of foodborne diseases. *Journal of food protection*, 51(8), pp.663-673.
- Bryan, F.L., 1990. Hazard analysis critical control point (HACCP) concept. *Dairy, Food and Environmental Sanitation*, 10(7), pp.416-418.
- Bryan, F.L. and World Health Organization, 1992. Hazard analysis critical control point evaluations: a guide to identifying hazards and assessing risks associated with food preparation and storage.
- Buchanan, R.L., 1997. Identifying and controlling emerging foodborne pathogens: research needs. *Emerging infectious diseases*, 3(4), p.517.
- Buchrieser, C., Gangar, V.V., Murphree, R.L., Tamplin, M.L. and Kaspar, C.W., 1995. Multiple *Vibrio vulnificus* strains in oysters as demonstrated by clamped homogeneous electric field gel electrophoresis. *Applied and Environmental Microbiology*, 61(3), pp.1163-1168.
- Busch, L., 2008. Nanotechnologies, food, and agriculture: next big thing or flash in the pan? *Agriculture and Human Values*, 25(2), pp.215-218.
- Butt, A.D., Aldridge K. E and Sanders, C. V. 2004 Infections related to the ingestion of seafood Part 1: viral and bacterial infections. *The Lancet*. Vol. 4 April.
- Button, G., 1993. *Technology in working order: Studies of work, interaction, and technology*. Routledge.
- Cadilhon, J.J., Moustier, P., Poole, N.D., Tam, P.T.G. and Fearne, A.P., 2006. Traditional vs. modern food systems? Insights from vegetable supply chains to Ho Chi Minh City (Vietnam). *Development Policy Review*, 24(1), pp.31-49.
- Callon, Michel. 1986. "Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of St Brieuc Bay." In John Law (ed.), *Power, Action and Belief: A New Sociology of Knowledge* (London: Routledge & Kegan Paul).
- Callon, M., 1987. Society in the making: the study of technology as a tool for sociological analysis. *The social construction of technological systems: New directions in the sociology and history of technology*, pp.83-103.
- Callon, M., 1998a. Introduction: the embeddedness of economic markets in economics. *The Sociological Review*, 46(S1), pp.1-57.
- Callon, M. ed., 1998. *The laws of the markets*. Blackwell Publishers/Sociological Review.
- Callon, M., 1999. Actor-network theory—the market test. *The Sociological Review*, 47(1\_suppl), pp.181-195.
- Callon, M. and Latour, B., 1981. Unscrewing the big Leviathan: how actors macro-structure reality and how sociologists help them to do so. *Advances in social theory and methodology: Toward an integration of micro-and macro-sociologies*, pp.277-303.
- Callon, M. and Latour, B., 1997. 'Tu ne calculeras pas!' ou comment symétriser le don et le capital. *Revue du MAUSS*, 9(1), pp.45-70.
- Callon, M. and Law, J., 1997. After the individual in society: Lessons on collectivity from science, technology and society. *Canadian Journal of Sociology/Cahiers canadiens de sociologie*, pp.165-182.
- Callon, M. and Law, J., 2005. On qualculation, agency, and otherness. *Environment and Planning D: Society and Space*, 23(5), pp.717-733.

- Campbell, H., Burton, R., Cooper, M., Henry, M., Heron, E.L., Heron, R.L., Lewis, N., Pawson, E., Perkins, H., Roche, M. and Rosin, C., 2009. From agricultural science to “biological economies”?
- Carmalt Jones, D. W. New Zealand Views on Goitre. *Proc R Soc Med*. 1928 May; 21(7): 1217–1230.
- Carolan, M.S., 2004. Ontological politics: mapping a complex environmental problem. *Environmental Values*, pp.497-522.
- Carolan, M., 2013. *The real cost of cheap food*. Routledge.
- Carrel, H., 2009. The ideology of punishment in late medieval English towns. *Social History*, 34(3), pp.301-320.
- Cassell, E.J., 1986. Ideas in conflict: the rise and fall (and rise and fall) of new views of disease. *Daedalus*, pp.19-41.
- Castree, Noel. 2002. “False Antitheses? Marxism, Nature and Actor-networks.” *Antipode* 34(1): 111–46.
- Caswell, J.A. and Johnson, G.V., 1991. Firm strategic response to food safety and nutrition regulation. *Economics of food safety*, pp.273-297.
- CCSTA (Canadian Council of Science and Technology Advisors), 1999. Science Advice for Government Effectiveness (SAGE). Council of Science and Technology Advisors Secretariat, Ottawa, Canada.
- CDC (Centers for Disease Control and Prevention), 1993. Vibrio vulnificus infections associated with raw oyster consumption--Florida, 1981-1992. *MMWR. Morbidity and mortality weekly report*, 42(21), p.405.
- CDC (Centers for Disease Control and Prevention), 2006. Principles of epidemiology in public health practice: an introduction to applied epidemiology and biostatistics.
- Chagla, A.H., Pillai, D.K., Khan, M.A. and Zaman, A.U., 1988. Septicaemia caused by *Vibrio vulnificus*. *Journal of Infection*, 17(2), pp.135-138.
- Chakraborty, S. and Newton, A.C., 2011. Climate change, plant diseases and food security: an overview. *Plant Pathology*, 60(1), pp.2-14.
- Chavez, Christina. "Conceptualizing from the inside: Advantages, complications, and demands on insider positionality." *The Qualitative Report* 13.3 (2008): 474-494.
- Cheek, P., 2006. Factors impacting the acceptance of traceability in the food supply chain in the United States of America. *Revue scientifique et technique-Office international des épizooties*, 25(1), p.313.
- Chiou, C.S., Hsu, S.Y., Chiu, S.I., Wang, T.K. and Chao, C.S., 2000. *Vibrio parahaemolyticus* serovar O3: K6 as cause of unusually high incidence of food-borne disease outbreaks in Taiwan from 1996 to 1999. *Journal of Clinical Microbiology*, 38(12), pp.4621-4625.
- Chong, Y., Palk, M.Y., Lee, S.Y., Kim, K.S. and Lee, S.I., 1982. *Vibrio vulnificus* septicemia in a patient with liver cirrhosis. *Yonsei Medical Journal*, 23(2), pp.146-152.
- Chuang, Y.C., Yuan, C.Y., Liu, C.Y., Lan, C.K. and Huang, A.H.M., 1992. *Vibrio vulnificus* infection in Taiwan: report of 28 cases and review of clinical manifestations and treatment. *Clinical Infectious Diseases*, 15(2), pp.271-276.
- Clark, W.C. and Majone, G., 1985. The critical appraisal of scientific inquiries with policy implications. *Science, Technology, & Human Values*, 10(3), pp.6-19.
- Cochoy, F., 1998. Another discipline for the market economy: marketing as a performative knowledge and know-how for capitalism. *The Sociological Review*, 46(S1), pp.194-221.

- Cockerill, K., 2003. Testing language: Media language influence on public attitudes about river management. *Applied Environmental Education and Communication*, 2(1), pp.23-37.
- Cockerill, K., Armstrong, M., Richter, J. and Okie, J.G., 2017. *Environmental Realism: Challenging Solutions*. Springer.
- Codex, 1969. CAC/RCP 1-1969, Rev. 4, 2003. *Recommended International Code of Practice General Principles of Food Hygiene*, 3.
- Codex, 2003 Joint FAO/WHO, Joint FAO/WHO Food Standards Programme and World Health Organization, 2003. *Codex Alimentarius: Food hygiene, basic texts*. Food & Agriculture Org.
- Codex, 2010. Guidelines on the application of general principles of food hygiene to the control of pathogenic *Vibrio* species in seafood (CAC/GL 73-2010). Codex Alimentarius, Rome. <http://www.fao.org/fao-who->
- Cohen, M.L., 2000. Changing patterns of infectious disease. *Nature*, 406(6797), pp.762-767.
- Colagar, A.H., Marzony, E.T. and Chaichi, M.J., 2009. Zinc levels in seminal plasma are associated with sperm quality in fertile and infertile men. *Nutrition Research*, 29(2), pp.82-88.
- Colwell, R.R., 1984. *Vibrios in the environment* John Wiley and Sons New York.
- Connell, D.J., Smithers, J. and Joseph, A., 2008. Farmers' markets and the "good food" value chain: a preliminary study. *Local Environment*, 13(3), pp.169-185.
- Consumers' Association 1997. *Gene Cuisine – a consumer agenda for genetically modified foods* (S. Davies) policy report. Consumers' Association, London
- Consumers' Association 1999. *Confronting Risk – a new approach to food safety* (S. Davies) policy report. Consumers' Association. London.
- Cook, D.W., 1994. Effect of time and temperature on multiplication of *Vibrio vulnificus* in postharvest Gulf Coast shellstock oysters. *Applied and environmental microbiology*, 60(9), pp.3483-3484.
- Cook, D.W., 1997. Refrigeration of oyster shellstock: conditions which minimize the outgrowth of *Vibrio vulnificus*. *Journal of Food Protection*, 60(4), pp.349-352.
- Cook, D.W., O'Leary, P., Hunsucker, J.C., Sloan, E.M., Bowers, J.C., Blodgett, R.J. and DePaola, A., 2002. *Vibrio vulnificus* and *Vibrio parahaemolyticus* in US retail shell oysters: a national survey from June 1998 to July 1999. *Journal of food protection*, 65(1), pp.79-87.
- Cook, D.W. and Ruple, A.D., 1992. Cold storage and mild heat treatment as processing aids to reduce the numbers of *Vibrio vulnificus* in raw oysters. *Journal of Food Protection*, 55(12), pp.985-989.
- Cook, I., 2004. Follow the thing: Papaya. *Antipode*, 36(4), pp.642-664.
- Coomes, S. Oyster Craze. *Seafood Business Magazine*. June 2014. [www.seafoodsource.com/archive/seafood-business/2014/top-story-oyster-craze](http://www.seafoodsource.com/archive/seafood-business/2014/top-story-oyster-craze) Accessed 23rd March 2018.
- Cooper, M.H., 2015. Measure for measure? Commensuration, commodification, and metrology in emissions markets and beyond. *Environment and Planning A*, 47(9), pp.1787-1804.
- Coppock, R. (1983) *The Integration of Physio-technical and Socio-physical Elements in the Management of Technological Hazards*, mimeo (Berlin, FRG: Science Center, International Institute for Environment and Society).
- Cressman, D., 2009. A brief overview of actor-network theory: Punctualization, heterogeneous engineering & translation.
- Crim, Stacy M., et al. "Incidence and trends of infection with pathogens transmitted commonly through food—Foodborne Diseases Active Surveillance Network, 10 US sites, 2006–2013." *MMWR Morb Mortal Wkly Rep* 63.15 (2014): 328-32.

- CSPI, 2001. *Death on the Half Shell – the Failure of Regulators and the Shellfish Industry to Prevent Deaths and Illnesses from Gulf Coast Shellfish*. Center for Science in the Public Interest, Washington DC.
- CSPI, 2012. Petition for Regulatory Action to Establish a Performance Standard of Non-detectable Levels for *Vibrio vulnificus* in Molluscan Shellfish. Submitted by the Centre for Science in the Public Interest to the U.S. Department of Health and Human Services Food and Drug Administration. February 9, 2012.
- Cutcliffe, S.H., 1990. The STS curriculum: What have we learned in twenty years?. *Science, Technology, & Human Values*, 15(3), pp.360-372.
- Daniel, G., 1950. A hundred years of archaeology. *London: Duckworth*.
- Daniels, N.A., 2011. *Vibrio vulnificus* oysters: pearls and perils. *Clinical Infectious Diseases*, 52(6), pp.788-792.
- Daniels, N.A. and Shafaie, A., 2000. A review of pathogenic *Vibrio* infections for clinicians. *Infections in medicine*, 17(10), pp.665-685.
- Dankert, R., 2010. Using Actor-Network Theory (ANT) doing research. *Publicaties vanaf*.
- Das, V., Jackson, D., Kleinman, A., and Singh, B. (Eds.). (2014). *The Ground Between: Anthropologists Engage Philosophy*. Durham: Duke University Press. Hoholm (2011), refer note 14
- Davies, P.R., 2012. One world, one health: the threat of emerging swine diseases. A North American perspective. *Transboundary and emerging diseases*, 59(s1), pp.18-26.
- Dean, M. (1999). *Governmentality: Power and Rule in Modern Society*. London: Sage.
- Dean, M. 2010a. *Governmentality: Power and Rule in Modern Society* (2<sup>nd</sup> ed.) London:Sage
- Dean, M. (2010b). Introduction: *Governmentality Today*. *Governmentality: Power and Rule in Modern Society* (2<sup>nd</sup> ed., pp. 1-15). London: Sage.
- Deleuze, G. and Guattari, F., 1983. Anti-Oedipus: Capitalism and schizophrenia, trans. *Robert Hurley, Mark Seem, and Helen R. Lane (Minneapolis: University of Minnesota Press, 1983)*, 5.s
- Deleuze G and Guattari F., 1986. *Kafka. Toward a minor literature Poland trans University of Minnesota Press, Minneapolis MN*
- Deleuze, G. and Guattari, F., 1987. Introduction: Rhizome In *A thousand plateaus: Capitalism and schizophrenia* (B. Massumi, Trans., pp. 3–25). *Minneapolis, MN: University of Minnesota Press*. (Original work published 1980).
- Deleuze, G. and Parnat, C. 2006. *Dialogues II*, Edited by: Tomlinson, H. and Habberjam, B. London: Continuum. (Orig. pub. 1987).
- De Marchi, B. Ravetz, J. Risk Management and governance: a post-normal science approach. *Futures* 31 (1999) 743-757.
- Denzin, N.K. and Lincoln, Y., 2000. Qualitative research. *Thousand Oaks ua*, pp.413-427.
- Dery, D. (1984). *Problem Definitions in Policy Analysis*. Lawrence, Ka: University of Kansas Press.
- DePaola, A., Hopkins, L.H., Peeler, J.T., Wentz, B. and McPhearson, R.M., 1990. Incidence of *Vibrio parahaemolyticus* in US coastal waters and oysters. *Applied and Environmental Microbiology*, 56(8), pp.2299-2302.
- DePaola, A., Capers, G.M. and Alexander, D., 1994. Densities of *Vibrio vulnificus* in the intestines of fish from the US Gulf Coast. *Applied and Environmental Microbiology*, 60(3), pp.984-988.
- DePaola, A., Ulaszek, J., Kaysner, C.A., Tenge, B.J., Nordstrom, J.L., Wells, J., Puhr, N. and Gendel, S.M., 2003. Molecular, serological, and virulence characteristics of *Vibrio parahaemolyticus* isolated

