Food Standards Agency
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# Risk Profile: Oysters

# Contents

# 1 Executive summary

The Exposure Assessment and Trade (EAT) Team at the Food Standards Agency (FSA) was commissioned by the UK Office for Sanitary and Phytosanitary Trade Assurance (UKOSPSTA) to produce a risk profile to inform the potential risks associated with importing oysters into the United Kingdom (UK) from any trading partner.

This risk profile considered the hazards that may be associated with the import of oysters into the UK that may pose a risk to public health, considering the general population. These occur naturally or through anthropogenic sources, either via introduction of the hazard into the environment and/ or during the processing (including transit and storage) of the commodity. Animal health hazards which do not pose a public health risk were not within the scope.

A risk profile was developed with the following sections: hazard identification, hazard characterisation, risk mitigation and management options, legislation and control, UK consumption patterns and, international trade and production. Discussion around uncertainties and knowledge gaps were included, as well as future considerations regarding emerging hazards and a changing environment. This was intended to provide information for auditors and risk managers within the process of market access requests.

Hazard identification was performed via a literature review. The seafood risk tool (SRT) for assessing and mitigating chemical and pathogen hazards in the aquaculture supply chain published in February 2022 by Stentiford *et al* (1), international guidance and standard documents from CODEX, the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) were main sources of information.

The SRT is a publication identifying hazards associated with all seafood and assessing the impact of hazards affecting the supply chain via a two-step semi-quantitative schema to provide scores for severity of harm caused and likelihood of harm occurring, then multiplied to provide the in final impact score (SRT score).

Three hazard categories were identified; chemical hazards (CH), defined as from natural or anthropogenic sources which may affect the health or survival of seafood, and humans consuming seafood; animal hazards (AH), defined as those which may affect the growth, performance, survival or quality of seafood; and human hazards (HH), defined as those which may affect the health and survival of human consumers of seafood. The hazard groups are broken down as follows:

- Six CH groups with multiple hazards identified for each: heavy metals (CH1), persistent organic chemicals (CH2), radiological contaminants (CH3), natural biotoxins (CH4), veterinary pharmaceuticals and personal care products[1] (CH5), allergens (CH6).
- Five AH groups with multiple hazards identified for each: viral pathogens (AH1), bacterial pathogens (AH2), protistan pathogens (AH3), metazoan pathogens (AH4), syndromes[2] (AH5).
- Three HH groups with multiple hazards for each: environmental pathogens (HH1), anthropogenically derived pathogens (HH2), zoonotic pathogens (HH3).

The hazard list was refined before hazard characterisation in consideration of the risk profile scope. AH hazards were not included unless also considered under HH. Allergens and physical hazards were also excluded as they do not relate specifically to import, and hence there was no requirement for characterisation. Additionally hazards identified via sources other than the SRT were also included.

The refined hazards list was organised into two main categories for hazard characterisation: microbiological hazards and chemical hazards. Some microbiological hazards were removed from the list to be taken forwards for hazard characterisation when it became clear that they were not associated with oysters

[1] For example, over the counter medication, cosmetic products, recreational drugs.
[2] Syndromes are groupings of clinical signs associated with a particular health condition but for which specific aetiology has not been elucidated 1. Stentiford GD, Peeler EJ, Tyler CR, Bickley LK, Holt CC, Bass D, et al. A seafood risk tool for assessing and mitigating chemical and pathogen hazards in the aquaculture supply chain. Nat Food. 2022;3(2):169-78..

and/ or were more commonly associated with other routes of transmission. For microbiological hazards, eight bacterial hazard groups, four viral hazards and four parasitic hazards were characterised. For chemical hazards, seven hazard groups were characterised: heavy metals, persistent organic chemicals (POCs), radiological contaminants, veterinary pharmaceuticals and personal care products, microplastics, high production volume (HPV) chemicals and natural biotoxin hazards. Ten marine biotoxin groups were characterised under natural biotoxin hazards.

In most cases, the hazards were well-defined in terms of health effects and composition. Where hazards were less well-defined it was due to limited information on severity of illness (high, medium or low severity of illness not assigned in literature), geographical prevalence of the hazard and disease prevalence. Where possible, information from the WHO on disability adjusted life years (DALYs)[3] was included to indicate the global prevalence of disease caused by the hazard. This was not possible in all cases, particularly for chemical hazards and for microbiological hazards where a high, medium or low severity had not been assigned in literature. High, medium or low severity was only assigned for microbiological hazards because chemical hazards are not generally considered in terms of severity, but rather disease outcome based on the dose response relationship and toxicological concern. Severity was provided using the qualitative categories for the severity of detriments adopted by the Advisory Committee on the Microbiological Safety of Food (ACMSF) on multidimensional representation of risks (3). Where possible severity assigned by the International Commission on Microbiological Specifications for Foods (ICMSF) was used (4). In cases where this was not possible, DALYs and/ or literature sources have been used to assign severity using the ACMSF's severity of detriments (3). The severity assigned was for the general population, not for vulnerable individuals with health conditions which may affect their immune response.

[3] Disability adjusted life years (DALYs) is the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability 2. WHO. WHO ESTIMATES OF GLOBAL BURDEN OF FOODBORNE DISEASES..

SRT impact scores were also presented where possible; they were not provided in cases where hazards had been identified using sources other than the SRT. The SRT scores were derived from the SRT article where the tool was applied to a hypothetical aquaculture scenario intending to produce farmed bivalve molluscs in coastal waters of a non-European Union (EU) marine state for live export and raw consumption within the EU. Impact scores were calculated as part of the SRT for the hazards identified within the article as a multiple of “severity of harm” (part one) and “likelihood of occurrence” (part two). Scores for part one and part two were calculated using the schema, considering six phases (early life, grow out, harvest, processing, trade and consumption) and three control states (uncontrolled, control one: where control measures are applied at discrete phases of supply; control two: where the benefit of controls applied at one phase are accrued in subsequent phases of supply). An overall impact score for each control state was derived with a maximum score for each control state of 216. This was for Live Bivalve Molluscs (LBMs).

Generally, SRT scores indicated where controls may reduce the impact of hazards and where these controls could have effects to reduce the impact later on in the supply chain. It is recommended that, as a tool to identify the impact of controls on hazards in seafood, the SRT is utilised to consider which hazards and/ controls should be further investigated using the impacts set out within the article to determine which may ensure safety of imports from specific countries of origin where some hazards may be of more concern.

Of the 16 individual microbiological hazards characterised, there was limited information on presence of *Staphylococcus aureus* in oysters because these bacteria are mostly associated with contamination during processing. However, this hazard was still characterised because it could not be ruled out due to potential introduction during the processing of oysters in the supply chain. Furthermore, the POC, veterinary pharmaceutical and personal care products, and HPV chemical groups are potentially extremely large groups of chemicals which could not all be fully characterised. It should be borne in mind that these groups may continue to expand and that information around the toxicity and prevalence of the chemicals within them is likely to be dynamic and could become quickly out of date. Finally, of

the marine biotoxins discussed, yessotoxin, pectenotoxin and cyclic imines were not well-defined in humans.

Risk mitigation and management options have been presented (at the time of publication) via the summarisation and comparison of the SRT recommendations, the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs' Sanitation Programmes and CODEX standards associated directly with LBMs, hygiene and chemical hazards. The FAO and CODEX guidance reviewed were also noted within the SRT in a Risk Mitigation Matrix (RMM)[4] applied to the LBM scenario, and EU legislation is also quoted and considered in line with this guidance. It is clear that guidance takes into account identified hazards and also the role that the physiology of LBMs takes in the presence of potential hazards. This is important to note because LBMs, and more specifically oysters, obtain food by filter feeding and so are bioaccumulators of diverse hazards from aquatic environments. Therefore, risk mitigation measures are aimed at various areas of the production process to prevent bioaccumulation where possible. This means that while there may be unknown emerging hazards or that some hazards are difficult to monitor, there are multiple steps where risks to the consumer may be mitigated by aiming to generally prevent the accumulation of chemical and microbiological hazards. Guidance for early stages of the supply chain is comprehensively provided mostly via the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs' Sanitation Programmes. Additional guidance and standards set out for the latter parts of the supply chain were predominantly via CODEX standards. The conclusions drawn from the interpretation of the SRT analysis suggest that measures applied early in the supply chain, i.e., at the point of growing area selection and management, may reduce the risk in the latter phases. Therefore, in many cases, this reduces the requirement for additional control measures outside of the general hygiene measures set out in CODEX guidance. There are, however, options for when the growing area is under a classification that is not ideal for risk mitigation, such as relaying (movement to a different site) and

[4] An RMM is a bespoke inventory of measures aimed at reducing risk associated with specific hazards impacting specific supply chain phases.

depuration (decontamination via purging). However, the limitations of these methods should be considered, for example, depuration will not remove biotoxins. Given that EU legislation is in line with the FAO and CODEX guidance, as discussed via the SRT, UK law is also in line with this due to the current status of Retained EU Law (REUL).

The guidance set out here has been used to create a proposed checklist for auditors in appendix 14.7. This is not an exhaustive list of all points to be considered by UK auditors and is not intended to replace any current checklists or programs used by UK auditors. It is intended as an additional information point to aid the efficiency of auditing when considering oysters specifically.