- from environmental, food, and clinical sources in North America and Asia. *Applied and Environmental Microbiology*, 69(7), pp.3999-4005.
- Dept of Health, 1981. *Explanatory Commentary Food Hygiene Regulations 1974*. Second Edition, 1981, Prepared by the Division of Public Health, Department of Health, Wellington
- Desmarchelier P M (2003) Pathogenic vibrios. In: *Foodborne microorganisms of public health significance Sixth Edition*, Ed: A. D. Hocking, pp.333-358. Australian Institute of Food Science and Technology (NSW Branch) Food Microbiology Group: Waterloo, NSW.
- De Solla Price. (1965) *Little Science, Big Science*. New York: Columbia University Press.
- Devaney, L., 2013. Spaces of security, surveillance and food safety: interrogating perceptions of the Food Safety Authority of Ireland's governing technologies, power and performance. *The Geographical Journal*, 179(4), pp.320-330.
- Dewsbury, J.D., 2011. The Deleuze-Guattarian assemblage: plastic habits. *Area*, 43(2), pp.148-153.
- Dietz, T., Ostrom, E. and Stern, P.C., 2003. The struggle to govern the commons. *science*, 302(5652), pp.1907-1912.
- DiSalvo, C., Lukens, J., Lodato, T., Jenkins, T. and Kim, T., 2014, April. Making public things: how HCI design can express matters of concern. In *Proceedings of the 32nd annual ACM conference on Human factors in computing systems* (pp. 2397-2406). ACM.
- DiStefano, P., Muth, M.K., Arsenault, J.E., Cajka, J.C., Cates, S.C., Coglaiti, M.C., Karns, S.A., O'Neil, M. and Viator, C., 2011. Analysis of How Post-harvest Processing Technologies for Controlling *Vibrio vulnificus* Can Be Implemented.
- Doble, J., 1996. Productive policy depends on public's understanding of scientific issues.
- Dovers, S., 1996. Processes and institutions to inform decisions in the longer term. *Tracking Progress Linking Environmental and Economy through Indicators and Accounting Systems*. Australian Academy of Science Fenner Conference on the Environment. Institute of Environmental Studies. The University of New South Wales, Sydney.
- Drake, S.L., DePaola, A. and Jaykus, L.A., 2007. An overview of *Vibrio vulnificus* and *Vibrio parahaemolyticus*. *Comprehensive Reviews in Food Science and Food Safety*, 6(4), pp.120-144.
- Draper, A., and J. Green. 2002. Food safety and consumers: Constructions of choice and risk. *Social Policy and Administration* 36(6): 610–625.
- Dubos, R. J. (1959) *Mirage of Health: Utopias, Progress and Biological Changes*. Harper & Brothers. New York.
- Duffy, J., 1992. *The sanitarians: a history of American public health*. University of Illinois Press.
- Dunbar, R.I.M., 1995. *The trouble with science*. Harvard University Press.
- Dwyer, S.C. and Buckle, J.L., 2009. The space between: On being an insider-outsider in qualitative research. *International journal of qualitative methods*, 8(1), pp.54-63.
- Echols, M.A., 1998. Food safety regulation in the European Union and the United States: different cultures, different laws. *Colum. J. Eur. L.*, 4, p.525.
- Eckinger, J. ed., 2008. *The ethics of intensification: Agricultural development and cultural change* (Vol. 16). Springer Science & Business Media.
- Edelmann, R.H., 1908. *Text-book of meat hygiene*. GE Howard Press.
- Edwards, D.S., Johnston, A.M. and Mead, G.C., 1997. Meat inspection: an overview of present practices and future trends. *The Veterinary Journal*, 154(2), pp.135-147.
- Einagel, V., 2002. Telling stories, making selves. *Subjectivities, knowledges and feminist geographies*. Lanham: Rowman and Littlefield, pp.223-235.

- Ellis, D.I., Brewster, V.L., Dunn, W.B., Allwood, J.W., Golovanov, A.P. and Goodacre, R., 2012. Fingerprinting food: current technologies for the detection of food adulteration and contamination. *Chemical Society Reviews*, 41(17), pp.5706-5727.
- Ehiri, J.E. and Ejere, H., 2008. Hand washing for preventing diarrhoea. *Cochrane Database of Systematic Reviews*, 1.
- Emerson, R.M., Fretz, R.I. and Shaw, L.L., 2001. Participant observation and fieldnotes. *Handbook of ethnography*, pp.352-368.
- Engeström, Y. and Blackler, F., 2005. On the life of the object.
- Entman, R.M., 1993. Framing: Toward clarification of a fractured paradigm. *Journal of communication*, 43(4), pp.51-58.
- Ercsey-Ravasz, M., Toroczka, Z., Lakner, Z. and Baranyi, J., 2012. Correction: Complexity of the International Agro-Food Trade Network and Its Impact on Food Safety. *PLoS one*, 7(10).
- Escalante-Maldonado, O., Kayali, A.Y., Yamazaki, W., Vuddhakul, V., Nakaguchi, Y. and Nishibuchi, M., 2015. Improvement of the quantitation method for the tdh+ *Vibrio parahaemolyticus* in molluscan shellfish based on most-probable-number, immunomagnetic separation, and loop-mediated isothermal amplification. *Frontiers in microbiology*, 6.
- Escobar, A., 1998. Whose knowledge, whose nature? Biodiversity, conservation, and the political ecology of social movements. *Journal of political ecology*, 5(1), pp.53-82.
- ESR, 2016. *Risk Profile: Vibrio parahaemolyticus in Bivalve Molluscan Shellfish*. Prepared by Nicola King, Dorothy-Jean McCoubrey and Peter Cressey. [www.mpi.govt.nz](http://www.mpi.govt.nz)
- EC, 2002. European Commission *Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on Norwalk-like viruses*.
- EC, 2001. European Commission) *Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on Vibrio vulnificus and Vibrio parahaemolyticus (in raw and undercooked seafood)*.
- EFSA, 2006. Risk perception and food safety: where do European consumers stand today? European Food Safety Authority Press Release, February 2006. [www.efsa.europa.eu/en/press/news/060207](http://www.efsa.europa.eu/en/press/news/060207). Accessed 25<sup>th</sup> March 2018.
- EU Food Safety Authority working group on the microbiological monitoring of bivalve mollusc harvesting areas. May 2006. *Guide to Good Practice: Technical Application*.
- European Union Council Directive of 15<sup>th</sup> July 1991. *Laying down the health conditions for the production and the placing on the market of live bivalve molluscs*.
- Eyles, Michael J., and George R. Davey. "Microbiology of commercial depuration of the Sydney rock oyster, *Crassostrea commercialis*." *Journal of Food Protection* 47.9 (1984): 703-712.
- Faisal, M., MacIntyre, E.A., Adham, K.G., Tall, B.D., Kothary, M.H. and La Peyre, J.F., 1998. Evidence for the presence of protease inhibitors in eastern (*Crassostrea virginica*) and Pacific (*Crassostrea gigas*) oysters. *Comparative Biochemistry and Physiology Part B: Biochemistry and Molecular Biology*, 121(2), pp.161-168.
- FAO/WHO, 1995. Application of risk analysis to food standards issues. Report of the Joint FAO/WHO Expert Consultation. Geneva, March, 1995.
- FAO, 1996. Food and Agriculture Organization, 1996. *Rome Declaration on World Food Security and World Food Summit Plan of Action: World Food Summit 13-17 November 1996, Rome, Italy*. FAO.
- FAO/WHO, 1997. *Risk Management and Food Safety*. Report of a Joint FAO/WHO Expert Consultation, Rome, Italy, 1997. FAO Food and Nutrition Paper, Number 65.

FAO, 1998. *Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System*. Food and Agriculture Organization Of The United Nations. Rome, 1998 M-83 ISBN 92-5-104115-6.

FAO/WHO, 2002. Global forum of food safety regulators. *Marrakech, Morocco: World Health Organisation*.

FAO, 2003. Food and Nutrition Paper 76 *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*. Food and Agriculture Organization of the United Nations World Health Organization. Rome, 2003. ISBN 92-5-104918.

FAO, 2004. Expert Consultation on Food Safety: Science and Ethics. Rome, Italy, 3-5<sup>th</sup> September 2002.

FAO/WHO, 2005a. The Codex Alimentarius Commission. <http://www.fao.org/fao-who-codexalimentarius/about-codex/science/en/> Accessed 23<sup>rd</sup> March 2018.

FAO/WHO, 2005b. Risk assessment of *Vibrio vulnificus* in raw oysters. Microbiological risk assessment series No. 8. Food and Agriculture Organization of the United Nations and the World Health Organization, Rome.

FAO/WHO, 2006. Food Safety Risk Analysis. A Guide for National Food Safety Agencies. ISBN 978-92-5-105604-2

FAO/WHO, 2007. FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition [www.fao.org/3/a-a1296e.pdf](http://www.fao.org/3/a-a1296e.pdf)

FAO. 2008. Expert meeting on bioenergy policy, markets and trade and food security and global perspectives on fuel and food security. FAO Headquarters Rome, 18-20 February 2008, options for decision makers. <[http://www.fao.org/ag/agn/agns/files/HLCi\\_Climate\\_Change\\_and Food Safety.pdf](http://www.fao.org/ag/agn/agns/files/HLCi_Climate_Change_and_Food_Safety.pdf)

FAO/WHO, 2011. Risk assessment of *Vibrio parahaemolyticus* in seafood. Microbiological risk assessment series No. 16. Food and Agriculture Organization of the United Nations and the World Health Organization, Rome. <http://www.fao.org/3/a-i2225e.pdf> (accessed: 26 July 2016).

FAO, 2012. *Fisheries and Aquaculture Statistics 2010*. [www.fao.org](http://www.fao.org) (accessed 23<sup>rd</sup> March 2018).

FAO, 2012. *Fisheries and Aquaculture Fact Sheet*. [www.fao.org](http://www.fao.org) 2012

FAO/WHO (2016) Selection and application of methods for the detection and enumeration of human-pathogenic halophilic *Vibrio* spp. in seafood. Food and Agriculture Organization of the United Nations, World Health Organization, Rome. <http://www.fao.org/publications/card/en/c/004643ce-e2eb-4498-8f44-53adc00f1f0e/> (accessed: 12 October 2016).

Farkas, J., and J. Beczner. "Climate change and food safety." *Acta Alimentaria* 40.3 (2011): 313-314.

Farmer Iii, J.J. and Hickman-Brenner, F.W., 2006. The genera vibrio and photobacterium. In *The prokaryotes* (pp. 508-563). Springer New York.

FDA, 2010. *2010 Food Safety Survey: Key Findings and Topline Frequency Report*. [http://google2.fda.gov/search?q=food+safety+survey&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&requiredfields=-archive%3AYes&output=xml\\_no\\_dtd&getfields=\\*](http://google2.fda.gov/search?q=food+safety+survey&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&requiredfields=-archive%3AYes&output=xml_no_dtd&getfields=*)

Featherstone, D., 2011. On assemblage and articulation. *Area*, 43(2), pp.139-142.

Fetterman, D.M. ed., 2010. *Ethnography: Step-by-step* (Vol. 17). Sage.

FIICC (Fishing Industry Inspection and Certification Council). (1995). *New Zealand Fishing Industry Agreed Implementation Standards 005.1 Shellfish Quality Assurance Circular*.

Fisher K, Williams M, FitzHerbert S, Instone L, Duffy M, Wright S, Suchet-Pearson S, Lloyd K, Burarrwanga L, Ganambarr R, Ganambarr-Stubbs M, Ganambarr B, Maymuru D, Bawaka Country (2015). Writing difference differently. *New Zealand Geographer* 71(1): 18-33.

Fitzherbert, S. J., 2015. Geographies of economy-making: the articulation and circulation of taewa Māori across Aotearoa New Zealand PhD thesis Geography University of Auckland, 2015.

- Flattery, J. and Bashin, M., 2003. A baseline survey of raw oyster consumers in four states. In *International Shellfish Sanitation Conference*.
- Flick, U., 2015. *Introducing research methodology: A beginner's guide to doing a research project*. Sage.
- Food Standards.( 2012)  
<http://www.foodstandards.gov.au/consumer/nutrition/iodinefort/pages/default.aspx>
- Ford, J. and Harding, N., 2008. Fear and loathing in Harrogate, or a study of a conference. *Organization*, 15(2), pp.233-250.
- Foucault, M., 1991. *The Foucault effect: Studies in governmentality*. University of Chicago Press.
- Foucault, M., Mazumdar, P. and Sloterdijk, P., 2001. *Foucault*. Dt. Taschenbuch-Verlag.
- Foucault, M., 2003. *The essential Foucault: Selections from essential works of Foucault, 1954-1984*. New Press.
- Foucault, M., 2007. *Security, territory, population: lectures at the Collège de France, 1977-78*. Springer.
- Fraser, C. *Fonterra fined \$183m over contamination scandal*. [www.newshub.co.nz](http://www.newshub.co.nz). Dec, 2017. File accessed 23<sup>rd</sup> March 2018.
- French, M and Phillips, J. (1999). Protecting Consumers' Health and Pockets: approaches to food safety laws in Britain 1860-1938.
- Frewer, L.J., Howard, C. and Shepherd, R., 1997. Public concerns in the United Kingdom about general and specific applications of genetic engineering: Risk, benefit, and ethics. *Science, Technology, & Human Values*, 22(1), pp.98-124.
- Friends of the Earth, Scotland. 2003. *Citizen's Science: What Activists Need to Know*. Friends of Earth, Edinburgh.
- Froelich, B.A. and Noble, R.T., 2016. Vibrio bacteria in raw oysters: managing risks to human health. *Phil. Trans. R. Soc. B*, 371(1689), p.20150209.
- Fudge, E., 2013. The animal face of early modern England. *Theory, Culture & Society*, 30(7-8), pp.177-198.
- Fuenzalida, L., Armijo, L., Zabala, B., Hernández, C., Rioseco, M.L., Riquelme, C. and Espejo, R.T., 2007. Vibrio parahaemolyticus strains isolated during investigation of the summer 2006 seafood related diarrhea outbreaks in two regions of Chile. *International journal of food microbiology*, 117(3), pp.270-275
- Fujimura, J.H., 1992. Crafting science: Standardized packages, boundary objects, and" translation.". *Science as practice and culture*, 168, pp.168-169.
- Fukuda, Keiji. "Food Safety in a Globalized World." *Bulletin of the World Health Organization* 93.4 (2015): 212. *PMC*. Web. 2 Oct. 2015.
- Funtowicz, S.O., Aljer, J.M., Munda, G. and Ravetz, J.R., 1999. *Information tools for environmental policy under conditions of complexity*. Office for official publications of the European communities.
- Funtowicz, S.O. and Ravetz, J.R., 1993. The emergence of post-normal science. In *Science, politics and morality* (pp. 85-123). Springer Netherlands
- Gamson W, Modigliani A (eds). *The Changing Culture of Affirmative Action*. JAI: Greenwich, 1987
- Geneste, C., Dab, W., Cabanes, P.A., Vaillant, V., Quilici, M.L. and Fournier, J.M., 2000. Non-cholera Vibrio isolates in France: cases identified during 1995-1998 by the National Reference Centre. *Bulletin Épidémiologique Hebdomadaire*, (9), pp.38-40.

- Giddens, A., 1991. *Modernity and self-identity: Self and society in the late modern age*. Stanford university press.
- Glaser, B. Strauss (1967). *The Discovery of Grounded Theory; Strategies for Qualitative Research*. State University, Transaction Publishers, New Jersey.
- Goffman E. *Frame Analysis: An Essay in the Organisation of the Experience*. Harper Colophon: New York, 1974.
- Golinski, J., 2008. *Making Natural Knowledge: Constructivism and the History of Science, with a new preface*. University of Chicago Press.
- González-Escalona, N., Cachicas, V., Acevedo, C., Rioseco, M.L., Vergara, J.A., Cabello, F., Romero, J. and Espejo, R.T., 2005. Vibrio parahaemolyticus diarrhea, Chile, 1998 and 2004. *Emerging infectious diseases*, 11(1), p.129.
- Gordon, C. (1991). Governmental Rationality: An Introduction. In G. Burchell, C. Gordon & P. Miller(Eds.), *The Foucault Effect: Studies in Governmentality*. Chicago: The University of Chicago Press.
- Greene, J. C., Caracelli, V. J. and Graham, W. F. 1989. Toward a conceptual framework for mixed-method evaluation designs. *Educational Evaluation and Policy Analysis*, 11: 255–274.
- Greene, M.T., 1997. What cannot be said in science. *Nature*, 388(6643), pp.619-620.
- Greenhough, B., 2011. Assembling an island laboratory. *Area*, 43(2), pp.134-138.
- Gregory, P.J., Ingram, J.S. and Brklacich, M., 2005. Climate change and food security. *Philosophical Transactions of the Royal Society of London B: Biological Sciences*, 360(1463), pp.2139-2148.
- Greimas, A.J., Courtés, J., Crist, L. and Patte, D., 1982. *Semiotics and language: An analytical dictionary* (p. 278). Bloomington: Indiana University Press.
- Griffith, C.J., 2006. Food safety: where from and where to? *British Food Journal*, 108(1), pp.6-15.
- Grunert, K.G., 2005. Food quality and safety: consumer perception and demand. *European review of agricultural economics*, 32(3), pp.369-391.
- Guardino, R.F., 2005. Early history of microbiology and microbiological methods. *Encyclopedia of rapid microbiological methods*, 1, pp.1-27.
- Gupta, D., 2002. Capacity building and technical assistance. New approaches and building alliances. In *FAO/WHO Global Forum of Food Safety Regulators, Marrakesh (Morocco), 28-30 Jan 2002*. FAO.
- Hacking, I., 1999. *The social construction of what?* Harvard university press.
- Hackney, C.R and Pierson, M.D. (1994). *Environmental Indicators and Shellfish Safety*. Chapman & Hall. New York.
- Hage, G. (2005). A Not so multi-sited ethnography for a not so imagined community. *Anthropological Theory*, 5, 463-475.
- Hagendijk, R. and Irwin, A., 2006. Public deliberation and governance: engaging with science and technology in contemporary Europe. *Minerva*, 44(2), pp.167-184.
- Halkier, B. and Holm, L., 2006. Shifting responsibilities for food safety in Europe: An introduction. *Appetite*, 47(2), pp.127-133.
- Hammersley, M. and Atkinson, P., 1995. *Ethnography: Practices and principles*. New York: Routledge.
- Hammond, C., 2005. The wider benefits of adult learning: An illustration of the advantages of multi-method research. *International Journal of Social Research Methodology*, 8(3), pp.239-255.

- Hanft R. (1981). Use of Social Science Data for Policy Analysis and Policy Making. *Milbank Memorial Fund. Quarterly*. 596-613.
- Hanson, T., L. House, S. Sureshwaran, B. Posadas, and A. Liu. July 2003. Opinions of U.S. Consumers Toward Oysters: Results of a 2000-2001 Survey. Mississippi Agricultural and Forestry Experiment Station Bulletin 1133. Mississippi State, MS: Mississippi State University. Available at <http://msucares.com/pubs/bulletins/b1133.pdf>. Accessed July 24, 2010.
- Hara-Kudo, Y. and Kumagai, S., 2014. Impact of seafood regulations for *Vibrio parahaemolyticus* infection and verification by analyses of seafood contamination and infection. *Epidemiology and Infection*, 142(11), pp.2237-224
- Haraway, D., 1988. Situated knowledges: The science question in feminism and the privilege of partial perspective. *Feminist studies*, 14(3), pp.575-599.
- Hardy, A., 1999. Food, hygiene, and the laboratory. A short history of food poisoning in Britain, circa 1850–1950. *Social History of Medicine*, 12(2), pp.293-311.
- Harris, J., 2005. The ordering of things: Organization in Bruno Latour. *The Sociological Review*, 53(1\_suppl), pp.163-177.
- Harris-Young, L., Tamplin, M.L., Mason, J.W., Aldrich, H.C. and Jackson, J.K., 1995. Viability of *Vibrio vulnificus* in Association with Hemocytes of the American Oyster (*Crassostrea virginica*). *Applied and environmental microbiology*, 61(1), pp.52-57.
- Hassard J, Law J, Lee N. Preface. Organization. 1999 Aug;6(3):387-90.
- Hathaway, S.C., 1997. Development of food safety risk assessment guidelines for foods of animal origin in international trade. *Journal of Food Protection*, 60(11), pp.1432-1438.
- Hathaway, S. C. and McKenzie, A.I., 1991. Postmortem meat inspection programs; separating science and tradition. *Journal of Food Protection*, 54(6), pp.471-475.
- Havelaar, A.H., Brul, S., De Jong, A., De Jonge, R., Zwietering, M.H. and Ter Kuile, B.H., 2010. Future challenges to microbial food safety. *International Journal of Food Microbiology*, 139, pp.S79-S94.
- Hay, B.E., Grant, C.M. and McCoubrey, D.J., 2000. A review of the marine biotoxin monitoring programme for non-commercially harvested shellfish. *Report for NZ Ministry of Health*.
- Hayes, P.R. and Forsythe, S.J., 2013. *Food hygiene, microbiology and HACCP*. Springer Science & Business Media.
- Hazen, T.H., Lafon, P.C., Garrett, N.M., Lowe, T.M., Silberger, D.J., Rowe, L.A., Frace, M., Parsons, M.B., Bopp, C.A., Rasko, D.A. and Sobecky, P.A., 2015. Insights into the environmental reservoir of pathogenic *Vibrio parahaemolyticus* using comparative genomics. *Frontiers in microbiology*, 6.
- Health Canada, 2017. Risk Management of *Vibrio parahaemolyticus* in oysters in Canada 1997-2014. *Presentation to 2017 ISSC Vp workshop*.
- Hedberg, C.W., MacDonald, K.L. and Osterholm, M.T., 1994. Changing epidemiology of food-borne disease: a Minnesota perspective. *Clinical infectious diseases*, pp.671-680.
- Heilbron, John L., ed. (2003). *The Oxford Companion to the History of Modern Science*. New York: Oxford University Press. [ISBN 0-19-511229-6](https://doi.org/10.1093/acprof:oso/9780195112296).
- Haendiges, J., Timme, R., Allard, M.W., Myers, R.A., Brown, E.W. and Gonzalez-Escalona, N., 2015. Characterization of *Vibrio parahaemolyticus* clinical strains from Maryland (2012–2013) and comparisons to a locally and globally diverse *V. parahaemolyticus* strains by whole-genome sequence analysis. *Frontiers in microbiology*, 6.
- Hell, K., Mutege, C. and Fandohan, P., 2010. Aflatoxin control and prevention strategies in maize for Sub-Saharan Africa. *Julius-Kühn-Archiv*, (425), p.534.
- Henson, S., 2008. *Public and private incentives to adopt enhanced food safety controls*. International Food Economy Research Group, University of Guelph.

- Henson, S. and Caswell, J., 1999. Food safety regulation: an overview of contemporary issues. *Food policy*, 24(6), pp.589-603.
- Henson, S. and Jaffee, S., 2008. Understanding developing country strategic responses to the enhancement of food safety standards. *The World Economy*, 31(4), pp.548-568.
- Henson, S., Masakure, O. and Boselie, D., 2005. Private food safety and quality standards for fresh produce exporters: The case of Hortico Agrisystems, Zimbabwe. *Food policy*, 30(4), pp.371-384.
- Henwood, K. and Pidgeon, N. (1996) *Grounded theory*. In J. T. E. Richardson (ed.), *Handbook of Qualitative Research Methods*. Leicester: BPS.
- Henry, M. and Roche, M., 2013. Valuing lively materialities: Bio-economic assembling in the making of new meat futures. *New Zealand Geographer*, 69(3), pp.197-207.
- Herbert, S. 2000. For ethnography. *Progress in human geography*, 24(4), pp.550-568.
- Hess, D.J., 1997. *Science studies: An advanced introduction*. NYU press.
- Hetherington, K. and Law, J., 2000. After networks.
- Higgins, V. Dibden, J. Biosecurity, trade liberalisation, and the (anti)politics of risk analysis: the Australia New Zealand apples dispute. *Environment and Planning A* 2011. Volume 43, pages 393 – 409.
- Hill, A., 2015. Moving from “matters of fact” to “matters of concern” in order to grow economic food futures in the Anthropocene. *Agriculture and human values*, 32(3), pp.551-563.
- Hinchliffe, S., 2001. Indeterminacy in-decisions—science, policy and politics in the BSE (Bovine Spongiform Encephalopathy) crisis. *Transactions of the Institute of British Geographers*, 26(2), pp.182-204.
- Hinchliffe, S., 2007. *Geographies of nature: societies, environments, ecologies*. Sage.
- Hine, C. (2007). Multi-sited ethnography as a middle range methodology for contemporary STS. *Science, Technology & Human Values*, 32, 653-671.
- Hlady, W.G., Mullen, R.C. and Hopkin, R.S., 1993. *Vibrio vulnificus* from raw oysters. Leading cause of reported deaths from foodborne illness in Florida. *The Journal of the Florida Medical Association*, 80(8), pp.536-538.
- Hoge, C.W., Watsky, D., Peeler, R.N., Libonati, J.P., Israel, E. and Morris Jr, J.G., 1989. Epidemiology and spectrum of *Vibrio* infections in a Chesapeake Bay community. *Journal of Infectious Diseases*, 160(6), pp.985-993.
- Holleran, E., Bredahl, M.E. and Zaibet, L., 1999. Private incentives for adopting food safety and quality assurance. *Food policy*, 24(6), pp.669-683.
- Hollis, D.G., Weaver, R.E., Baker, C.N. and Thornsberry, C., 1976. Halophilic *Vibrio* species isolated from blood cultures. *Journal of Clinical Microbiology*, 3(4), pp.425-431.
- Hooghe, L. and Marks, G., 2003. Unraveling the Central State, But How? Types of Multi-Level Governance. IHS Political Science Series: 2003, No. 87.
- Horkheimer, M., Adorno, T.W. and Noeri, G., 2002. *Dialectic of enlightenment*. Stanford University Press.
- Horseman, M.A. and Surani, S., 2011. A comprehensive review of *Vibrio vulnificus*: an important cause of severe sepsis and skin and soft-tissue infection. *International Journal of Infectious Diseases*, 15(3), pp.e157-e166.