GB import legislation has been summarised at the time of publication to illustrate controls around the import of LBMs, specifically oysters, this is currently in line with that of the EU due to REUL. Relevant domestic legislation in force at time of publication, on oyster production is also presented to demonstrate the compliance of GB with the international guidance and standards set out under risk mitigation and management options. Furthermore, international legislation, reviewed at the time of publication, is summarised for comparison with international guidance and standards, and GB legislation. It was not possible to summarise the legislation for all countries globally, therefore specific countries or states were selected based on their contributions to international guidance, noted production of oysters, presence as large world powers and available information. These countries and states include the EU, Australia, New Zealand, United States of America (USA), Canada, China and Japan. Legislation was comparable in all circumstances (except for China where information was more limited); however, it was self-reported and therefore difficult to determine exactly to what extent countries follow international guidance and standards. It is recommended that the legislation for countries seeking to import into the UK is reviewed to ascertain if it is comparable to the best practice established within FAO and CODEX guidance and standards.

For UK consumption patterns, the National Diet and Nutrition Survey (NDNS) and Diet and Nutrition Survey for Infants and Young Children (DNSIYC) indicated that oysters were rarely eaten by the general population, which was supported by the

FSA Food and You survey (5, 6, 7, 8, 9). Therefore, it was difficult to determine the demographic of those who may be higher consumers, how often they may eat them and what their portion sizes may be. Evidence taken from the FSA Food and You survey indicated that oysters were most commonly eaten raw and by groups in higher socio-economic classes.

In regard to trade and production of oysters, generally, there are two main types of oysters used in aquaculture – the Pacific cupped oyster (*Crassostrea gigas* – also known more recently as *Magallana gigas*) and the European flat oyster (*Ostrea edulis*). However, there are up to 14 key species of farmed oysters. The UK generally produces the Pacific cupped oyster, at approximately 1.2 million kg per year and exports approximately 1.6 million kg per year. A percentage of UK exports include oysters landed abroad, hence the difference in production vs. export. The UK imports approximately 350,000 kg of oysters per year and where they are imported, they are more commonly processed (prepared or preserved; smoked; frozen), however there were significant imports of live oysters. The main exporters of oysters to the UK were (in the order of weight of import) the Republic of Korea, France and New Zealand between 2016 and 2022. Globally, France, China, Republic of Korea, Ireland and Canada were the highest exporters of oysters between 2016 and 2022 (in order of weight of export).

Notable uncertainties associated with the UK consumption and trade data were considered. It was not possible to find comprehensive data on consumption of oysters in the UK and the specific types of oysters traded. This was not considered to detrimentally impact the risk profile as it was possible to determine that oysters were more commonly consumed raw and not as a common occurrence by the general public, and which countries were the highest producers and exporters of oysters globally. Additionally, the highest exporters to the UK were ascertained.

Other notable uncertainties were those associated with legislation in other countries following international guidance and standards, it is recommended that this is investigated for specific market access requests. Furthermore, there were some uncertainties associated with hazard identification and hazard characterisation such as limited information. This is considered to be of low concern given the literature

consulted and GB import controls in place, including audits for third countries. Finally, uncertainties around future considerations were key as it is clear that factors such as vulnerable population changes, emergence of hazards, climate change, globalisation of the seafood market and changing human behaviours will have an impact on risk associated with oysters, but not how this may occur and what hazards may emerge.

Knowledge gaps were identified amongst the noted uncertainties. These were not considered to impact the risk profile significantly because data were generally available, and it was possible to summarise key risks and mitigation measures within the scope of the profile. However, factors noted under future considerations should continue to be reviewed through risk analysis work. Furthermore, these were not identified with a view to pose suggestions for additional research as this is not considered within the scope of the risk profile.

Overall, it is clear that oysters are a high-risk product for import, particularly for certain population groups, given their physiology (i.e., filter feeding which allows the bioaccumulation of hazards) and likelihood for raw consumption, but that measures are available to mitigate risks in many cases. Risk mitigation is, however, variable, depending on the hazard of concern. Notably, there are a number of emerging chemical hazards which are less well-defined and/ or may comprise a vast hazard group which is not fully characterised and continues to expand (microplastics, POCs, veterinary pharmaceuticals and personal care products, HPV chemicals, radionuclides). Furthermore, marine biotoxin hazards cannot be controlled after accumulation within the commodity except for the removal of the commodity from the supply chain because purification techniques will not reduce their presence. Mitigation measures must be in place very early on during the supply chain, i.e., at the stage of selecting and monitoring growing areas.

Information on future considerations regarding hazards associated with oysters was reviewed, including vulnerable population changes, emerging hazards, climate change and globalisation of the seafood trade. These could have a significant effect on the types and prevalence of hazards observed in oysters, but also their potential effects on the population. It is not intended to provide a comprehensive list but to

summarise potential factors which may affect the hazards identified within the risk profile, and also emerging hazards. It is also not intended to predict the effects of these factors but to illustrate the necessity for continued review. It is difficult to predict future events and also to incorporate a large amount of related literature. There are likely to be knowledge gaps in these areas given they are emerging issues. However, many of the standards and guidance discussed in this risk profile are aimed at identifying changes in currently identified hazards and monitoring them, they are also owned by international organisations which monitor emerging risks and update the documents. It is recommended that these areas are monitored by risk assessors and risk managers for emerging risks, including emerging hazards, an increase in the vulnerable population and effects of climate change and globalisation on the seafood trade, as well as changes in human behaviour. Also, that the guidance and standards provided are reviewed to ensure that updates are considered.

The final conclusions of this risk profile, in the context of importing into the UK were that where market access requests are made, measures in place in the country of origin should be investigated, with reference to the international guidance and standards and relevant domestic import legislation set out in the risk profile, to estimate the relative safety of the product from that specific country. Furthermore, if these initial investigations do not provide clarity, or indicate a concern, it is recommended that a full country audit and/ or full import risk assessment be considered to gather further information and/ or estimate the risk associated specifically with oysters from the country of origin in order to ensure safety of imports into the UK.

# 2 Aims

This is a risk profile produced by the Exposure Assessment and Trade (EAT) Team at the Food Standards Agency (FSA), commissioned by the UK Office for Sanitary and Phytosanitary Trade Assurance (UKOSPSTA), to inform the potential risks associated with importing oysters into the UK from any trading partner.

# 3 Scope

Risks associated with importing oysters into the UK can be defined as any potential hazards identified within the specified commodity (oysters) which may pose a public health risk. These may occur naturally (for example marine biotoxins or naturally present microorganisms) or through anthropogenic sources (human interaction with the commodity) either via introduction of the hazard into the environment (for example agricultural or sewage waste entering marine systems resulting in the presence of certain chemicals or microorganisms) and/ or during the processing (including transit and storage) of the commodity (for example poor storage conditions or insufficient processing leading to microbial growth or poor hygiene leading to introduction of microbes).

Animal health hazards which cause disease in oysters but do not pose a public health risk are not within the scope of this risk profile. Physical (for example, foreign objects) and allergen hazards are known and do cause a public health risk but are not considered within the scope of this risk profile because they are considered to be potentially universal considerations in regard to oysters. These hazards are not considered to be a risk for introduction of a particular public health hazard to the UK. For example, specific controls within domestic oyster production in the UK are known and considered to reduce the risk of microbial contamination, and some microbial hazards present in other countries are not present in the UK. Similarly, many chemicals are banned or not approved for use in the UK but may be in use in other countries.

The risk profile focuses on the general population. However, where appropriate, specific concerns for particular hazards for vulnerable groups are noted.

The scope also includes the provision of a summary of key risk mitigation measures, production methods and management processes from international standards and guidelines. Additionally, relevant domestic import controls, UK consumption patterns and information on key global producers and international trade. This is intended to provide information for auditors within the process of market access requests.

A risk profile is not an import risk assessment in that a final risk output is not provided. Furthermore, commodities from specific countries are not discussed, except where information on international legislation, global trade and production of oysters is provided.

# 4 Introduction

Foodborne diseases are an important cause of human mortality and morbidity worldwide, they also have a significant socio-economic impact. According to a World Health Organisation (WHO) report on the estimation of the global burden of foodborne diseases, there were 600 million foodborne illnesses in 2010, resulting in 420,000 deaths and 33 million Disability Adjusted Life Years (DALYs)[5] (10). In the United Kingdom (UK), there were an estimated 2.4 million foodborne disease-related cases in 2018, costing the UK approximately £9.1 billion a year (11).

The growth of global aquaculture production has increased dramatically over the years and oysters are the leading molluscan species accounting for 21% of all global aquaculture production by weight in 2016 (12). Most species of oyster used in aquaculture can be found naturally in marine and brackish areas close to the coast in shallow depths (13). Like other bivalve molluscs, oysters are filter feeders and do so by extracting marine algae and nutrients from the surrounding water. Because of this, chemical and microbiological hazards can accumulate and become concentrated within oysters. Therefore, it is important to control production of oysters to reduce the risk of foodborne disease. There are multiple ways to control the hazards during the six key phases of the seafood supply chain: early life, grow-out, harvesting, processing, trading and consumption. In general, control is often through identification and monitoring of growing areas. Depuration and relaying are additional strategies to reduce the level of contamination, although these do not mitigate the risk of all possible contaminants, for example marine biotoxins would remain unaffected and usually controlled via selection of growing area (14).