- Huehn, S., Eichhorn, C., Urmersbach, S., Breidenbach, J., Bechlars, S., Bier, N., Alter, T., Bartelt, E., Frank, C., Oberheitmann, B. and Gunzer, F., 2014. Pathogenic vibrios in environmental, seafood and clinical sources in Germany. *International Journal of Medical Microbiology*, 304(7), pp.843-850.
- Hulebak, K.L. and Schlosser, W., 2002. Hazard analysis and critical control point (HACCP) history and conceptual overview. *Risk analysis*, 22(3), pp.547-552.
- Hurley, C.C., Quirke, A., Reen, F.J. and Boyd, E.F., 2006. Four genomic islands that mark post-1995 pandemic *Vibrio parahaemolyticus* isolates. *BMC genomics*, 7(1), p.104.
- Hussain, M.A. and Dawson, C.O., 2013. Economic impact of food safety outbreaks on food businesses. *Foods*, 2(4), pp.585-589.
- Hunt, L., 2010. How Writing Leads to Thinking (And not the other way around). *Art of History Column, Perspectives on History*.
- Huxley, M., 2008. Space and government: Governmentality and geography. *Geography Compass*, 2(5), pp.1635-1658.
- ICMSFS National Advisory Committee on Microbiological Criteria for Foods. HACCP report. November 1989. Section 4.1, p. 6).
- Ivakhiv, A., 2014. On Matters of Concern.
- Jackson, L.S., 2009. Chemical food safety issues in the United States: past, present, and future. *Journal of agricultural and food chemistry*, 57(18), pp.8161-8170.
- Jacob, C., Mathiasen, L. and Powell, D., 2010. Designing effective messages for microbial food safety hazards. *Food Control*, 21(1), pp.1-6.
- Jacobs, J., 2016. *The death and life of great American cities*. Vintage.
- Jamieson, D., 2000. Prediction in society. *Prediction: Science, decision-making and the future of nature*, eds., DR Sarewitz, RA Pielke, and R. Byerly, pp.315-26.
- Jasanoff, S., 1992. Pluralism and convergence in international science policy. *Science and Sustainability: Selected Papers on IIASA'S 20th Anniversary*, pp.157-180.
- Jasanoff, S., 1995. Procedural choices in regulatory science. *Technology in society*, 17(3), pp.279-293.
- Jasanoff, S., 1997. Civilization and madness: the great BSE scare of 1996. *Public understanding of science*, 6(3), pp.221-232. Jasanoff, S., 1997. Civilization and madness: the great BSE scare of 1996. *Public understanding of science*, 6(3), pp.221-232.
- Jasanoff, S., 2003. Technologies of humility: citizen participation in governing science. *Minerva*, 41(3), pp.223-244.
- Jasanoff, S., 2012. *Science and public reason*. Routledge.
- Jasanoff, S., Markle, G.E. and Petersen, J.C., Trevor Pinch, eds. 1995. *Handbook of science and technology studies*, p.478.
- Jay, J.M. (2000) *Modern Food Microbiology*, sixth edition, p. 7. Aspen Publishers Inc., Gaithersburg, Maryland.
- Johnecheck, W., 2008. *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO*. By Alberto Alemanno (Vol. 11, No. 2, pp. 495-500). Oxford University Press.
- Jones, J.L., Lüdeke, C.H., Bowers, J.C., Garrett, N., Fischer, M., Parsons, M.B., Bopp, C.A. and DePaola, A., 2012. Biochemical, serological, and virulence characterization of clinical and oyster *Vibrio parahaemolyticus* isolates. *Journal of clinical microbiology*, pp.JCM-00196.

- Jones J L, Kinsey T P, Johnson L W, Porso R, Friedman B, Curtis M, Wesighan P, Schuster R and Bowers J C (2016) Effects of intertidal harvest practices on *Vibrio parahaemolyticus* and *Vibrio vulnificus* levels in oysters. *Applied and Environmental Microbiology*; 82: 4517-4522.
- Johnson, C.N., Bowers, J.C., Griffitt, K.J., Molina, V., Clostio, R.W., Pei, S., Laws, E., Paranjpye, R.N., Strom, M.S., Chen, A. and Hasan, N.A., 2012. Ecology of *Vibrio parahaemolyticus* and *Vibrio vulnificus* in the coastal and estuarine waters of Louisiana, Maryland, Mississippi, and Washington (United States). *Applied and environmental microbiology*, 78(20), pp.7249-7257.
- Johnson, C.N., Flowers, A.R., Noriega, N.F., Zimmerman, A.M., Bowers, J.C., DePaola, A. and Grimes, D.J., 2010. Relationships between environmental factors and pathogenic vibrios in the northern Gulf of Mexico. *Applied and environmental microbiology*, 76(21), pp.7076-7084.
- Johnson, R.B. and Onwuegbuzie, A.J., 2004. Mixed methods research: A research paradigm whose time has come. *Educational researcher*, 33(7), pp.14-26.
- Johnston, S.F., 2018. Alvin Weinberg and the promotion of the technological fix. *Technology and Culture*.
- Joseph, Sam W., Rita R. Colwell, and James B. Kaper. "Vibrio parahaemolyticus and related halophilic vibrios." *Critical reviews in microbiology* 10.1 (1982): 77-124.
- Judt, T., 2010. Ill fares the land: A treatise on our present discontent. NY: Penguin Books.
- Käferstein, F., and Mohammed Abdussalam. "Food safety in the 21st century." *Bulletin of the World Health Organization* 77.4 (1999): 347.
- Kahneman, D., 2011. *Thinking, fast and slow*. Macmillan.
- Kahneman, D. and Tversky, A., 1979. Prospect theory: An analysis of decision under risk. *Econometrica: Journal of the econometric society*, pp.263-291.
- Kaneko, T. and Colwell, R.R., 1973. Ecology of *Vibrio parahaemolyticus* in Chesapeake Bay. *Journal of bacteriology*, 113(1), pp.24-32.
- Kathariou, S., 2002. *Listeria monocytogenes* virulence and pathogenicity, a food safety perspective. *Journal of food protection*, 65(11), pp.1811-1829.
- Kawharu, M. Kaitiakitanga: A Maori Anthropological Perspective of The Maori Socio-Environmental Ethic of Resource Management. *The Journal of the Polynesian Society*. Vol. 109, No. 4, December 2000.
- Keener, K.M., Bashor, M.P., Curtis, P.A., Sheldon, B.W. and Kathariou, S., 2004. Comprehensive review of *Campylobacter* and poultry processing. *Comprehensive Reviews in Food Science and Food Safety*, 3(2), pp.105-116.
- Kerr, D., 1999. Beheading the king and enthroning the market: A critique of Foucauldian governmentality. *Science & Society*, pp.173-202.
- Kim, Y.B., Okuda, J., Matsumoto, C., Takahashi, N., Hashimoto, S. and Nishibuchi, M., 1999. Identification of *Vibrio parahaemolyticus* strains at the species level by PCR targeted to the *toxR* gene. *Journal of Clinical Microbiology*, 37(4), pp.1173-1177.
- Kimbrell, E., 2001. What is codex alimentarius?
- Kinsey, T.P., Lydon, K.A., Bowers, J.C. and Jones, J.L., 2015. Effects of dry storage and resubmersion of oysters on total *Vibrio vulnificus* and total and pathogenic (*tdh+*/*trh+*) *Vibrio parahaemolyticus* levels. *Journal of food protection*, 78(8), pp.1574-1580.
- Kirs M, Depaola A, Fyfe R, Jones J L, Krantz J, Van Laanen A, Cotton D and Castle M (2011) A survey of oysters (*Crassostrea gigas*) in New Zealand for *Vibrio parahaemolyticus* and *Vibrio vulnificus*. *International Journal of Food Microbiology*; 147: 149-153.

- Kleinman, D.L. and Suryanarayanan, S., 2013. Dying bees and the social production of ignorance. *Science, Technology, & Human Values*, 38(4), pp.492-517.
- Klontz, K.C., Desenclos, J.C.A., Wolfe, L.E., Hoecherl, S.A., Roberts, C. and Gunn, R.A., 1991. The Raw Oyster Consumer: A Risk Taker? Use of the Behavioral Risk Factor Surveillance System. *Epidemiology*, pp.437-440.
- Klontz, K.C., Timbo, B., Fein, S. and Levy, A., 1995. Prevalence of selected food consumption and preparation behaviors associated with increased risks of food-borne disease. *Journal of Food Protection*, 58(8), pp.927-930.
- Klontz, K. C., Williams, L., Baldy, L. M. and Campos, M. 1993. Raw oyster-associated *Vibrio* infections: linking epidemiologic data with laboratory testing of oysters obtained from a retail outlet. *J. Food Protect.*, 56: 977–979.
- Knechtges, P.L., 2011. *Food safety: Theory and practice*. Jones & Bartlett Publishers.
- Knight, D.M., 1975. *Sources for the History of Science, 1660-1914*. CUP Archive.
- Koo, J., DePAOLA, A.N.G.E.L.O. and Marshall, D.L., 2000a. Effect of simulated gastric fluid and bile on survival of *Vibrio vulnificus* and *Vibrio vulnificus* phage. *Journal of food protection*, 63(12), pp.1665-1669.
- Koo, J., DePAOLA, A.N.G.E.L.O. and Marshall, D.L., 2000b. Impact of acid on survival of *Vibrio vulnificus* and *Vibrio vulnificus* phage. *Journal of food protection*, 63(8), pp.1049-1052.
- Koo, J., Marshall, D.L. and DePaola, A., 2001. Antacid increases survival of *Vibrio vulnificus* and *Vibrio vulnificus* phage in a gastrointestinal model. *Applied and environmental microbiology*, 67(7), pp.2895-2902.
- Koolmees, P.A., 2000. Veterinary inspection and food hygiene in the twentieth century. *Food, Science, Policy and Regulation in the Twentieth Century: International and Comparative Perspectives (London, New York: Routledge, 2000)*, pp.53-68.
- Kopytoff, I., 1986. The cultural biography of things: commoditization as process. *The social life of things: Commodities in cultural perspective*, 68, pp.70-73.
- Koren, H. and Bisesi, M.S., 2002. *Handbook of environmental health, volume I: Biological, chemical, and physical agents of environmentally related disease (Vol. 1)*. CRC Press.
- Krurup, T.M. and Blok, A., 2011. Unfolding the social: quasi-actants, virtual theory, and the new empiricism of Bruno Latour. *The Sociological Review*, 59(1), pp.42-63.
- Kuhn, T.S., 1962. 1970. *The structure of scientific revolutions*, pp.31-65.
- Kuiper, H.A., Kleter, G.A., Noteborn, H.P. and Kok, E.J., 2001. Assessment of the food safety issues related to genetically modified foods. *The plant journal*, 27(6), pp.503-528.
- Kumagai, S. Occurrence of *Vibrio parahaemolyticus* foodborne infections. Report on *Vibrio parahaemolyticus* foodborne infections [in Japanese]. Tokyo: Committee of Milk, Meat and Seafood in Food Sanitation Investigation Council, pp. 4-6, 2000.
- Kurlansky, M., 2007. *The big oyster: history on the half shell*. Random House.
- Kushi, L.H., Lenart, E.B. and Willett, W.C., 1995. Health implications of Mediterranean diets in light of contemporary knowledge. 1. Plant foods and dairy products. *The American journal of clinical nutrition*, 61(6), pp.1407S-1415S.
- Kwan, S., 2009. Framing the fat body: contested meanings between government, activists, and industry. *Sociological Inquiry*, 79(1), pp.25-50.
- Labaree, R.V., 2002. The risk of 'going observationalist': negotiating the hidden dilemmas of being an insider participant observer. *Qualitative Research*, 2(1), pp.97-122.

- Lake R, Hudson J and Cressey P (2003) Risk Profile: *Vibrio parahaemolyticus* in seafood. Institute of Environmental Science and Research Limited, Christchurch. <http://www.foodsafety.govt.nz/science-risk/risk-assessment/risk-profiles/> (accessed: 28 June 2016).
- Lammerding, A.M. and Fazil, A., 2000. Hazard identification and exposure assessment for microbial food safety risk assessment. *International journal of food microbiology*, 58(3), pp.147-157.
- Lang, T., 2005. Food control or food democracy? Re-engaging nutrition with society and the environment. *Public health nutrition*, 8(6a), pp.730-737.
- Lásztity, R., Petró-Turza, M. and Földesi, T., 2009. History of food quality standards. *Food Quality and Standards-Volume I*, 10, p.62.
- Latimer, J. and Miele, M., 2013. Naturecultures? Science, affect and the non-human. *Theory, Culture & Society*, 30 (7-8), pp.5-31.
- Latour, B., 1983. Give me a laboratory and I will raise the world. *Science observed*, pp.141-170.
- Latour, B., 1986. The powers of association. *The Sociological Review*, 32(S1), pp.264-280.
- Latour, B., 1987. *Science in action: How to follow scientists and engineers through society*. Harvard university press.
- Latour, B., 1988. The pasteurization of France (A. Sheridan and J. Law, Trans.) Harvard University Press. Cambridge, MA.
- Latour, B., 1992. One more turn after the social turn: Easing science studies into the non-modern world. *The social dimensions of science*, 292.
- Latour, B., 1993 *We Have Never Been Modern*. London: Harvester Wheatsheaf
- Latour, B., 1996. On actor-network theory: A few clarifications. *Soziale welt*, pp.369-381.
- Latour, B., 1999. On recalling ANT. *The Sociological Review*, 47(S1), pp.15-25.
- Latour, B., 2000. When things strike back: a possible contribution of 'science studies' to the social sciences. *The British Journal of Sociology*, 51(1), pp.107-123.
- Latour, B., 2003. Is re-modernization occurring-and if so, how to prove it? A commentary on Ulrich Beck. *Theory, culture & society*, 20(2), pp.35-48.
- Latour, B., 2004. Why has critique run out of steam? From matters of fact to matters of concern. *Critical inquiry*, 30(2), pp.225-248.
- Latour, B., 2005. *Reassembling the Social: An Introduction to Actor-Network-Theory*. Oxford: Oxford UP.
- Latour, B. and Woolgar, S., 1979. *Laboratory life: The social construction of scientific facts*. Beverly Hills.
- Law, J. 1987. Technology, Closure and Heterogeneous Engineering: The Case of Portuguese Expansion. In *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology*, ed. W E. Jijker, T. Pinch and T. Hughes, 111-134. Cambridge, MA, MIT Press.
- Law, J. (1991) 'Introduction: Monsters, machines and sociotechnical relations'. In J. Law (ed.) *A sociology of monsters: Essays on power, technology and domination*. London: Routledge
- Law, J., 1994. 1994: Organizing modernity. Oxford: Blackwell.
- Law, J. and Hassard, J., 1999. Actor network theory and after.
- Lee, K. 1989. *Food Neophobia: Major causes and treatments*. *Food Technol.* 43, 62–73.
- Lee, N. and Brown, S., 1994. Otherness and the actor network: the undiscovered continent. *American Behavioral Scientist*, 37(6), pp.772-790.

- Legard, R., Keegan, J. and Ward, K., 2003. In-depth interviews. *Qualitative research practice: A guide for social science students and researchers*, pp.138-169.
- Le Heron, E., Le Heron, R. and Lewis, N., 2013. Wine economy as open assemblage: thinking beyond sector and region. *New Zealand Geographer*, 69(3), pp.221-234.
- Lemke, T., 2001. 'The birth of bio-politics': Michel Foucault's lecture at the Collège de France on neo-liberal governmentality. *Economy and society*, 30(2), pp.190-207.
- Lemke, T., 2002. Foucault, governmentality, and critique. *Rethinking marxism*, 14(3), pp.49-64.
- Lengwiler, M., 2008. Participatory approaches in science and technology: Historical origins and current practices in critical perspective. *Science, Technology, & Human Values*, 33(2), pp.186-200.
- Lewis, J. (2003). Design Issues. In J. Ritchie & J Lewis (Eds). *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: Sage Publications Ltd.
- Lewis, N., 2016. Governmentality at work in shaping a critical geographical politics. In *Handbook of Neoliberalism* (pp. 101-111). Routledge.
- Lewis, N. and Rosin, C., 2013. Epilogue: Emergent (re-) assemblings of biological economies. *New Zealand Geographer*, 69(3), pp.249-256.
- Lewis, N., Le Heron, R. and Campbell, H., 2017. The Mouse That Died: Stabilizing Economic Practices in Free Trade Space. In *Assembling Neoliberalism* (pp. 151-170). Palgrave Macmillan US.
- Liao, Y., Li, Y., Wu, S., Mou, J., Xu, Z., Cui, R., Klena, J.D., Shi, X., Lu, Y., Qiu, Y. and Lin, Y., 2015. Risk factors for *Vibrio parahaemolyticus* infection in a Southern Coastal Region of China. *Foodborne pathogens and disease*, 12(11), pp.881-886.
- Life Magazine*, 1997. special edition on "The Millennium".
- Lippi, D. and Gotuzzo, E., 2014. The greatest steps towards the discovery of *Vibrio cholerae*. *Clinical Microbiology and Infection*, 20(3), pp.191-195.
- López-Hernández, K.M., Pardío-Sedas, V.T., Lizárraga-Partida, L., Williams, J.D.J., Martínez-Herrera, D., Flores-Primo, A., Uscanga-Serrano, R. and Rendón-Castro, K., 2015. Environmental parameters influence on the dynamics of total and pathogenic *Vibrio parahaemolyticus* densities in *Crassostrea virginica* harvested from Mexico's Gulf coast. *Marine pollution bulletin*, 91(1), pp.317-329.
- Loureiro, M.L. and Umberger, W.J., 2007. A choice experiment model for beef: What US consumer responses tell us about relative preferences for food safety, country-of-origin labeling and traceability. *Food policy*, 32(4), pp.496-514.
- Loyola, D.E., Navarro, C., Uribe, P., García, K., Mella, C., Díaz, D., Valdes, N., Martínez-Urtaza, J. and Espejo, R.T., 2015. Genome diversification within a clonal population of pandemic *Vibrio parahaemolyticus* seems to depend on the life circumstances of each individual bacteria. *BMC genomics*, 16(1), p.176.
- Lucretius. *The nature of the universe*. Harmondsworth, England: Penguin, 1951. (English translation by R. E. Latham.)
- Lüdeke, C.H., Gonzalez-Escalona, N., Fischer, M. and Jones, J.L., 2015. Examination of clinical and environmental *Vibrio parahaemolyticus* isolates by multi-locus sequence typing (MLST) and multiple-locus variable-number tandem-repeat analysis (MLVA). *Frontiers in microbiology*, 6.
- Lupton, D.A., 2005. Lay discourses and beliefs related to food risks: an Australian perspective. *Sociology of health & illness*, 27(4), pp.448-467.
- Macdonald, R.W., Harner, T. and Fyfe, J., 2005. Recent climate change in the Arctic and its impact on contaminant pathways and interpretation of temporal trend data. *Science of the total environment*, 342(1), pp.5-86.

- Macome, E., 2008. On implementation of an information system in the mozambican context: The EDM case viewed through ANT lenses. *Information Technology for Development*, 14(2), pp.154-170.
- Madigan, T., Smith, G., Wilson, K. and Turnbull, A. 2016. Pathogenic Vibrio species in Tasmanian Oysters. *PIRSA Power Point Presentation to Australian Shellfish Quality Assurance Workshop* 26<sup>th</sup> October 2016.
- Mahmoud, B.S.M., 2014. Controlling Vibrio vulnificus and spoilage bacteria in fresh shucked oysters using natural antimicrobials. *Letters in applied microbiology*, 58(1), pp.1-7.
- Malcolm, T.T.H., Cheah, Y.K., Radzi, C.W.J.W.M., Kasim, F.A., Kantilal, H.K., John, T.Y.H., Martinez-Urtaza, J., Nakaguchi, Y., Nishibuchi, M. and Son, R., 2015. Detection and quantification of pathogenic Vibrio parahaemolyticus in shellfish by using multiplex PCR and loop-mediated isothermal amplification assay. *Food control*, 47, pp.664-671.
- Malik, A., Masood, F. and Ahmad, S., 2014. Food processing: Strategies for quality assessment, a broad perspective. In *Food Processing: Strategies for Quality Assessment* (pp. 1-8). Springer New York.
- Mallard, A., 1998. Compare, standardize and settle agreement: On some usual metrological problems. *Social Studies of Science*, 28(4), pp.571-601.
- Marchak, P. M. (1991). *The Integrated Circus: The New Right and the Restructuring of Global Markets*. McGill-Queens University Press.
- Marcus, G.E., 1995. Ethnography in/of the world system: The emergence of multi-sited ethnography. *Annual review of anthropology*, 24(1), pp.95-117.
- Marks, H.M., Coleman, M.E., Lin, C.T.J. and Roberts, T., 1998. Topics in microbial risk assessment: dynamic flow tree process. *Risk Analysis*, 18(3), pp.309-328.
- Marsden, Terry. 2000. "Food Matters and the Matter of Food: Towards a New Food Governance?" *Sociologia Ruralis* 40(1):20–9.
- Martin, B., 1993. The critique of science becomes academic. *Science, Technology, & Human Values*, 18(2), pp.247-259.
- Marques, A., Nunes, M.L., Moore, S.K. and Strom, M.S., 2010. Climate change and seafood safety: human health implications. *Food Research International*, 43(7), pp.1766-1779.
- Martinez-Urtaza, J., Baker-Austin, C., Jones, J.L., Newton, A.E., Gonzalez-Aviles, G.D. and DePaola, A., 2013. Spread of Pacific Northwest Vibrio parahaemolyticus strain. *New England Journal of Medicine*, 369(16), pp.1573-1574.
- May, Peter J. "Regulatory regimes and accountability." *Regulation & Governance* 1.1 (2007): 8-26.
- Maxwell, E.L., Mayall, B.C., Pearson, S.R. and Stanley, P.A., 1991. A case of Vibrio vulnificus septicaemia acquired in Victoria. *The Medical journal of Australia*, 154(3), pp.214-215.
- Maxwell, S. and Slater, R., 2003. Food policy old and new. *Development policy review*, 21(5-6), pp.531-553.
- McCabe-Sellers, B.J. and Beattie, S.E., 2004. Food safety: emerging trends in foodborne illness surveillance and prevention. *Journal of the American Dietetic Association*, 104(11), pp.1708-1717.
- McCarthy, S.A. and Blackstone, G.M., 2000. DNA isolation methods for detection of pathogenic Vibrio parahaemolyticus by PCR. In *Lab. Inform. Bull.* (Vol. 4222, pp. 1-13). Department of Health and Human Services Rockville, MD.
- McCoubrey, 1996. Risk of Vibrio vulnificus Infection Following Consumption of Raw Commercially Harvested North Island Oysters. MPH thesis submitted to the University of Auckland.
- McCoubrey, D.J. (2007). *Negotiating the Boundary between Science and Policy to Protect New Zealand's Shellfish Harvest Areas*. MSc thesis submitted to the University of Auckland.

- McGinn, M.K. and Roth, W.M., 1999. Preparing students for competent scientific practice: Implications of recent research in science and technology studies. *Educational Researcher*, 28(3), pp.14-24.
- McKechnie, S. and S. Davies. (1999). "Consumers and Risk". In, *Risk Communication and Public Health*. P. Bennet and K. Calman, (eds), New York, Oxford University Press, pp. 170-182.
- McKee, K., 2009. Post-Foucauldian governmentality: What does it offer critical social policy analysis? *Critical social policy*, 29(3), pp.465-486.
- McKenzie, A. (July 2006). *The First Three Years*. Challenges for NZFSA. [www.nzfsa.govt.nz](http://www.nzfsa.govt.nz)
- McLaughlin, J.B., DePaola, A., Bopp, C.A., Martinek, K.A., Napolilli, N.P., Allison, C.G., Murray, S.L., Thompson, E.C., Bird, M.M. and Middaugh, J.P., 2005. Outbreak of *Vibrio parahaemolyticus* gastroenteritis associated with Alaskan oysters. *New England Journal of Medicine*, 353(14), pp.1463-1470.
- Mercer, J., 2007. The challenges of insider research in educational institutions: Wielding a double-edged sword and resolving delicate dilemmas. *Oxford Review of Education*, 33(1), pp.1-17.
- Merriam, S.B., Johnson-Bailey, J., Lee, M.Y., Kee, Y., Ntseane, G. and Muhamad, M., 2001. Power and positionality: Negotiating insider/outsider status within and across cultures. *International Journal of Lifelong Education*, 20(5), pp.405-416.
- Merrill, Richard A., and Jeffrey K. Francer. "Organizing federal food safety regulation." *Seton Hall L. Rev.* 31 (2000): 61
- Meyer-Rochow, V.B., 2009. Food taboos: their origins and purposes. *Journal of Ethnobiology and Ethnomedicine*, 5(1), p.18.
- Mill, R.C. (2001), *Restaurant Management: Customers, Operations, and Employees*, 2nd ed., Prentice Hall, Englewood Cliffs, NJ
- Miller, J. 1992. *Risk benefit*. In *Food Safety*, (J.M. Jones, ed.) Chapter 4, Eagan Press, MN.
- Miller, P., & Rose, N. (2008). Governing Economic Life. *Governing the Present* (pp.26-52). Cambridge: Polity Press.
- Millstone, E. and Van Zwanenberg, P., 2002. The evolution of food safety policy—Making institutions in the UK, EU and Codex Alimentarius. *Social Policy & Administration*, 36(6), pp.593-609.
- MPI (Ministry of Primary Enterprise). 2013. [www.foodsmart.govt.nz/food-safety/high-risk-foods/raw-milk/rawmilk.htm](http://www.foodsmart.govt.nz/food-safety/high-risk-foods/raw-milk/rawmilk.htm). Accessed 15<sup>th</sup> November 2014.
- MPI (Ministry of Primary Industries). *Russia (RUS) Overseas Market Access Requirements* [www.mpi.govt.nz](http://www.mpi.govt.nz). Accessed November 2017.
- Miraglia, M., Marvin, H.J.P., Kleter, G.A., Battilani, P., Brera, C., Coni, E., Cubadda, F., Croci, L., De Santis, B., Dekkers, S. and Filippi, L., 2009. Climate change and food safety: an emerging issue with special focus on Europe. *Food and chemical toxicology*, 47(5), pp.1009-1021.
- Mol, A., 2002. *The body multiple: Ontology in medical practice*. Duke University Press.
- Mol, A., 2010. Actor-network theory: Sensitive terms and enduring tensions. *Kölner Zeitschrift für Soziologie und Sozialpsychologie. Sonderheft*, 50, pp.253-269.
- Morens, D.M., Folkers, G.K. and Fauci, A.S., 2004. The challenge of emerging and re-emerging infectious diseases. *Nature*, 430(6996), pp.242-249.
- Morgan, O.A., G.S. Martin, and W.L. Huth. 2009. "Oyster Demand Adjustments to Counter-Information and Source Treatments in Response to *Vibrio vulnificus*." *Journal of Agricultural and Applied Economics* 41(3):683-696.
- Moriarty, D.J.W., 1998. Control of luminous *Vibrio* species in penaeid aquaculture ponds. *Aquaculture*, 164(1), pp.351-358.