The Food and Agricultural Organisation of the United Nations (FAO) Risk Based Imported Food Control Manual recommends that imported food controls should include evaluation of the risks posed by the imported food itself, the risk and controls implemented by the source country and the risk and controls implemented by the

[5] Disability adjusted life years (DALYs) is the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.

importer (15). Furthermore, imported food controls based on risk require the development of a profile including information which can reduce or increase risk such as processing and transportation controls (15). Literature was used to identify, and characterise hazards associated with oysters specifically which may pose a public health risk. These include microbiological and chemical hazards. The risk profile does not focus on a specific country but has identified risk mitigation and management processes which are generally recommended to minimise the risk. Any relevant international guidance, such as from the FAO, has been identified and information gaps noted. International guidance is summarised in section 7. Therefore, the profile may inform audits in/on countries requesting market access for export of oysters to the UK to determine the risk associated with the country of origin and any third parties.

Between 2016 and 2022, the UK imported on average approximately 350,000 kg of oysters per year from different countries (16), this is discussed further in section 10. The Diet and Nutrition Survey for Infants and Young Children (DNSIYC) and the National Diet and Nutrition Survey (NDNS) provide UK consumption patterns of oysters in recent years and are discussed in section 9.

# 5 Hazard identification

## 5.1 Literature review to define hazards in oysters

Hazard identification was performed via a literature review using Google Scholar and Science Direct. The seafood risk tool (SRT) for assessing and mitigating chemical and pathogen hazards in the aquaculture supply chain published in February 2022 by Stentiford *et al*.(1) was a predominant source of information. The literature review was performed by two analysts to ensure review of as much relevant literature as possible. The literature review method and sources of information consulted are detailed in this section.

The SRT is a publication associated with Weymouth Laboratory, Centre for Environment, Fisheries and Aquaculture Science (Cefas); Centre for Sustainable Aquaculture Futures, University of Exeter; Department of Epidemiology and Population Health, Institute of Infection and Global Health, University of Liverpool; Biosciences, University of Exeter; Department of Botany, University of British Columbia; Lowestoft Laboratory, Cefas. Colleagues at Cefas were also consulted for data sources to consider within this risk profile. Included in the suggestions was the SRT and international guidance noted later within this section.

In the SRT, three broad hazard categories were considered (1):

1. Chemical hazards (CH) from natural or anthropogenic sources which may affect the health or survival of seafood, and humans consuming seafood.
2. Animal pathogen hazards (AH) which may affect the growth, performance, survival or quality of seafood.
3. Human pathogen hazards (HH) associated with seafood which may affect the health and survival of human consumers of seafood.

As part of the SRT, literature associated with hazards from different seafood species groups and chemical and pathogen categories listed in international aquatic animal health and seafood safety guidelines (FAO and WHO) was reviewed. This resulted in the proposal of 14 hazard subcategories within the CH, AH and HH categories. The

SRT article presented the CH, AH and HH hazard categories in a table, which has been adapted and presented in appendix 14.2.

While oysters alone are within the scope of this risk profile, hazards identified in aquatic animals and Live Bivalve Molluscs (LBMs) generally may be relevant to oysters specifically. The SRT was generalised for aquatic animals, therefore, international guidance and standard documents for LBMs, as well as specific literature for the hazards listed, were reviewed to finalise a list of hazards associated with oysters which may pose a public health risk. All hazards listed in the SRT are noted in Table 29 in appendix 14.2. Using this, a list of hazards determined to be within the scope of the risk profile, and therefore carried forward to the hazard characterisation, was derived and presented in Table 1 in section 5.2. International guidance and standard documents were also used to check that all potential hazards associated with oysters were included in Table 1, even if not noted in the SRT (Table 29). The international guidance and standards reviewed include:

- CODEX Standard for Live and Raw Bivalve Molluscs – CXS 292-2008. Adopted in 2008. Amendment: 2013. Revision: 2014 and 2015 (17).
- CODEX Code of Practice for Fish and Fishery Products – CXC 52-2003. Adopted 2003. Revised 2004, 2005, 2007, 2008, 2010, 2011, 2016. Amended 2011, 2013, 2016 (18).
- CODEX General Principles of Food Hygiene – CXC 1-1969. Adopted in 1969. Revised in 1997, 2003, 2020. Editorial corrections in 2011 (19).
- CODEX Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods – CAC/GL 21 – 1997 (20).
- CODEX Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* species in seafood – CAC/GL 73-2010 (21).
- CODEX Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Viruses in Seafood – CAC/GL 79-2012 (22).
- FAO and WHO Technical Guidance for the Development of Growing Area Aspects of Bivalve Mollusc Sanitation Programmes Second Edition – 2021 (23).

- FAO The State of the World Fisheries and Aquaculture – 2022 (24).
- Joint FAO and WHO Toxicity Equivalency Factors for Marine Biotoxins Associated with Bivalve Molluscs – 2016 (25).

The online search performed using both Google Scholar and Science Direct checked for any additional literature from the period between the submission of the SRT (December 2021) and the production of this risk profile (July 2023). This was reviewed for any emerging hazards not already included. Searches were performed by two different analysts (one each for Google Scholar and Science Direct) to enable cross checking. Search terms included:

- "Hazards associated with": "LBMs" OR "Live Bivalve Molluscs" OR "Oysters" OR "Aquaculture" OR "Seafood".
- "Risks associated with": "LBMs" OR "Live Bivalve Molluscs" OR "Oysters" OR "Aquaculture" OR "Seafood".

Many information sources were found; however, few of relevance were more recent than December 2021 – July 2023. In both Google Scholar and Science Direct, there was a return of approximately 50,000 results for each. In both cases, screening was stopped after 500 publications and these were filtered for hazards not already identified within the SRT. No articles of similar scope to the SRT were identified in the period since it was submitted for publication. Some additional information sources for specific hazards were identified. These are listed below:

- Microplastics and nanoplastics in oysters – over 12,000 microplastics publications were identified. Many were related to oysters; others were less specific. Examples of relevant publications are noted below:
  - Microplastics and Linear Alkyl Benzyl in *Crassostrea gigas* (Pacific Oysters) 2022 (26).
  - Microplastic in Oysters: A Review of Global Trends and Comparison to Southern Australia (27).
  - Seasonal Change of Microplastics Uptake in the Pacific Oysters *Crassostrea gigas* Cultured in the Yellow Sea and Bohai Sea, China (28).

- An Overview of Microplastics in Oysters: Analysis, Hazards, and Depuration (29).
- Abundance of Microplastics in Cultured Oysters (*Crassostrea gigas*) from Danang Bay of Vietnam (30).
- Microplastic Contamination in Seafood from Dongshan Bay in South Eastern China and its Health Risk Implication for Human Consumption (31).
- Occurrence of Microplastics in Wild Oysters (*Crassostrea tulipa*) from the Gulf of Guinea and Their Potential Human Exposure (32).
- Microplastic Concentrations in Cultured Oysters in Two Seasons from Two Bays of Baja California, Mexico (33).
- Oysters and Mussels as Equivalent Sentinels of Microplastics and Natural Particles in Coastal Environments (34).
- The Relationship Between Microplastics in Eastern Oysters (*Crassostrea virginica*) and Surrounding Environmental Compartments in Long Island Sound (35).
- The Underestimated Toxic Effects of Nanoplastics Coming From Marine Sources: A Demonstration on Oysters (*Isognomon alatus*) (36).

- High production volume (HPV) chemicals[6] – identified from one additional literature source (37).
- Additional publications on radionuclides, *Vibrio* spp., protozoan parasites, harmful algal blooms (HABs), heavy metals, Persistent Organic Chemicals (POCs), polyfluoroalkyl substances (PFASs) and veterinary pharmaceuticals and personal care products were also identified. However, these hazards were already considered as part of the hazard list derived from the SRT.

[6] High production volume (HPV) chemicals were defined by the Organisation for Economic Cooperation and Development (OECD) as chemicals with a production of over 1000 tonnes/ year and by the US Environmental Protection Agency (EPA) as compounds produced at a minimum of 500 tonnes/ year. Examples include organophosphate esters (OPEs), phthalate esters (PAEs) and benzotriazoles (BTRs) 37. *al* C*e*. High production volume chemicals in seafood: A review of analytical methods, occurrence and population risk. TrAC Trends in Analytical Chemistry. 2022;157:116743..

HABs were considered within biotoxin hazards as major contributor to marine biotoxin production. Protozoan parasites listed had already been noted.

- Two additional animal health hazards were identified: shell-boring polychaetes (mud blister worms (38, 39) , Annelida: *Spionidae* (39)). These are not within the scope of the risk profile so were not included in the refined hazard list – see section 5.2.

Nine additional hazard categories not previously identified via the SRT were included from the literature sources listed above (including international guidance and standards, and via the Google Scholar and Science Direct literature search). These are noted as follows (with the information source noted in brackets):

- *Yersinia enterocolitica* (FAO and WHO Technical Guidance for the Development of Growing Area Aspects of Bivalve Mollusc Sanitation Programmes; CODEX Code of Practice for Fish and Fishery Products).
- *Staphylococcus aureus* (CODEX Code of Practice for Fish and Fishery Products).
- *Toxoplasma gondii* (FAO and WHO Technical Guidance for the Development of Growing Area Aspects of Bivalve Mollusc Sanitation Programmes).
- *Microsporidia* (FAO and WHO Technical Guidance for the Development of Growing Area Aspects of Bivalve Mollusc Sanitation Programmes).
- Microplastics and nanoplastics (references listed above) – included in hazard characterisation as microplastics.
- Yessotoxin (Joint FAO and WHO Toxicity Equivalence Factors for Marine Biotoxins Associated with Bivalve Molluscs).
- Pectenotoxin (Joint FAO and WHO Toxicity Equivalence Factors for Marine Biotoxins Associated with Bivalve Molluscs).
- Cyclic imines (Joint FAO and WHO Toxicity Equivalence Factors for Marine Biotoxins Associated with Bivalve Molluscs).
- HPV chemicals (reference noted above).

Yessotoxins and Pectenotoxins were also identified within legislation. Both are referenced in Chapter III of Annex V (Recognised methods for the detection of marine biotoxins in accordance with Article 60) of Retained European Union (EU)

Law (REUL) Regulation 2019/627 (under lipophilic detection methods) and Chapter V (Health Standards for Live Bivalve Molluscs) of Section VII of Annex III of REUL Regulation 853/2004 (under the list of marine biotoxins that LBMs should not contain) (40, 41).

## 5.2 Refinement of hazard list

Table 1 is a refined list of hazards considered to be within the scope of this risk profile derived from the full list of SRT hazards in Table 29 in appendix 14.2 (adapted from the SRT) and reviewed using the additional data sources listed in section 5.1. These hazards are characterised in section 6.

AH hazards have not been included in this table unless also considered under HH, as the scope of this risk profile is to consider hazards associated with oysters which may pose a public health risk. Allergens have also not been included within this table as they were not carried forward for hazard characterisation because they are considered to be present in all types of oysters and not related specifically to import, and therefore do not require additional hazard characterisation. Physical hazards, such as foreign matter (for example, metal fragments from processing) were not noted in the SRT but were in the international standards and codes of practice noted in section 5.1. Similarly, to allergens, these have not been included in Table 1 as they are not considered to be related specifically to import or even specifically to oysters. They do not require additional hazard characterisation.

Finally, some hazards were not typically considered to be associated with oysters or were more commonly associated with ready to eat (RTE) or cooked foods. Cross referencing with reviews on the epidemiology of LBMs (Potasman *et al*, 2002; Iwamoto *et al*, 2010 (42, 43)) helped to determine where some hazards were not associated with oysters. Furthermore, it is considered that oysters are more often consumed raw or undercooked, so hazards not associated with these conditions have not been characterised. These were subsequently removed from the list for hazard characterisation (Table 1). Those removed are listed as follows (with justification for removal in brackets):

Bacterial hazards:

- *Listeria monocytogenes* (associated with cooked foods (44)),
- *Streptococcus agalactiae* (not typically associated with foodborne transmission (45)),
- *Clostridium* spp. (associated with preserved/ processed foods - *C. botulinum* (46), cooked foods - *C. perfringens* (47) and hospital infections - *C. difficile* (48, 49)),
- *Mycobacterium* spp. (more commonly associated with fish - *M. shottsi* (50), wound infection - *M. marinum* (51) and/ or meat and dairy or aerosols - *M. bovis* (52)),
- *Aeromonas* species spp. (more commonly associated with topical transmission or RTE seafood products and foodborne outbreaks lack evidence (53)).

Viral hazards: poliovirus (more commonly transmitted from person-to-person and via water (54)).

Parasitic hazards:

- *Opisthorchis* spp. (associated with fish (55)),
- *Clonorchis* spp. (associated with fish (56)),
- *Metorchis* spp. (associated with fish (57)),
- *Echinostoma* spp. (associated with fish, amphibians and reptiles (58)),
- *Haplorchis* spp. (associated with fish and freshwater snails (59)),
- *Gnathostoma* spp. (associated with fish (60)),
- *Anisakis* spp. (associated with fish and cephalopods (61)),
- *Paragonimus* spp. (associated with freshwater crustaceans (62)),
- *Diphyllobothrium* spp. (associated with fish (63))
- *Dibothriocephalus latus* (associated with fish (64)).

Table 1: Refined hazard list within the scope of this risk profile

| Hazard category | Hazard type | Specific hazards |
|---|---|---|
| **Microbiological hazards** | Bacteria | *Vibrio* spp.: *V. parahaemolyticus*, *V. vulnificus*, *V. cholerae.* Other *Vibrio* spp. (65).<br>*Salmonella* spp.: *S.* Typhi, *S.* Paratyphi (typhoidal). Other *Salmonella* serotypes (non-typhoidal).<br>*Escherichia coli* – Shiga Toxigenic *E. coli* (STEC).<br>*Shigella*.<br>*Campylobacter jejuni*. Other *Campylobacter* spp.<br>*S. aureus*.<br>*Y. enterocolitica*.<br>Faecal indicators/ coliforms – generally used for testing for faecal contamination in growing areas (see section 7). Includes *E. coli* and *Yersinia,* and others discussed in section 6.4. |
| | Viruses | Rotavirus, Norovirus, Hepatitis A and E. |
| | Parasites | *Cryptosporidium*, *Giardia*, *Microsporidia*, *Toxoplasma gondii*. |
| **Chemical hazards** | Heavy metals | Cadmium, mercury, lead, zinc, arsenic and copper. |
| | Persistent organic chemicals (POCs) | Dioxins, furans, polychlorinated biphenyls (PCBs), perfluorinated compounds (PFCs), polybrominated diphenyl ethers (PBDEs), polycyclic aromatic hydrocarbons (PAHs) and a range of emerging contaminants. |
| | Radiological contaminants | Radioactive isotopes, in particular strontium-90, caesium-137, plutonium isotopes and naturally occurring radioactive elements, such as radium-226 and polonium-210. |
| | Veterinary pharmaceutical and personal care chemicals | Antibiotics, growth promoters (hormones), feed additives, ibuprofen, recreational drugs, sertraline, tamoxifen, salicylic acid and a range of emerging contaminants. |
| | Microplastics | Multiple types of plastic – see section 6.5.5. Includes nanoplastics. |
| | High production volume (HPV) chemicals | Chemicals with a production of over 1000 tonnes/ year or compounds produced at a minimum of 500 tonnes/ year – see section 6.5.6.(37). |
| | Natural biotoxins | Groups of marine biotoxins based on their chemical structures (66): azaspiracid (AZA), brevetoxin (BTX), cyclic imines (CIs), domoic acid (DA), okadaic acid (OA), pectenotoxin (PTX), saxitoxin (STX), yessotoxin (YTX), palytoxins (PITX).<br>Other marine biotoxins: tetrodotoxin (TTX). |

# 6 Hazard characterisation

## 6.1 Introduction to hazard characterisation

The CODEX Alimentarius defines hazard characterisation as “the qualitative and/ or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food (67)”. In this section, each hazard or hazard group identified in Table 1 are characterised. Information is provided on the adverse effects that may result from ingestion, the severity of associated adverse health effects if information was obtainable (assigned as high, medium or low) and the impact scores derived from the SRT, where applicable (refer to section 6.2). Other notable information in relation to the hazard specifically is also included, for example, health-based guidance values (HBGVs) provided for some chemical hazards.

For microbiological hazards, severity was provided using the qualitative categories for the severity of detriments adopted by the Advisory Committee on the Microbiological Safety of Food (ACMSF) (Table 2) (3). Where possible severity assigned by the International Committee on Microbiological Specifications for Foods (ICMSF) (4) has been used. In cases where this was not possible, DALYs[7] and/ or other literature sources have been used to assign severity using the ACMSF’s severity of detriments (68). The severity assigned is for the general population, not for vulnerable individuals with health conditions which may affect their immune response. Where it is of note, the adverse effects for vulnerable groups have been discussed for each hazard, separately to the assigned severity.

For chemical hazards, the severity has not been assigned as severity of illness depends on the dose response relationship and literature does not generally provide information on the severity assigned to a particular chemical. Rather, literature usually provides information around the toxicological concern associated with a particular chemical hazard and information on any HBGVs.

[7] Disability adjusted life years (DALYs) is the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.

Table 2: A qualitative scale for the severity of detriments of (microbiological) foodborne risks

| Severity category | Interpretation |
|---|---|
| Negligible | No effects, or so mild they do not merit to be considered |
| Low | Mild illness: not usually life-threatening, usually no sequelae, normally of short duration, symptoms are self-limiting (for example, transient diarrhoea). |
| Medium | Moderate illness: incapacitating but not usually life-threatening, sequelae rare, moderate duration (for example, diarrhoea requiring hospitalisation). |
| High | Severe illness: causing life-threatening or substantial sequelae or illness of long duration (for example, chronic hepatitis). |

## 6.2 Seafood Risk Tool (SRT) impact scores

Microbiological and chemical hazards interact differently within discrete phases of the supply chain. Supply chain phases include the early phase (for example, hatchery production of larvae), grow-out (growth in farm settings), harvesting, processing, trading and consumption. The impacts affecting processing, trade and consumption phases may be economic, for example, limiting the processing efficiency and trade or the capacity to place products on the market, but also health related, where intake of hazards via seafood consumption has public health consequences (1).

Estimating the impact of specific hazards on specific phases of the supply chain facilitates understanding of where interventions for control may have the greatest impact. The SRT may therefore be applied in three control states:

1. When assessing the potential impact of uncontrolled hazards on supply from a specific aquaculture scenario (uncontrolled state).
2. When assessing the benefit of applying discrete phase-specific control measures for limiting the impact of hazards which may affect that supply chain phase (control state one/ control one).
3. When assessing multi-phase (cumulative or stepwise) control measures in limiting impact of hazards affecting the supply from a specific aquaculture scenario (control state two/ control two).