- Morris Jr, J.G. and Acheson, D., 2003. Cholera and other types of vibriosis: a story of human pandemics and oysters on the half shell. *Clinical Infectious Diseases*, 37(2), pp.272-280.
- Moser, I. and Law, J., 2006. Fluids or flows? Information and qualculation in medical practice. *Information Technology & People*, 19(1), pp.55-73.
- Motarjemi, Y., Käferstein, F., Moy, G. and Quevedo, F., 1993. Contaminated weaning food: a major risk factor for diarrhoea and associated malnutrition. *Bulletin of the World Health Organization*, 71(1), p.79.
- Motarjemi, Y. and Käferstein, F., 1999. Food safety, Hazard Analysis and Critical Control Point and the increase in foodborne diseases: a paradox? *Food Control*, 10(4-5), pp.325-333.
- Motes, M.L. and DePaola, A., 1996. Offshore suspension relaying to reduce levels of *Vibrio vulnificus* in oysters (*Crassostrea virginica*). *Applied and Environmental Microbiology*, 62(10), pp.3875-3877.
- Motes, M.L., DePaola, A., Cook, D.W., Veazey, J.E., Hunsucker, J.C., Garthright, W.E., Blodgett, R.J. and Chirtel, S.J., 1998. Influence of Water Temperature and Salinity on *Vibrio vulnificus* in Northern Gulf and Atlantic Coast Oysters (*Crassostrea virginica*). *Applied and environmental microbiology*, 64(4), pp.1459-1465.
- Moturi, W.K.N., 2008. Factors likely to enhance mycotoxin introduction into the human diet through maize in Kenya. *African Journal of Food, Agriculture, Nutrition and Development*, 8(3), pp.265-277.
- Mossel, D.A.A., Corry, J.E., Struijk, C.B. and Baird, R.M., 1995. *Essentials of the microbiology of foods: a textbook for advanced studies*. John Wiley & Sons.
- Mulkay, M., 1979. Knowledge and utility: Implications for the sociology of knowledge. *Social Studies of Science*, 9(1), pp.63-80.
- Muniesa, F., Millo, Y. and Callon, M., 2007. An introduction to market devices. *The sociological review*, 55(s2), pp.1-12.
- Murdoch, J., 1997. Inhuman/nonhuman/human: actor-network theory and the prospects for a nondualistic and symmetrical perspective on nature and society. *Environment and planning D: Society and Space*, 15(6), pp.731-756.
- Nachman K and Lawrence, R.S. (2013). *An Introduction to the US Food System; Perspective from Public Health*. Johns Hopkins Bloomberg School of Public Health (on line course).
- Nair, G.B., Ramamurthy, T., Bhattacharya, S.K., Dutta, B., Takeda, Y. and Sack, D.A., 2007. Global dissemination of *Vibrio parahaemolyticus* serotype O3: K6 and its serovariants. *Clinical microbiology reviews*, 20(1), pp.39-48.
- NAS, U., 1983. National Academy of Science: risk assessment in the federal government: managing the process. National Research Council, Committee on the Institutional Means for Assessment of Risks to Public Health.
- NAS. (National Academy of Sciences) 1994. *Science and Policy in Risk Assessment* Washington, D.C.
- Natarajan R, Abraham M and Nair G B (1980) Distribution of *Vibrio parahaemolyticus* in Porto Novo environment. *Indian Journal of Medical Research*; 71: 679-687.
- National Assessment Institute (1994), *Handbook for Safe Food Service Management*, Upper Saddle River, Regents/Prentice Hall, Englewood Cliffs, NJ.
- National Research Council, 1996. *Understanding risk: Informing decisions in a democratic society*. National Academies Press.
- NSSP (National Shellfish Sanitation Programme) 2015. [www.issc.org](http://www.issc.org). Accessed 23<sup>rd</sup> March 2018
- NSSP. *Manual Part 1*. (1995). Historical section
- Nell, John A. "Farming triploid oysters." *Aquaculture* 210.1 (2002): 69-88.

- Nell, J.A. and Holliday, J.E., 1988. Effects of salinity on the growth and survival of Sydney rock oyster (*Saccostrea commercialis*) and Pacific oyster (*Crassostrea gigas*) larvae and spat. *Aquaculture*, 68(1), pp.39-44.
- Nestle, M., 2013. *Food politics: How the food industry influences nutrition and health* (Vol. 3). Univ of California Press.
- Newell, D.G., Koopmans, M., Verhoef, L., Duizer, E., Aidara-Kane, A., Sprong, H., Opsteegh, M., Langelaar, M., Threfall, J., Scheutz, F. and van der Giessen, J., 2010. Food-borne diseases—the challenges of 20 years ago still persist while new ones continue to emerge. *International journal of food microbiology*, 139, pp. S3-S15.
- Newton, A.E., Garrett, N., Stroika, S.G., Halpin, J.L., Turnsek, M. and Mody, R.K., 2014. Notes from the field: increase in *Vibrio parahaemolyticus* infections associated with consumption of atlantic coast shellfish-2013. *MMWR Morb Mortal Wkly Rep*, 63, pp.335-336.
- Neyland, D., 2006. Dismissed content and discontent: An analysis of the strategic aspects of actor-network theory. *Science, technology, & human values*, 31(1), pp.29-51.
- Nigro, O.D. and Steward, G.F., 2015. Differential specificity of selective culture media for enumeration of pathogenic vibrios: Advantages and limitations of multi-plating methods. *Journal of microbiological methods*, 111, pp.24-30.
- Nimmo, R., 2011. Bovine mobilities and vital movements: Flows of milk, mediation and animal agency. *Animal Movements-Moving Animals: Essays on Direction, Velocity and Agency in Humanimal Encounters*, pp.57-74.
- Nip-Sakamoto, C.J. and Pien, F.D., 1989. *Vibrio vulnificus* infection in Hawaii. *International journal of dermatology*, 28(5), pp.313-316.
- Nordstrom, J.L., Kaysner, C.A., Blackstone, G.M., Vickery, M.C.L., Bowers, J.C. and DePaola, A., 2004. Effect of intertidal exposure on *Vibrio parahaemolyticus* levels in Pacific Northwest oysters. *Journal of food protection*, 67(10), pp.2178-2182.
- Nowotny, H., 1990. Knowledge for certainty: poverty, welfare institutions and the institutionalization of social science. In *Discourses on Society* (pp. 23-41). Springer Netherlands.
- Nowotny, Helga. "A New Branch of Science, Inc." *Science, Politics and Morality*. Springer Netherlands, 1993. 63-84.
- Nowotny, H., 1993. Socially distributed knowledge: five spaces for science to meet the public. *Public Understanding of Science*, 2(4), pp.307-319.
- Nydam, S.D., Shah, D.H. and Call, D.R., 2014. Transcriptome analysis of *Vibrio parahaemolyticus* in type III secretion system 1 inducing conditions. *Frontiers in cellular and infection microbiology*, 4.
- NZFSA. *Food Focus* November 2005. [www.nzfsa.govt.nz](http://www.nzfsa.govt.nz)
- Odeyemi, O.A., 2016. Incidence and prevalence of *Vibrio parahaemolyticus* in seafood: a systematic review and meta-analysis. *SpringerPlus*, 5(1), p.464.
- OECD-FAO, 21 Fish and seafood - OECD-FAO Agricultural Outlook 2013-2022. <http://www.oecd.org/site/oecd-faoagriculturaloutlook/fish-seafood.htm> Accessed 25<sup>th</sup> March 2018
- O'Leary, Z., 2005. *Researching real-world problems: A guide to methods of inquiry*. Sage.
- Oliver, J., 2015. *The biology of Vibrio vulnificus*. *Microbiol. Spect.* 3. doi: 10.1128/microbiolspec. VE-0001-2014.
- Oliver, J.D., Roberts, D.M., White, V.K., Dry, M.A. and Simpson, L.M., 1986. Bioluminescence in a strain of the human pathogenic bacterium *Vibrio vulnificus*. *Applied and environmental microbiology*, 52(5), pp.1209-1211.

- O'Neill, K.R., Jones, S.H. and Grimes, D.J., 1992. Seasonal incidence of *Vibrio vulnificus* in the Great Bay estuary of New Hampshire and Maine. *Applied and Environmental Microbiology*, 58(10), pp.3257-3262.
- (OMRA) Ontario Ministry of Agriculture Food and Rural Affairs. 1997. A General Framework for Food Safety Risk Assessment.
- Opara, L.U., 2003. Traceability in agriculture and food supply chain: a review of basic concepts, technological implications, and future prospects. *Journal of Food Agriculture and Environment*, 1, pp.101-106.
- ORC Macro. 2004. Raw Oyster Consumer Follow-up Survey: 2004 Technical report. www.issc.org
- Ottaviani, D., Santarelli, S., Bacchiocchi, S., Masini, L., Ghittino, C. and Bacchiocchi, I., 2005. Presence of pathogenic *Vibrio parahaemolyticus* strains in mussels from the Adriatic Sea, Italy. *Food microbiology*, 22(6), pp.585-590
- Otto, S. L. (2011) *Fool me Twice Fighting the Assault on Science in America*. New York; Rodale.
- Oyekale, K.O., Daniel, I.O., Ajala, M.O. and Sanni, L.O., 2012. Potential longevity of maize seeds under storage in humid tropical seed stores. *Nature and Science*, 10(8), pp.114-124.
- OXERA, 2000. *Policy, risk and science: Securing and using scientific advice*. 205. Oxera Economic Research Associates Ltd. Oxford. United Kingdom
- Pan, A., Sun, Q., Bernstein, A.M., Schulze, M.B., Manson, J.E., Stampfer, M.J., Willett, W.C. and Hu, F.B., 2012. Red meat consumption and mortality: results from 2 prospective cohort studies. *Archives of internal medicine*, 172(7), pp.555-563.
- Panicker, G., Call, D.R., Krug, M.J. and Bej, A.K., 2004. Detection of pathogenic *Vibrio* spp. in shellfish by using multiplex PCR and DNA microarrays. *Applied and Environmental Microbiology*, 70(12), pp.7436-7444.
- Paranjpye, R., Hamel, O.S., Stojanovski, A. and Liermann, M., 2012. Genetic diversity of clinical and environmental *Vibrio parahaemolyticus* strains from the Pacific Northwest. *Applied and environmental microbiology*, 78(24), pp.8631-8638.
- Park, Seok Don, Hyung Sun Shon, and Nam Joong Joh. "Vibrio vulnificus septicemia in Korea: clinical and epidemiologic findings in seventy patients." *Journal of the American Academy of Dermatology* 24, no. 3 (1991): 397-403.
- Paustenbach, D.J., 1995. The practice of health risk assessment in the United States (1975–1995): How the US and other countries can benefit from that experience. *Human and Ecological Risk Assessment*, 1(1), pp.29-79.
- Pawson, E. and Perkins, H., 2013. Worlds of wool: Recreating value off the sheep's back. *New Zealand Geographer*, 69(3), pp.208-220.
- Paz, S., Bisharat, N., Paz, E., Kidar, O. and Cohen, D., 2007. Climate change and the emergence of *Vibrio vulnificus* disease in Israel. *Environmental Research*, 103(3), pp.390-396.
- PCE - Parliamentary Commissioner for the Environment. (2004). *Missing Links: Connecting science with environmental policy*.
- Petersen, A., 1997. Risk, governance and the new public health. *Foucault, health and medicine*, pp.189-206.
- Phillips, J., 2006. Agencement/assemblage. *Theory Culture and Society*, 23(2/3), p.108.
- Picciotto, S., 2002. Introduction: Reconceptualizing regulation in the era of globalization. *Journal of Law and society*, pp.1-11.
- Pickering, A. ed., 1992. *Science as practice and culture*. University of Chicago Press.

- Pien, F.R.A.N.C.I.S., Lee, K.H.E.N.G. and Higa, H.E.N.R.Y., 1977. *Vibrio alginolyticus* infections in Hawaii. *Journal of clinical microbiology*, 5(6), p.670.
- Pillsbury Company (1973) '*Food Safety Through the Hazard Analysis and Critical Control Point System*', Contract no. FDA 72-59, Pillsbury Company, Research & Development Department, Minneapolis, USA 1973).
- Plotkin, B.J., Kilgore, S.G. and McFarland, L., 1990. Polyvibrio infections: *Vibrio vulnificus* and *Vibrio parahaemolyticus* dual wound and multiple site infections. *Journal of Infectious Diseases*, 161(2), pp.364-365.
- Poortinga, W. and Pidgeon, N.F., 2005. Trust in risk regulation: cause or consequence of the acceptability of GM food? *Risk analysis*, 25(1), pp.199-209.
- Posadas, B.C., and R.A. Posadas. 2004. "Consumer Preferences for Postharvest Processed Raw Oyster Products in Coastal Mississippi." In Final Report: Integrated Oyster Market Research, Product Development, Evaluation, Promotion and Consumer Education for the Gulf of Mexico's Oyster Industry, T. Jamir, et al., ed., pp. 56– 73. Sea Grant Contract #NA16RG2195 (GSAFF # 88) Project R/LR-Q-23 Year II. Tampa, FL: Gulf and South Atlantic Fisheries Foundation, Inc. Available at [http://www.gulfsouthfoundation.org/report&publications\\_info.htm](http://www.gulfsouthfoundation.org/report&publications_info.htm). As obtained on November 12, 2010.
- Powell, Mark, Wayne Schlosser, and Eric Ebel. "Considering the complexity of microbial community dynamics in food safety risk assessment." *International journal of food microbiology* 90.2 (2004): 171-179.
- Powell, D.A., Jacob, C.J. and Chapman, B.J., 2011. Enhancing food safety culture to reduce rates of foodborne illness. *Food Control*, 22(6), pp.817-822.
- Powitz, R.W., 2004. Inspections. 2. Expectations. *Foodsafety magazine*.
- Prasad, A.S., Mantzoros, C.S., Beck, F.W., Hess, J.W. and Brewer, G.J., 1996. Zinc status and serum testosterone levels of healthy adults. *Nutrition*, 12(5), pp.344-348.
- Pratt, S. and Matthews, K., 2006. *Superfoods: Fourteen foods that will change your life*. Random House.
- Proctor, R., 1991. *Value-free science?: Purity and power in modern knowledge*. Harvard University Press.
- Raghunath, P., 2011. Genetic markers of pandemic *Vibrio parahaemolyticus*: are they truly unique? *Foodborne pathogens and disease*, 8(5), pp.653-654.
- Ralston, E.P., Kite-Powell, H. and Beet, A., 2011. An estimate of the cost of acute health effects from food-and water-borne marine pathogens and toxins in the USA. *Journal of water and health*, 9(4), pp.680-694.
- Ramesh, C.K. and Jamuna, K.S., 2012. Concepts and trends of functional foods: a review. *International Journal of Pharmaceutical Research and Development (IJPRD)*. UPRD, 4(06), pp.273-290.
- Ramos, R.J., Miotto, M., Squella, F.J.L., Cirolini, A., Ferreira, J.F. and Vieira, C.R.W., 2012. Depuration of oysters (*Crassostrea gigas*) contaminated with *Vibrio parahaemolyticus* and *Vibrio vulnificus* with UV light and chlorinated seawater. *Journal of food protection*, 75(8), pp.1501-1506.
- Ravetz, J.R., 1987. Usable knowledge, usable ignorance: incomplete science with policy implications. *Knowledge*, 9(1), pp.87-116.
- Reid, J. 2013. *Governing Sustainable Agriculture: A case study of the farming of highly erodible hill country in the Manawatu-Wanganui region of New Zealand*. PhD Thesis. Massey University.
- Reille, P., 1907. Huitres et fièvres typhoïdes. *Anni. ihyg. publ. et T'Med. Le'gale. Par*, 4.