Where hazard impact can be mitigated by intervention in examples such as biosecurity control plans, active monitoring and, post-harvest processing, either at single or multiple supply chain phases, the SRT provides a basis to target measures most efficiently and to calculate benefits of intervention compared with the uncontrolled state. In situations where application of controls is unable to adequately limit the impact of specific hazards, an amendment of the scenario, such as alternative farmed species, sites, intended markets and product use, may improve outcomes for the safe production and consumption of seafood (1).

Risk mitigation and management options are discussed in section 7.

The SRT uses a two-step semi-quantitative risk assessment schema to calculate impact. The application of the SRT requires the aquaculture scenario to be defined, including data on specific taxonomy, geography, seasonality, production method, product type, proposed market and intended end use of the products. The SRT has been applied to a hypothetical aquaculture scenario intending to produce farmed bivalve molluscs in coastal waters of a non-EU state for live export and raw consumption within the EU. The SRT articles states that this was chosen as it represents a scenario where multiple CH, AH and HH hazards are likely to interact with different supply chain phases, and where recognised control measures are available at different levels to mitigate hazard impact. Impact scores for hazard categories included within the SRT article, which interact with discrete phases of the seafood supply chain, were calculated as a multiple of “severity of harm” (part one) and “likelihood of occurrence” (part two) (1).

The full method is described within the SRT article. However, the schema and a short summary are also presented in appendix 14.3 of this risk profile. SRT impact scores derived from the scenario discussed above and presented in the SRT article are provided for characterised hazards sections 6.4 and 6.5.

The top-ranking risks within the characterised hazards over the whole supply chain according to the SRT were *V. parahaemolyticus*; marine biotoxins (specifically amnesic, paralytic and lipophilic toxins); hepatitis A virus (HAV), norovirus and *Salmonella* spp.; heavy metals (specifically cadmium, mercury and lead); and

diseases caused by various other *Vibrio* spp. Pronounced impacts of AH were predicted within the SRT for early-life and grow-out phases when specific supply phases were considered, for example, viral, bacterial and parasite-induced mortality of animals on farms. There was further potential for impact during the international trading phase, where pathogens of concern are listed in various international legislation. These hazards are not characterised here as the scope of this risk profile only includes public health hazards. HH hazards had a less pronounced impact on production phases but presented a higher risk of impacting harvest and processing (for example, HAV and norovirus), trading (for example, *Salmonella* spp. or high levels of indicator bacteria indicative of faecal contamination) and, particularly, consumption phases. CH also showed less impact on early-life and grow-out phases but impacted harvest and processing (for example, natural biological toxins above safe concentrations), trading (for example, heavy metals above safe concentrations) and consumption phases (for example, natural biotoxins directly impact human health). In the biotoxin example, this is because marine biotoxins cannot be removed by purification, they cannot be controlled post-harvest except for removal of contaminated commodities from the supply chain.

## 6.3 Hazard characterisation summary

Table 3 is provided as a summary of the hazards characterised in sections 6.4 and 6.5. This is intended to provide an overview of the characterised hazards in terms of their health effects, severity (where applicable), SRT scores (where applicable) and other notable information. Sections 6.4 and 6.5 provide more in-depth information and include the references reviewed to provide the characterisation.

Table 3: Hazard characterisation summary table

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| Microbiological - bacteria | *Vibrio* spp. | *V. parahaemolyticus*, *V. cholerae* and *V. vulnificus* are the main species associated with foodborne illness. | See species below. | See species below. |
| | | *V. parahaemolyticus* – symptoms include explosive watery diarrhoea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills. Most cases are self-limiting, however, severe cases of gastroenteritis requiring hospitalisation have been reported. | Low | Uncontrolled: 48<br>Control 1: 34<br>Control 2: 25 |
| | | *V. cholerae* - strains belonging to O1 and O139 serotypes possess the *ctx* gene (*ctx* +) and produce cholera toxin (CT) and are responsible for epidemic cholera. Cholera is characterised by profuse watery diarrhoea and vomiting which can cause life threatening dehydration. Symptoms normally last between three and seven days. This is associated with O1 and O139 serotypes more commonly associated with waterborne transmission. Non- O1 and O139 serotypes are more commonly associated with raw or undercooked seafood consumption. Symptoms of infections with these serotypes may range from mild gastroenteritis to life-threatening necrotising fasciitis. | O1 and O139 strains (choleragenic): high.<br><br>Non O1 and non O139 strains: low | O1 and O139 strains (choleragenic):<br>Uncontrolled: 52<br>Control 1: 32<br>Control 2: 17<br><br>Non O1 and non O139 strains:<br>Uncontrolled: 67<br>Control 1: 47<br>Control 2: 32 |
| | | *V. vulnificus* - can occasionally cause mild gastroenteritis in healthy individuals, but it can cause primary septicaemia in individuals with chronic pre-existing conditions. | High | Uncontrolled: 33<br>Control 1: 23<br>Control 2: 18 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | *Salmonella* spp. | Non-typhoidal *Salmonella* (NTS) serovars include Typhimurium and Enteritidis. Patients with NTS have self-limiting, acute gastroenteritis and watery diarrhoea, nausea, vomiting, abdominal pain, and fever. With NTS infection, symptoms generally appear 6–12 hours after the ingestion of the pathogen and clinical symptoms last less than ten days. | Medium | Controlled: 71<br>Control 1: 59<br>Control 2: 31 |
| | | *S. enterica* serovars including Typhi, Sendai, and Paratyphi A, B, or C are collectively referred to as typhoidal *Salmonella* serovars and are the causative agents of enteric fever (also known as typhoid or paratyphoid fever if caused by serovar Typhi or Paratyphi, respectively).<br>Enteric fever caused by typhoidal serovars is different from the gastroenteritis associated with NTS. The average incubation period for typhoidal serovars is 14 days with symptoms persisting for up to three weeks. Patients generally present with a gradual onset of sustained fever (39–40°C).<br>Frequent symptoms include chills, abdominal pain, hepatosplenomegaly (spleen and liver enlargement), rash, nausea, anorexia, diarrhoea or constipation, headache, and a dry cough. | High | Uncontrolled: 66<br>Control 1: 58<br>Control 2: 24 |
| | *E. coli* (STEC) | Commonly found in the gut of humans and warm-blooded animals. Most strains are harmless, but some strains produce toxins which can cause severe foodborne disease, known as Shiga-toxigenic *E. coli* (STEC). Transmission to humans is primarily through consumption of contaminated | High (EHEC) | Uncontrolled: 54<br>Control 1: 38<br>Control 2: 26<br>(Unspecified in SRT – noted only as *E. coli*) |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | foods, less associated with seafood and more with contamination of meat and vegetables. However, *E. coli* is also an indicator of faecal contamination. Enterohemorrhagic *E. coli* (EHEC) are a subset of STEC. *E. coli* O157:H7 is the predominant strain of the EHEC infections worldwide. Symptoms tend to appear three to four days after infection and include abdominal cramps, watery and/or bloody diarrhoea, fever and vomiting. Vulnerable people may develop more severe complications such as haemolytic-uraemic syndrome (HUS) which can lead to kidney failure. This is more common in children under five years old and in those with a weakened immune system | | |
| | *Shigella* spp. | There are four species: *S. dysenteriae*, *S. flexneri*, *S. boydii* and *S. sonnei* (also referred to as group A, B, C, and D, respectively).<br>Symptoms common for gastrointestinal illnesses - diarrhoea, stomach cramps or pain, nausea, vomiting and fever. | Medium | Uncontrolled: 24<br>Control 1: 21<br>Control 2: 16 |
| | *Campylobacter* spp. | Most frequently reported in humans: *C. jejuni* and *C. coli*. Other species such as *C. lari* and *C. upsaliensis* have also been isolated from patients with diarrhoeal disease but are reported less frequently.<br>Associated with seafood but more common in undercooked meat products.<br>Apart from diarrhoea, other symptoms include abdominal pain, fever, headache, nausea, and or vomiting. The symptoms typically last three to six days. | Low (*C. jejuni*) | Uncontrolled: 31<br>Control 1: 22<br>Control 2: 16<br>(*C. jejuni*) |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | *S. aureus* | Common commensal in humans – skin and nose. Does not usually cause illness in healthy people but produces enterotoxins which can cause food poisoning – staphylococcal food poisoning is a gastrointestinal (GI) illness. Cannot be ruled out in oysters as may be introduced during processing, but more commonly associated with RTE products. Symptoms include nausea, vomiting, stomach cramps, diarrhoea. Severe illness is rare and due to the cause being enterotoxins, not passed from one person to another. | Low | NA – not identified within SRT. |
| | *Y. enterocolitica* | Strains from porcine reservoirs are considered the largest source of yersiniosis in humans but *Y. enterocolitica* has be identified in fish and shellfish, including oysters in both wild and aquaculture settings.<br>Symptoms vary depending on the individual infected, particularly due to age. Young children: fever, abdominal pain, diarrhoea. Older children and adults: fever, pain on right of abdomen.<br>Complications are rare but can include skin rash, joint pain and septicaemia. | Medium | NA – not identified within SRT. |
| | Faecal indicator/ coliforms | A group of bacterial organisms used as indicators of faecal contamination. Consumption of water with coliform bacteria does not always cause illness however if disease-causing bacteria are present, symptoms could include GI upset and general flu-like symptoms. These bacteria are only found in the faeces of warm-blooded animals. Coliforms are a subgroup of the Enterobacteriaceae. They are | Not defined – group considered as indicator organisms. Where relevant to oysters, they are discussed in | Uncontrolled: 42<br>Control 1:38<br>Control 2: 18 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | comprised mostly of the *Escherichia, Klebsiella, Citrobacter, Enterobacter* and *Serratia* genera. | dedicated hazard groups. | |
| Microbiological - viruses | Rotavirus | Primary transmission is via the faecal-oral route, including contaminated food and water. Commonly associated with shellfish.<br>Symptoms: watery diarrhoea, vomiting, abdominal pain, fever. Severity of symptoms can vary depending on the individual. Complications tend to occur due to fluid loss. | Low | Uncontrolled: 38<br>Control 1: 26<br>Control 2: 19 |
| | Norovirus | Enters the marine environment via untreated human sewage, primarily, commonly associated with shellfish, particularly oysters and particularly from raw consumption. Symptoms are typical of gastroenteritis and are usually mild but can be more severe in high-risk groups. | Low | Uncontrolled: 64<br>Control 1: 52<br>Control 2: 33 |
| | Hepatitis A Virus (HAV) | Associated with food or water contaminated with faeces of an infected person. Oyster consumption has been linked to HAV infection.<br>HAV is a cause of acute viral hepatitis – inflammation of the liver. Some infections occur without symptoms. Persons over 40 generally have symptoms in over 80% of cases and it may result in more severe outcomes. | High | Uncontrolled: 92<br>Control 1: 72<br>Control 2: 37 |
| | Hepatitis E Virus (HEV) | Associated with raw and undercooked meat, especially pork and shellfish.<br>HEV is a cause of hepatitis. Infection can be asymptomatic or mild illness, or severe. Symptoms can include fatigue, nausea, abdominal pain, loss of appetite, jaundice, dark urine, and pale stools. Most cases resolve on their own but there may be severe | Low | Uncontrolled: 21<br>Control 1: 21<br>Control 2: 18 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | complications, particularly in pregnant women or other high-risk individuals. | | |
| Microbiological – parasites | *Cryptosporidium* spp. | Protozoan parasite causing cryptosporidiosis. *C. parvum* and *C. hominis* – the most common to affect humans. Can contaminate food and water sources. Symptoms: watery diarrhoea, stomach cramps, nausea, vomiting, fever. Self-limiting in healthy individuals but can be severe in people with weakened immune systems. | Low | Uncontrolled: 30<br>Control 1: 22<br>Control 2: 16 |
| | *Giardia* spp. | Protozoan parasite causing giardiasis. The most common species that infects humans is *Giardia lamblia* (also known as *Giardia intestinalis*). Oysters are a potential source. Symptoms: diarrhoea, abdominal pain, bloating, gas, nausea, vomiting and weight loss. Can be more severe in high-risk individuals but some people can be asymptomatic. | Low | Uncontrolled: 24<br>Control 1: 18<br>Control 2: 16 |
| | *Microsporidia* spp. | Small unicellular, eukaryotic, intracellular parasites which rely on host cell to replicate. Spores are the primary means of transmission and are extremely resistant to environmental conditions.<br>Found in various food sources, including fruits, vegetables, and seafood. Prevalence in food is relatively low compared to other pathogens, and the risk of foodborne transmission is generally considered to be low. Prevalence in oysters can vary depending on the environmental conditions and the quality of the water they are harvested from. Symptoms include diarrhoea, myositis, keratitis, bronchitis and in rare cases encephalitis. Infection can also be asymptomatic. | Low | NA – not identified within SRT. |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | *T. gondii* | Protozoan parasite causing toxoplasmosis. More commonly associated in raw or undercooked meat, especially pork, lamb and venison, but has also been detected in oysters. *T. gondii* in oysters is associated with contaminated waters. In healthy individuals, *T. gondii* infection often goes unnoticed or causes mild flu-like symptoms. However, it can pose serious risks to pregnant women (and foetuses) and individuals with weakened immune systems. Congenital infection can lead to severe birth defects or foetal loss. In immunocompromised individuals, *T. gondii* can cause severe encephalitis or disseminated infection. | Low | NA – not identified within SRT. |
| Chemical | Heavy metals | Fish and seafood are regarded as one of the main food sources of cadmium (Cd), mercury (Hg) and lead (Pb). Other heavy metals include methylmercury, arsenic and copper. Heavy metals identified within the SRT are discussed further. | NA | See below for individual metals. |
| | | Cadmium – highest levels are found in the kidney and liver of mammals fed with cadmium-rich diets and in certain species of oysters, scallops, mussels and crustaceans. The dose required to cause illness varies depending on factors such as duration of exposure, route of exposure, and individual susceptibility. In humans, chronic cadmium intake is responsible for different organ systems toxicity with reproductive and fertility impairments, skeletal damage, urinary and cardiovascular disorders, central and peripheral nervous deficiency, kidney disease and cancer. | NA | Uncontrolled: 35<br>Control 1: 33<br>Control 2: 19 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | Lead – reported high levels in oysters in certain environments. Lead can accumulate in the body and may be distributed to the brain, liver, kidneys, and be stored in the teeth and bones. Lead stored in the bones can be released into the blood during pregnancy and become a source of exposure for the developing foetus. In children particularly, exposure to lead at high levels affects the brain and nervous systems, causing coma, convulsions and possible death. Lead poisoning has been linked to the incidence of neurodevelopment conditions and disorders. At lower levels, lead may cause no obvious symptoms, but can cause behaviour changes over time. Lead exposure also causes anaemia, hypertension, renal impairment, immunotoxicity and reproductive toxicity in all age groups. Neurological effects are thought to be irreversible. | NA | Uncontrolled: 35<br>Control 1: 33<br>Control 2: 19 |
| | | Mercury – exists in various forms, namely: elemental and inorganic and organic (for example, methylmercury, to which people may be exposed through their diet). These forms of mercury differ in their degree of toxicity and in their effects on the nervous, digestive and immune systems, and on lungs, kidneys, skin and eyes. Neurological and behavioural disorders may be observed after inhalation, ingestion or dermal exposure of different mercury compounds. Symptoms include tremors, insomnia, memory loss, neuromuscular effects, | NA | Uncontrolled: 35<br>Control 1: 33<br>Control 2: 19 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | headaches and cognitive and motor dysfunction. Studies have shown accumulation in oysters. | | |