- Reilly, A. and Käferstein, F., 1997. Food safety hazards and the application of the principles of the hazard analysis and critical control point (HACCP) system for their control in aquaculture production. *Aquaculture research*, 28(10), pp.735-752.
- Rempel, G., 2003. Age of enlightenment.
- Rennie, D., 2003. Editorial peer review: its development and rationale. *Peer review in health sciences*, 2, pp.1-13.
- Richards, G.P., Fay, J.P., Dickens, K.A., Parent, M.A., Soroka, D.S. and Boyd, E.F., 2012. Predatory bacteria as natural modulators of *Vibrio parahaemolyticus* and *Vibrio vulnificus* in seawater and oysters. *Applied and environmental microbiology*, 78(20), pp.7455-7466.
- Richardson, G., 2001. A tale of two theories: monopolies and craft guilds in medieval England and modern imagination. *Journal of the history of economic thought*, 23(2), pp.217-242.
- Rittel, H.W. and Webber, M.M., 1973. Dilemmas in a general theory of planning. *Policy sciences*, 4(2), pp.155-169.
- Roberts, G.C., 1975. Sex and achievement motivation effects on risk taking. *Research Quarterly. American Alliance for Health, Physical Education and Recreation*, 46(1), pp.58-70.
- Rodrigues, D.P., Ribeiro, R.V. and Hofer, E., 1992. Analysis of some virulence factors of *Vibrio vulnificus* isolated from Rio de Janeiro, Brazil. *Epidemiology & Infection*, 108(3), pp.463-467.
- Roemer van Toorn, "No More Dreams?" *Harvard Design Magazine*, no. 21 (Fall 2004/Winter 2005): 30
- Roizman, B. Editor. (1995). *Infectious Diseases in an Age of Change: the Impact of Human Ecology and Behaviour on Disease Transmission*. The National Academies Press.
- Ropkins, K. and Beck, A.J., 2000. Evaluation of worldwide approaches to the use of HACCP to control food safety. *Trends in Food Science & Technology*, 11(1), pp.10-21.
- Rothstein, H.F., 2004. Precautionary bans or sacrificial lambs? Participative risk regulation and the reform of the UK food safety regime. *Public Administration*, 82(4), pp.857-881.
- Rose, N., O'Malley, P., & Valverde, M. (2006). Governmentality. *Annual Review of Law and Social Science*, 2, 83-104.
- Rosec, J.P., Causse, V., Cruz, B., Rauzier, J. and Carnat, L., 2012. The international standard ISO/TS 21872-1 to study the occurrence of total and pathogenic *Vibrio parahaemolyticus* and *Vibrio cholerae* in seafood: ITS improvement by use of a chromogenic medium and PCR. *International journal of food microbiology*, 157(2), pp.189-194.
- Ross, A.I., 1958. The Food Hygiene Regulations, with Special Reference to Food Poisoning. *Journal (Royal Society of Health)*, 78(6), pp.715-723.
- Rouse, J., 1987. Knowledge and power: Toward a political philosophy of science.
- Royal Society (1983). *Risk Assessment*. A Study Group Report. (London, U.K: The Royal Society).
- Royal Society. 1992. *Risk, Analysis, Perception, Management: Report of a Royal Society Study Group*, London: The Royal Society.
- Ryan C. 1991. *Prime Time Activism: Media Strategies for Grass Roots Organizing*. South End Press: Boston, MA.
- Rykovskaia, O.A., Mazrukho, A.V., Smolikova, L.M., Monakhova, E.V., Chemisova, O.S., Podoinitsyna, O.A., Allenov, A.V., Khomenko, T.V., Zhironov, A., Sanamiants, E.M. and Gaevskaia, N.M., 2013. O3: K6 serogroup vibrio parahaemolyticus-the causative agent of food toxic infection outbreaks in Primorsky region of Russian federation. *Zhurnal mikrobiologii, epidemiologii, i immunobiologii*, (4), pp.57-61.
- Sachs, I., 2009. Revisiting development in the twenty-first century. *International Journal of political economy*, 38(3), pp.5-21.

- SAGE. (1999). Council of Science and Technology Advisors. *SAGE Science Advice for Government Effectiveness. A Report of the Council and Technology Advisors*. May 1999.
- Saguy, A.C. and Almeling, R., 2008, March. Fat in the fire? Science, the news media, and the “obesity epidemic”. In *Sociological Forum* (Vol. 23, No. 1, pp. 53-83). Blackwell Publishing Ltd.
- Saito, S., Iwade, Y., Tokuoka, E., Nishio, T., Otomo, Y., Araki, E., Konuma, H., Nakagawa, H., Tanaka, H., Sugiyama, K. and Hasegawa, A., 2015. Epidemiological Evidence of Lesser Role of Thermostable Direct Hemolysin (TDH)–Related Hemolysin (TRH) Than TDH on *Vibrio parahaemolyticus* Pathogenicity. *Foodborne pathogens and disease*, 12(2), pp.131-138.
- SALMON, J.W., 1989. Dilemmas in studying social change versus individual change: Considerations from political economy. *Health Promotion International*, 4(1), pp.43-49.
- Salter, L. (1988). *Mandated Science. Science and Scientists in the Making of Standards*. Kluwer Academic Publishers.
- Sassen, S., 2008. *Territory, authority, rights: From medieval to global assemblages*. Princeton university press.
- Saraswathi, K., Barve, S.M. and Deodhar, L.P., 1989. Septicaemia due to *Vibrio vulnificus*. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 83(5), p.714.
- Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., Roy, S.L., Jones, J.L. and Griffin, P.M., 2011. Foodborne illness acquired in the United States—major pathogens. *Emerging infectious diseases*, 17(1), p.7.
- Schafer, R.B., Schafer, E., Bultena, G.L. and Hoiberg, E.O., 1993. Food safety: An application of the health belief model. *Journal of Nutrition Education*, 25(1), pp.17-24.
- Schiedek, D., Sundelin, B., Readman, J.W. and Macdonald, R.W., 2007. Interactions between climate change and contaminants. *Marine pollution bulletin*, 54(12), pp.1845-1856.
- Schlosser, E. (2002). *Fast Food Nation*. Harpers Collins Publications, New York.
- Scholthof, K.B.G., 2007. The disease triangle: pathogens, the environment and society. *Nature Reviews Microbiology*, 5(2), pp.152-156.
- Scott, C., 2002. Private regulation of the public sector: a neglected facet of contemporary governance. *Journal of Law and Society*, 29(1), pp.56-76.
- Scrinis, G., 2008. Functional foods or functionally marketed foods? A critique of, and alternatives to, the category of functional foods'. *Public health nutrition*, 11(5), p.541.
- SCVMRPH (2001) Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on *Vibrio vulnificus* and *Vibrio parahaemolyticus* (in raw and undercooked seafood). Adopted on 19-20 September 2001. European Commission, Brussels.
- Seaman, P. and Eves, A., 2006. The management of food safety—the role of food hygiene training in the UK service sector. *International Journal of Hospitality Management*, 25(2), pp.278-296.
- Seamon, D. and Zajonc, A. eds., 1998. *Goethe's way of science: A phenomenology of nature*. SUNY Press.
- Serageldin, I., 1999. Biotechnology and food security in the 21st century. *Science*, 285(5426), pp.387-389.
- Shah, D.V., Watts, M.D., Domke, D. and Fan, D.P., 2002. News framing and cueing of issue regimes: Explaining Clinton's public approval in spite of scandal. *Public Opinion Quarterly*, 66(3), pp.339-370.
- Shapin, S., 1992. Discipline and bounding: The history and sociology of science as seen through the externalism-internalism debate. *History of science*, 30(4), pp.333-369.
- Shumway, S.E. and Rodrick, G.E. eds., 2009. *Shellfish safety and quality*. Elsevier.

- Silbergeld, E.K., Graham, J. and Price, L.B., 2008. Industrial food animal production, antimicrobial resistance, and human health. *Annu. Rev. Public Health*, 29, pp.151-169.
- Siegel, M., Doner, L. and Lotenberg, L., 1998. Marketing public health. *Gaithersburg, Maryland: Aspen Publishers*.
- Silvester, R., Alexander, D., Santha, S. and Hatha, M., 2016. RAPD PCR discloses high genetic heterogeneity among *Vibrio parahaemolyticus* from various environments along the southwest coast of India. *Annals of Microbiology*, 66(2), pp.925-929.
- Simmons, G. Garbutt, C. Hewitt, J. Greening, G. (2007). A New Zealand outbreak of norovirus gastroenteritis linked to the consumption of imported raw Korean oysters. *Journal of New Zealand Medical Association* 26<sup>th</sup> October 2007. Volume 120. No 1264.
- Sims, J.N., Isokpehi, R.D., Cooper, G.A., Bass, M.P., Brown, S.D., St John, A.L., Gulig, P.A. and Cohly, H.H., 2011. Visual analytics of surveillance data on foodborne vibriosis, United States, 1973–2010. *Environmental health insights*, 5, p.71.
- Singh, O.V., Ghai, S., Paul, D. and Jain, R.K., 2006. Genetically modified crops: success, safety assessment, and public concern. *Applied microbiology and biotechnology*, 71(5), pp.598-607.
- Sismondo, S., 2004. Pharmaceutical maneuvers. *Social Studies of Science*, 34(2), pp.149-159.
- Skovgaard, N., 2007. New trends in emerging pathogens. *International journal of food microbiology*, 120(3), pp.217-224.
- Slovic, P. (1987). Perception of risk. *Science*, 236, 280–285.
- Smith, M. and Marx, L., 1994. Technological determinism in American culture.
- Smith, W., 2001. *Measuring and Ensuring Excellence in Government Science and Technology: International Practices. New Zealand and Australia*. University of Auckland, New Zealand.
- Smith, W. (2002). *A Report to the Office of the Chief Scientist: Health Canada*
- Smith, W. and Halliwell, J., 1999. *Principles and practices for using scientific advice in government decision making: international best practices*. Industry Canada.
- Smith, L.E., Stoltzfus, R.J. and Prendergast, A., 2012. Food chain mycotoxin exposure, gut health, and impaired growth: a conceptual framework. *Advances in Nutrition: An International Review Journal*, 3(4), pp.526-531.
- Somers, E., 1995. Perspectives on risk management. *Risk Analysis*, 15(6), pp.677-684.
- Sperber, W.H., 2005. HACCP does not work from farm to table. *Food control*, 16(6), pp.511-514.
- Spinuzzi, C., 2003. <http://spinuzzi.blogspot.co.nz/2007/01/reading-body-multiple.html>
- Spinuzzi, C., 2008. *Theorizing knowledge work in telecommunications*. Cambridge, UK: Cambridge University Press.
- Starr, C., 1969. Social benefit versus technological risk. *Science*, pp.1232-1238.
- Starr, C., 1985. Risk management, assessment, and acceptability. *Risk Analysis*, 5(2), pp.97-102.
- Starr, P., 1978. *The social transformation of American medicine* (Doctoral dissertation, Harvard University).
- Stavric, Stanislava, and Barbara Buchanan. "Does *Vibrio vulnificus* present a health threat to Canadians?" *Canadian Journal of Infectious Diseases and Medical Microbiology* 8, no. 5 (1997): 279-285.
- Stern, P.C. and Fineberg, H.V., 1996. National Research Council Committee on Risk Characterization Understanding Risk. Informing Decisions in a Democratic Society.