| | | Copper – commonly accumulates in drinking water. Has been reported in oysters. Under Codex General Standard for Contaminants and Toxins in Food and Feed, copper is not considered as a contaminant with public health significance, hence there is no standard for copper. Chronic exposure to high levels could lead to liver damage and GI symptoms (for example, abdominal pain, cramps, nausea, diarrhoea, and vomiting). | NA | Uncontrolled: 11<br>Control 1: 10<br>Control 2: 8 |
| | | Arsenic – has been reported in shellfish, including oysters. Inorganic arsenic is a carcinogenic – linked with skin, bladder and lung cancer. Inorganic arsenic compounds (such as those found in water) are highly toxic while organic arsenic (such as those found in seafood) are less harmful. Symptoms of acute arsenic poisoning include vomiting, abdominal pain and diarrhoea, followed by later onset of numbness and tingling of the extremities, muscle cramping, and death in extreme cases. The first symptoms of chronic exposure to high levels of inorganic arsenic are usually observed in the skin as pigmentation changes, skin lesions and hard patches on the hands and feet – considered to occur after a minimum exposure of approximately five years and may be a precursor to skin cancer. Other adverse effects associated with chronic exposure include developmental effects, diabetes, pulmonary disease and cardiovascular disease. Arsenic- | NA | Uncontrolled: 14<br>Control 1: 20<br>Control 2: 12 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | induced myocardial infarction can be a significant cause of mortality. Arsenic is also associated with adverse pregnancy outcomes and infant mortality, with exposure in utero and in early childhood linked with multiple cancers, lung disease, heart attacks and kidney failure. | | |
| | Persistent Organic Chemicals (POCs) | POCs also known as persistent organic pollutants (POPs) are organic substances that persist in the environment, accumulate in living organisms and pose a risk to health and the environment. Previously, POCs were used in the manufacture of pesticides and industrial chemicals, which would later be released into the environment during chemical or agricultural processes. Examples of POCs include endosulfan, tetrabromodiphenyl ether (TBE), pentabromodiphenyl ether (PBE), hexabromodiphenyl ether (HBE), heptabromodiphenyl ether (HBE), polychlorinated biphenyls (PCBs), perfluorinated compounds (PFCs), polybrominated diphenyl ethers (PBDEs), polycyclic aromatic hydrocarbons (PAHs), perfluorooctane sulfonic acid (PFOS) and its derivatives. For the purpose of this risk profile, the focus will be on PCBs, PFCs, PBDEs, PAHs, dioxins and furans because they were identified by the SRT. Due to their nature, POPs are often present in food, especially food of animal origin such as meat or fish. Shellfish are filter feeders, which means when POP particles are in the water, shellfish can accumulate the substance in their bodies. There is the possibility | NA | PCBs:<br>Uncontrolled: 20<br>Control 1: 18<br>Control 2: 13<br><br>PFCs, PBDEs:<br>Uncontrolled: 20<br>Control 1: 14<br>Control 2: 12<br><br>PAHs:<br>Uncontrolled: 20<br>Control 1: 13<br>Control 2: 13<br><br>Dioxins:<br>Uncontrolled: 20<br>Control 1: 20<br>Control 2: 18<br><br>Furans: NA |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | that they may reach levels potentially harmful to consumers.<br>Some of the health effects of exposure to POPs include, increased cancer risk, reproductive disorders, alteration of the immune system, neurobehavioral impairment, endocrine disruption, genotoxicity and increased birth defects. This depends on the type of POP and exposure. | | |
| | Radiological contaminants | Radionuclides also known as radioactive materials or radioactive isotopes are unstable forms of elements that emit radiation as they undergo radioactive decay. The presence of radionuclides in food, including oysters, can pose health risks if consumed in excessive amounts. The prevalence of radioactive contamination in the environment and food varies depending on historical nuclear activities, accidents, and local monitoring practices. Examples of radionuclides include caesium, cobalt, iodine, ionising radiation, plutonium, radium, radon. Consuming food contaminated with radionuclides increases the amount of radioactivity in the body and could increase the health risks. For example, if radioactive iodine is ingested with contaminated food or drink, or inhaled with contaminated air, it can accumulate in the thyroid gland and increase the risk of thyroid cancer, particularly in children. Exposure to radionuclides can result in an increased risk of certain types of cancer depending on the type of radionuclide and exposure. | NA | Uncontrolled: 14<br>Control 1: 6<br>Control 2: 6 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | Radiological contaminants identified and discussed within the risk profile are Strontium-90, Polonium-210, Caesium-137, Plutonium and Radium-226 as they were identified within the SRT. | | |
| | Veterinary pharmaceuticals and personal care products | Veterinary pharmaceutical and personal care chemicals enter the environment by a number of different pathways. It has also been highlighted that during the treatment of fish with medicated feed pellets, some of these tend to enter the environment and are therefore accessible to wild fish, shellfish and crustaceans. Other routes into the sea include through wastewater treatment plants, agricultural runoff, and industrial discharges. Therefore, these can accumulate within oysters. Examples include antibiotics, growth promoters, non-steroidal anti-inflammatory drugs (NSAIDs), feed additives, recreational drugs, sertraline, tamoxifen, salicylic acid. These are some notable chemicals identified within the SRT but there are many more possibilities. Symptoms vary depending on the chemical and the exposure level. | NA | Uncontrolled: 23<br>Control 1: 20<br>Control 2: 12<br>(Antimicrobials only) |
| | Microplastics | Microplastics are small plastic particles within the size range of 0.0001 – 5 mm and are found in the environment, including in the oceans, freshwater bodies, and even in the air. They can be categorised into two main types. Primary microplastics are intentionally produced as small particles for various purposes such as use in cosmetics and industrial applications. Secondary microplastics are formed by the breakdown of larger plastic items over time due | NA | NA – not identified within SRT. |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | to weathering, ultraviolet (UV) radiation, and mechanical action such as microfibers shedding from synthetic clothing and opening of water bottle lids. Primary microplastics enter the aquatic environment through household sewage discharge or spillage of plastic resin powders or pellets such as those used for air blasting in watercourses. Secondary microplastics are introduced to aquatic environments by wind dispersal, soil erosion or surface runoff. Microplastics have been found in various food sources, including seafood, water, salt, honey. The prevalence of microplastics in food can vary depending on the source and processing methods. Seafood, particularly shellfish like oysters, mussels, and clams, have been found to contain microplastics due to their filter-feeding nature. Oysters in particular have been shown to accumulate microplastics in their tissues. Nanoplastics (NPs) have also been identified in oysters. NPs are most recently defined as particles of a size between 1 and 1000nm which result mainly from degradation of larger plastic particles. The symptoms and diseases associated with microplastic and nanoplastic ingestion in humans are not well-defined. Some studies suggest that microplastics may pose several toxicity concerns, including acute and chronic toxicity (cytotoxicity, immunotoxicity and reproductive toxicity), carcinogenicity, and developmental toxicity. | | |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | High Production Volume (HPV) chemicals | HPV chemicals were defined by the Organisation for Economic Cooperation and Development (OECD) as chemicals with a production of over 1000 tonnes/ year and by the United States (US) Environmental Protection Agency (EPA) as compounds produced at a minimum of 500 tonnes/ year. This is large list of chemicals so only those noted in LBMs or oysters in a review of analytical methods by Castro *et al* have been characterised.<br>From the review it is clear that phthalate esters (PAEs), organophosphate esters (OPEs) and benzotriazoles (BTRs) of different types were observed in molluscs, or oysters specifically, at varying levels and in varied locations. Therefore, these compound families have been characterised. Symptoms vary depending on the chemical and the exposure level. | NA | NA – not identified within SRT. |
| Chemical – natural biotoxins | Azaspiracid (AZA) group | AZA group toxins are produced by the dinoflagellate *Amphidoma languida* and *Azadinium spinosum*. These toxins cause azaspiracid shellfish poisoning (AZP) in humans which is characterised by symptoms such as nausea, vomiting, diarrhoea and stomach cramps. This syndrome is very similar to diarrheic shellfish poisoning (DSP), with main symptoms appearing after a few hours from consumption and including diarrhoea, vomiting, and stomach cramps. | NA | Uncontrolled: 50<br>Control 1: 38<br>Control 2: 12.5<br>(Lipophilic toxins, (okadaic acid, DXT, AZAs)) |
| | Brevetoxin (BTX) group | BTX group toxins are mainly produced by the dinoflagellate *Karenia brevis* and cause neurologic shellfish poisoning (NSP). Symptoms and signs of | NA | Uncontrolled: 33<br>Control 1: 23<br>Control 2: 15.5 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | NSP include nausea, vomiting, diarrhoea, paraesthesia, cramps, bronchoconstriction, paralysis, seizures and coma. | | |
| | Cyclic imines (CIs) group | The CIs group includes gymnodimine (GYMs), spirolides (SPXs), pinnatoxins, prorocentrolide and spirocentrimine. SPXs and GYMs are produced by the dinoflagellates *Alexandrium ostenfeldii* and *Karenia selliformis*, respectively. The toxicological database for CIs group is limited. There have been no reports of adverse effects in humans. | NA | NA – not identified within SRT. |
| | Domoic Acid (DA) group | DA group toxins are mainly produced by marine red algae of the genus *Chondria* and diatoms of the genus *Pseudo-nitschia*. They cause amnesic shellfish poisoning (ASP) in humans. Symptoms of ASP include gastrointestinal symptoms (vomiting, diarrhoea or abdominal cramps) and/or neurological symptoms (confusion, loss of memory, or other serious signs such as seizure or coma) occurring within 24-48 hours after consuming contaminated shellfish. | NA | Uncontrolled: 50<br>Control 1: 42<br>Control 2: 16<br>(Amnesic shellfish toxins) |
| | Okadaic Acid (OA) group | OA group toxins are mainly produced by dinoflagellates *Dinophysis* spp. and *Prorocentrum lima.* OA toxins cause DSP, which is characterised by symptoms such as diarrhoea, nausea, vomiting and abdominal pain. These symptoms may occur in humans shortly after consumption of contaminated LBMs such as oysters. | NA | Uncontrolled: 50<br>Control 1: 38<br>Control 2: 12.5<br>(Lipophilic toxins (okadaic acid, DXT, AZAs)) |
| | Palytoxin (PITX) group | PITX group toxins have mainly been detected in soft corals of the genus *Palythoa* and in algae of the genus *Ostreopsis*. Signs and symptoms of PITX- | NA | Uncontrolled: 33<br>Control 1: 23<br>Control 2: 15.5 |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | group toxins intoxication are not well-defined, but include myalgia and weakness, possibly accompanied by fever, nausea and vomiting. Fatalities are usually rare although there are reports of severe cases, in which patients died after about 15 hours. | | |
| | Pectenotoxin (PTX) group | PTX group toxins are produced by the algae of the genus *Dinophysis*. The toxicological database for PTXs is limited. There is no evidence of an adverse effect of PTXs in humans. | NA | NA – not identified within SRT. |
| | Saxitoxin (STX) group | STX group toxins are mainly produced by dinoflagellates belonging to the genus *Alexandrium*: for example, *A. tamarensis*, *A. minutum* (syn. *A. excavate*), A. catenella, *A. fraterculus*, *A. fundyense* and *A. cohorticula*. They cause paralytic shellfish poisoning (PSP) in humans, characterised by symptoms varying from a slight tingling sensation or numbness around the lips to fatal respiratory paralysis. In fatal cases respiratory arrest occurs two to 12 hours following consumption of shellfish contaminated with STX group toxins. | NA | Uncontrolled: 42<br>Control 1: 32<br>Control 2: 19.5 |
| | Yessotoxin (YTX) group | YTX are produced by the marine dinoflagellates *Protoceratium reticulatum*. The toxicological database for YTX is limited. There are no reports of human intoxications caused by YTX. | NA | NA – not identified within SRT. |
| | Tetrodotoxin (TTX) | TTX are produced by bacteria that are more often found in certain fish species but there are reports of them in marine gastropods and bivalves. Symptoms of acute TTX intoxication include perioral numbness and paraesthesia, lingual numbness, early motor | NA | NA – not identified within SRT. |