- Strauss, A.L., 1987. *Qualitative analysis for social scientists*. Cambridge University Press.
- Strom, M.S. and Paranjpye, R.N., 2000. Epidemiology and pathogenesis of *Vibrio vulnificus*. *Microbes and infection*, 2(2), pp.177-188.
- Stuart, D. 2010. Science, Standards and Power: New Food Safety Governance in California. *Journal of Rural Social Science*, 25(3), 2010, pp 111-140.
- Suffredini, E., Lanni, L., Arcangeli, G., Pepe, T., Mazzette, R., Ciccaglioni, G. and Croci, L., 2014. Qualitative and quantitative assessment of viral contamination in bivalve molluscs harvested in Italy. *International journal of food microbiology*, 184, pp.21-26.
- Sultana, Farhana. 2007. "Reflexivity, Positionality and Participatory Ethics: Negotiating Fieldwork Dilemmas in International Research." *ACME* 6 (3): 374–385.
- Sun, Yi, and James D. Oliver. "Hot sauce: no elimination of *Vibrio vulnificus* in oysters." *Journal of Food Protection* 58.4 (1995): 441-442.
- Tamplin, M.L. and Capers, G.M., 1992. Persistence of *Vibrio vulnificus* in tissues of Gulf Coast oysters, *Crassostrea virginica*, exposed to seawater disinfected with UV light. *Applied and Environmental Microbiology*, 58(5), pp.1506-1510.
- Tamura, N., Kobayashi, S., Hashimoto, H. and Hirose, S., 1993. Reactive arthritis induced by *Vibrio parahaemolyticus*. *The Journal of rheumatology*, 20(6), pp.1062-1063.
- Tannenbaum, P.H., 1963. Communication of Science Information: Presentations in the mass media are often based on a misconception of the public's interests and views. *Science*, 140(3567), pp.579-583.
- Tashakkori, A. and Teddlie, C. eds., 2010. *Sage handbook of mixed methods in social & behavioral research*. Sage.
- Tauxe, R.V., 1997. Emerging foodborne diseases: an evolving public health challenge. *Emerging infectious diseases*, 3(4), p.425.
- Tauxe, R.V., 2002. Emerging foodborne pathogens. *International journal of food microbiology*, 78(1), pp.31-41.
- Taylor, B. Options for Resolving Environmental Risk Disputes. *Public Sector*, Vol.20. No. 3 Pp 1417
- Tebbutt, G.M., 1986. An evaluation of various working practices in shops selling raw and cooked meats. *Epidemiology & Infection*, 97(1), pp.81-90.
- Teubner, G., 2006. Rights of Non-humans? Electronic Agents and Animals as New Actors in Politics and Law. *Journal of Law and Society*, 33(4), pp.497-521.
- The Bug's Blog: Actor-Network-Theory: Terms and Concepts. *Bruno Latour, Action-Network-Theory, and Dismantling Hierarchies*. January 26, 2009.
- Thibodeau, P.H. and Boroditsky, L., 2013. Natural language metaphors covertly influence reasoning. *PloS one*, 8(1), p.52961.
- Thornton V, Hazell W and Simmons G (2002) Acute gastroenteritis associated with seafood privately imported from the Pacific Islands. *New Zealand Medical Journal*; 115: 234-236.
- Tirado, M.C., Clarke, R., Jaykus, L.A., McQuatters-Gollop, A. and Frank, J.M., 2010. Climate change and food safety: A review. *Food Research International*, 43(7), pp.1745-1765.
- Travis, G.D.L. and Collins, H.M., 1991. New light on old boys: Cognitive and institutional particularism in the peer review system. *Science, Technology, & Human Values*, 16(3), pp.322-341.
- Trienekens, J. and Zuurbier, P., 2008. Quality and safety standards in the food industry, developments and challenges. *International Journal of Production Economics*, 113(1), pp.107-122.

Turner, J.W., Paranjpye, R.N., Landis, E.D., Biryukov, S.V., González-Escalona, N., Nilsson, W.B. and Strom, M.S., 2013. Population structure of clinical and environmental *Vibrio parahaemolyticus* from the Pacific Northwest coast of the United States. *PLoS One*, 8(2), p.e55726.

Unnevehr, L.J., 2000. Food safety issues and fresh food product exports from LDCs. *Agricultural Economics*, 23(3), pp.231-240.

Unnevehr, L. and Hirschhorn, N., 2000. *Food safety issues in the developing world* (Vol. 469). World Bank Publications.

USFDA (1994) Proceedings of the 1994 *Vibrio vulnificus* workshop. June 15-26, 1994, Washington DC. United States Food and Drug Administration and the National Marine Fisheries Service.

US Food and Drug Administration circular. April 2003. *Raw Oyster Myths* April 2003

USFDA (2005) Quantitative risk assessment on the public health impact of pathogenic *Vibrio parahaemolyticus* in raw oysters (interpretive summary). United States Food and Drug Administration, Silver Spring, MD.  
<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm050421.htm> (accessed: 26 July 2016).

USFDA (2012) Bad bug book. Handbook of foodborne pathogenic microorganisms and natural toxins (2nd edition). United States Food and Drug Administration, Silver Spring, MD.  
<http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/default.htm> (accessed: 28 June 2016).

van Leeuwen, C.J. and Vermeire, T.G. eds., 2007. *Risk assessment of chemicals: an introduction*. Springer Science & Business Media.

Veenstra, J., Rietra, P.J.G.M., Coster, J.M., Slaats, E. and Dirks-Go, S., 1994. Seasonal variations in the occurrence of *Vibrio vulnificus* along the Dutch coast. *Epidemiology & Infection*, 112(2), pp.285-290.

Vermeulen, Sonja J., Bruce M. Campbell, and John SI Ingram. "Climate change and food systems." *Annual Review of Environment and Resources* 37.1 (2012): 195

Venkateswaran, K., Kiiyukia, C., Nakanishi, K., Nakano, H., Matsuda, O. and Hashimoto, H., 1990. The role of sinking particles in the overwintering process of *Vibrio parahaemolyticus* in a marine environment. *FEMS microbiology letters*, 73(2), pp.159-166.

Vezzulli, L., Grande, C., Reid, P.C., Hélaouët, P., Edwards, M., Höfle, M.G., Brettar, I., Colwell, R.R. and Pruzzo, C., 2016. Climate influence on *Vibrio* and associated human diseases during the past half-century in the coastal North Atlantic. *Proceedings of the National Academy of Sciences*, p.201609157.

Villee, Walker and Barnes. (1978). *General Zoology*. 5<sup>th</sup> Edition. 1978. Philadelphia, USA.

Vogel, D., 2003. The hare and the tortoise revisited: The new politics of consumer and environmental regulation in Europe. *British Journal of Political Science*, 33(4), pp.557-580.

Von Schomberg. (1993). *Science, Politics and Morality. Scientific Uncertainty in Decision Making*. Frankfurt, Germany.

Vuddhakul V, Chowdhury A, Laohaprerthisan V, Pungrasamee P, Patararungrong N, Thianmontri P, Ishibashi M, Matsumoto C and Nishibuchi M (2000) Isolation of a pandemic O3:K6 clone of a *Vibrio parahaemolyticus* strain from environmental and clinical sources in Thailand. *Applied and Environmental Microbiology*; 66: 2685-2689

Vugia, D.J., Tabnak, F., Newton, A.E., Hernandez, M. and Griffin, P.M., 2013. Impact of 2003 state regulation on raw oyster-associated *Vibrio vulnificus* illnesses and deaths, California, USA. *Emerging infectious diseases*, 19(8), p.1276.

- Wagley, S., Koofhethile, K., Wing, J.B. and Rangdale, R., 2008. Comparison of *V. parahaemolyticus* isolated from seafoods and cases of gastrointestinal disease in the UK. *International journal of environmental health research*, 18(4), pp.283-293.
- Wang C-Y, Huang H-W, Hsu C-P, Shyu Y-T and Yang B B (2013) Inactivation and morphological damage of *Vibrio parahaemolyticus* treated with high hydrostatic pressure. *Food Control*; 32: 348-353.
- Wang, H.Z., Wong, M.M., O'Toole, D., Mak, M.M., Wu, R.S. and Kong, R.Y., 2006. Identification of a DNA methyltransferase gene carried on a pathogenicity island-like element (VPAI) in *Vibrio parahaemolyticus* and its prevalence among clinical and environmental isolates. *Applied and environmental microbiology*, 72(6), pp.4455-4460.
- Wang, Y., Li, D., Wang, Y., Li, K. and Ye, C., 2016. Rapid and sensitive detection of *Vibrio parahaemolyticus* and *Vibrio vulnificus* by multiple endonuclease restriction real-time loop-mediated isothermal amplification technique. *Molecules*, 21(1), p.111.
- Watts, Duncan J. *Everything is Obvious; how common sense fails*. Duncan J. Watts. Atlantic Books, London. 2011.
- Watson, S.R., 1981. On risks and acceptability. *Journal of the society for radiological protection*, 1(4), p.21.
- Weeks, B.S. and Alcamo, I.E., 2008. *Microbes and society*. Jones & Bartlett Learning.
- Weinberg, A.M., 1972. Science and trans-science. *Minerva*, 10(2), pp.209-222.
- Weisbecker, A. Oysters, a Simple Food with a Complicated History. Food Safety News. February 2010. [www.foodsafetynews.com](http://www.foodsafetynews.com) Accessed 23<sup>rd</sup> March 2018.
- Weiss, R.A. and McMichael, A.J., 2004. Social and environmental risk factors in the emergence of infectious diseases. *Nature medicine*, 10(12s), pS70.
- Wennersten, J., 2007. *The oyster wars of Chesapeake Bay*. Lulu. com.
- Wesselink, A., Buchanan, K.S., Georgiadou, Y. and Turnhout, E., 2013. Technical knowledge, discursive spaces and politics at the science–policy interface. *Environmental Science & Policy*, 30, pp.1-9.
- Wetz, J.J., Blackwood, A.D., Fries, J.S., Williams, Z.F. and Noble, R.T., 2014. Quantification of *Vibrio vulnificus* in an estuarine environment: a multi-year analysis using QPCR. *Estuaries and coasts*, 37(2), pp.421-435.
- Whitham, C. Epidemiology talk. *Proceedings of the 1994 Vibrio vulnificus workshop*. June 1994. Sponsored by Department of Health & Human Services, Department of Commerce, ISSC.
- White, J.S., 2008. Straight talk about high-fructose corn syrup: what it is and what it ain't. *The American journal of clinical nutrition*, 88(6), pp.1716S-1721S.
- Whyte, A.V. and Burton, I., 1982. Perception of risks in Canada. *Living with risk*. Institute of Environmental Studies, University of Toronto.
- Wilcock, A., Pun, M., Khanona, J. and Aung, M., 2004. Consumer attitudes, knowledge and behaviour: a review of food safety issues. *Trends in Food Science & Technology*, 15(2), pp.56-66.
- Wildavsky, A., 1979. Views: No Risk Is the Highest Risk of All: A leading political scientist postulates that an overcautious attitude toward new technological developments may paralyze scientific endeavor and end up leaving us less safe than we were before. *American scientist*, 67(1), pp.32-37.
- Williams, R. and Edge, D., 1996. The social shaping of technology. *Research policy*, 25(6), pp.865-899.
- Wilson, G.S., 1943. The pasteurization of milk. *British Medical Journal*, 1(4286), p.261.
- Wilson, John Sullivan, and Tsunehiro Otsuki. *Global trade and food safety: winners and losers in a fragmented system*. Vol. 2689. World Bank Publications, 2001

- Wilson, R. and Crouch, E.A., 1987. Risk assessment and comparisons: an introduction. *Science*, 236, pp.267-271.
- Wongpaitoon, V., Sathapatayavongs, B., Prachaktam, R., Bunyaratvej, S. and Kurathong, S., 1985. Spontaneous *Vibrio vulnificus* peritonitis and primary sepsis in two patients with alcoholic cirrhosis. *American Journal of Gastroenterology*, 80(9).
- WHO, 1984. The role of food safety in health and development: report of a joint FAO/WHO expert committee on food safety. In *The role of food safety in health and development: report of a joint FAO/WHO expert committee on food safety*.
- WHO, 2002. *The world health report 2002: reducing risks, promoting healthy life*. World Health Organization.
- WHO, 2003. *Emerging Issues in Water and Infectious Disease*. World Health Organization Marketing and Dissemination. Geneva, Switzerland.
- WHO Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.
- WHO, FAO 2005. Risk assessment of *Vibrio vulnificus* in raw oysters: interpretative summary and technical report, microbiological risk assessment series 8: Geneva: World Health Organization. *Rome: Food and Agriculture Organization of the United Nations*.
- WHO, FAO 2006. World Health Organization and Food and Agriculture Organization. *Food safety risk analysis: A guide for national food safety authorities*.
- WHO, FAO, 2011. Risk assessment of *Vibrio parahaemolyticus* in seafood-Interpretative summary and technical report. *Microbiological risk assessment series, 200*.
- Wright, A.C., Hill, R.T., Johnson, J.A., Roghman, M.C., Colwell, R.R. and Morris, J.G., 1996. Distribution of *Vibrio vulnificus* in the Chesapeake Bay. *Applied and environmental microbiology*, 62(2), pp.717-724.
- Wright, A.C., Simpson, L.M., Oliver, J.D. and Morris, J.G., 1990. Phenotypic evaluation of acapsular transposon mutants of *Vibrio vulnificus*. *Infection and immunity*, 58(6), pp.1769-1773.
- Wright J M (1991) *Vibrio vulnificus*: Two case reports. *New Zealand Journal of Medical Laboratory Science*; 45: 55-56.
- WTO, 2005a. Sanitary and Phytosanitary Measures. Available from: [http://www.wto.org/english/tratop\\_e/sps\\_e/sps\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/sps_e.htm) (Last visited 23<sup>rd</sup> March, 2018).
- WTO, 2005b. Agreement on Technical Barriers to Trade. Available from: [http://www.wto.org/english/docs\\_e/legal\\_e/17-tbt\\_e.htm](http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm) (Last visited 23<sup>rd</sup> March, 2018).
- [www.fao.org](http://www.fao.org). FAO/WHO 1950. The 1950 Special Session of the Conference of FAO.
- [www.fda.gov](http://www.fda.gov). (2013). *USFDA The Imported Food Safety Program*.
- Zbilut, J.P. and Giuliani, A., 2008. Biological uncertainty. *Theory in Biosciences*, 127(3), pp.223-227.
- Zhang, X.H. and Austin, B., 2005. Haemolysins in *Vibrio* species. *Journal of Applied Microbiology*, 98(5), pp.1011-1019.
- Zimmerman, A.M., DePaola, A., Bowers, J.C., Krantz, J.A., Nordstrom, J.L., Johnson, C.N. and Grimes, D.J., 2007. Variability of total and pathogenic *Vibrio parahaemolyticus* densities in northern Gulf of Mexico water and oysters. *Applied and Environmental Microbiology*, 73(23), pp.7589-7596.
- Zlotkin, S., Siekmann, J., Lartey, A. and Yang, Z., 2010. The role of the Codex Alimentarius process in support of new products to enhance the nutritional health of infants and young children. *Food and nutrition bulletin*, 31(2\_suppl2), pp. S128-S133.
- Zsidosin, George A., et al. "An analysis of supply risk assessment techniques." *International Journal of Physical Distribution & Logistics Management* 34.5 (2004): 397-413. 64.