| Hazard type | Hazard category | Summary of hazard specific information | Severity [a] | SRT scores [b, c] |
|---|---|---|---|---|
| | | paralysis, incoordination, slurred speech to generalised flaccid paralysis, aphonia and fixed/ dilated pupils to hypoxia, hypotension, bradycardia, cardiac dysrhythmias and unconsciousness and in the end death. Death is caused by respiratory failure and cardiac collapse. There is no antidote against TTX poisoning. | | |

a) For the purposes of this risk profile severity is in consideration of the general population. Severity for vulnerable groups may differ and where it is notable, it is discussed in detail within the specific hazard section. Severity is only defined for microbiological hazards, as discussed in the introduction to the hazard characterisation.
b) Where marked NA within the SRT column, SRT scores were not provided for the hazard because it was not identified by the SRT.
c) Uncontrolled: when assessing the potential impact of uncontrolled hazards on supply from a specific aquaculture scenario.
Control one: when assessing the benefit of applying discrete phase-specific control measures for limiting the impact of hazards which may affect that supply chain phase.
Control two: when assessing multi-phase (cumulative or stepwise) control measures in limiting impact of hazards affecting the supply from a specific aquaculture scenario.

## 6.4 Microbiological hazards

### 6.4.1 Bacterial hazards

Table 4 provides the SRT impact score for bacterial hazards (HH only) from the refined hazard list (section 5.2). Scores were derived as part of the SRT supplementary information using the SRT schema (see section 6.2). Scores are provided for the uncontrolled state in which no controls are applied; control one - the controlled state where either standalone/non-accrued control measures are applied at discrete phases of supply; control two - the controlled state where the benefit of controls applied at one phase are accrued in subsequent phases of supply.

Table 4: SRT application to bacterial human health hazards (1)

| **Bacteria** | **Score** | | |
|---|---|---|---|
| | **Uncontrolled** | **Control 1** [a] | **Control 2** [b] |
| *Vibrio parahaemolyticus* | 48 | 34 | 25 |
| *Vibrio vulnificus* | 33 | 23 | 18 |
| *Vibrio cholerae* O1 and O139 strains (choleragenic) | 52 | 32 | 17 |
| *Vibrio cholerae* non-O1 and non-O139 strains | 67 | 47 | 32 |
| *Vibrio* spp. | 30 | 21 | 15 |
| *Salmonella* Typhi & *Salmonella* Paratyphi (typhoidal) | 66 | 58 | 24 |
| *Salmonella* spp. (non-typhoidal) | 71 | 59 | 31 |
| *Escherichia coli* (unspecified) | 54 | 38 | 26 |
| *Shigella* | 24 | 21 | 16 |
| *Campylobacter jejuni* | 31 | 22 | 16 |
| Faecal indicators/ coliforms | 42 | 38 | 18 |

a) Controlled state when hazards are controlled at discrete phases, they are standalone/ non-accrued control measures.
b) Controlled state when hazards are controlled at discrete phases and the benefit of controls are accrued in subsequent phases of supply.

The bacterial hazards characterised in this section include *Vibrio* spp., *Salmonella* spp., *E. coli*, *Shigella* spp., *Campylobacter* spp., *S. aureus*, *Y, enterocolitica* and faecal indicators/ coliforms.

According to Table 4, non-typhoidal *Salmonella* spp. and *Vibrio cholerae* O1 and O139 strains (choleragenic) had the highest impact scores in the uncontrolled state. Furthermore, there was a decrease in control one and two scores for all bacterial

hazards. This suggests that control measures are likely to reduce the impact of the hazard and for benefits to be accrued along the supply chain.

SRT scores were unavailable for *S. aureus* and *Y. enterocolitica* because they were not identified within the SRT.

Some bacterial infections require only a small number of organisms to cause potentially overwhelming infection. The five ways by which bacterial infections are transmitted include contact, airborne, droplet, vectors and vehicular (via food, water or fomites) (69). Bacterial infection due to food and water generally develops when bacteria enter the intestine through the mouth. Those organisms that survive the low pH of the stomach and are not swept away by the mucus of the small intestine may attach to the cell surfaces. There they may invade the host cells or release toxins, causing diarrhoea or other symptoms (69).

6.4.1.1 *Vibrio* spp.

The genus *Vibrio* contains at least twelve species pathogenic to humans, ten of which can cause foodborne illness. The majority of foodborne illness is caused by *V. parahaemolyticus*, choleragenic *V. cholerae*, or *V. vulnificus. V. parahaemolyticus* and *V. cholerae* are mainly isolated from gastroenteritis cases that are attributable to consumption of contaminated food, with *V. cholerae* also attributable to the ingestion of contaminated water. In contrast, *V. vulnificus* is primarily reported from extraintestinal infections (septicaemia, wounds, etc.), however, it may also be reported from primary septicaemia as *V. vulnificus* infection may also be associated with consumption of seafood (70). In tropical and temperate regions, these pathogenic species of *Vibrio* occur naturally in marine, coastal and estuarine (brackish) environments and are most abundant in estuaries. Pathogenic *Vibrio* spp., in particular *V. cholerae* and *V. vulnificus*, can also be recovered from freshwater reaches of estuaries, where they can also be introduced by faecal contamination. *V. cholerae*, unlike most other *Vibrio* spp., can survive in a freshwater environment (70).

It is now possible to differentiate between virulent and avirulent strains of *V. cholerae* and *V. parahaemolyticus* based on their ability to produce their major virulence factors. The pathogenic mechanisms of *V. vulnificus* have not been clearly

elucidated, and its virulence appears to be multifaceted and is not well understood, and therefore all strains are considered virulent (70). *Vibrio* spp. are sensitive to low pH but grow well at high pH, and thus infections caused by *Vibrio* spp. are frequently associated with low-acid foods. In addition, the ingestion of a large number of viable cells is needed for pathogenic *Vibrio* spp. to survive the acidic environment of the stomach and establish an infection. This is because they are sensitive to stomach acid and so many are required to increase likelihood of adherence to intestinal cells to cause infection (71). Cooking of food products readily inactivates *Vibrio* spp. even in highly contaminated products. The FSA advises to cook food until a core temperature of 70°C is reached, for two minutes (72). Hygienic practices used with all foodborne pathogens will in general control the growth of pathogenic *Vibrio* spp. (70). However, maintenance of the cold chain is more effective, as established by a study conducted in the US in which a decrease in presence of *V. parahaemolyticus was* observed in 75% of $10^3$ oyster shipments investigated across multiple states, when the cold chain was maintained (73).

There are characteristics specific to each of the three major pathogenic species of *Vibrio* described in the following sections.

##### *6.4.1.1.1 Vibrio parahaemolyticus*

*V. parahaemolyticus* is considered to be part of the autochthonous (naturally occurring) microflora in the estuarine and coastal environments in tropical to temperate zones. While *V. parahaemolyticus* is typically undetectable in seawater at 10°C or lower, it can be cultured from sediments throughout the year at temperatures as low as 1°C. In temperate zones, the life cycle consists of a phase of survival in winter in sediments and a phase of release with zooplankton when the temperature of the water increases up to 14 - 19 °C. *V. parahaemolyticus* is characterised by its rapid growth under favourable conditions (70). The vast majority of strains isolated from patients with diarrhoea produce a Thermostable Direct Haemolysin (TDH). It has therefore been considered that pathogenic strains possess a *tdh* gene and produce TDH, and non-pathogenic strains lack the gene and the trait. Additionally, strains that produce a TDH-Related Haemolysin (TRH) encoded by the *trh* gene should also be regarded as pathogenic (70).

Enterotoxins produced by *V. parahaemolyticus* affect the host cell enterocyte cytoskeleton to affect the intestinal secretion of water and electrolytes (74). Symptoms *of V. parahaemolyticus* infections include explosive watery diarrhoea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills. Most cases are self-limiting, however, severe cases of gastroenteritis requiring hospitalisation have been reported. Virulent strains are seldom detected in the environment or in foods, including seafoods, while they are detected as major strains from faeces of patients (70).

In Asia, *V. parahaemolyticus* is a common cause of foodborne disease. In general, the outbreaks are small in scale, involving fewer than ten cases, but occur frequently. *V. parahaemolyticus* has now spread to at least five continents and there is a suggestion that ballast discharge[8] (75) from ships may be a major mechanism for global spread of this bacteria, but a possibility of export/ import seafood-mediated international spread cannot be ruled out (70). Due to the symptoms associated with *V. parahaemolyticus* being commonly observed in multiple foodborne illnesses and that they are usually short-lived and self-limiting, the proportion of underreporting of infection with *V. parahaemolyticus* is high. In a quantitative risk assessment of *V. parahaemolyticus* in shellfish from retail in Eastern China in 2021, data collected was estimated to be approximately 10% of the actual cases. Underreporting is also noted by the WHO and the US Centre for Disease Control and Prevention (CDC) (76) (77) (78).

Oysters are listed amongst the foods associated with illness caused by *V. parahaemolyticus*, as are other types of seafood. These products include both raw,

[8] Water is used as ballast to stabilise vessels at sea. Ballast water is pumped into a ship to maintain safe operating conditions throughout a voyage. it improves propulsion and manoeuvrability, and compensates for weight changes, it can then be released when required. Ballast water may pose ecological, economic and health problems due to the multitude of marine species carried in ships' ballast water (International Maritime Organisation).[9] Diastereoisomer, also spelled diasteromer, either member of a pair of substances that differ with respect to the configurations of their molecules (i.e., stereoisomers) and that lack a mirror-image relationship (i.e., are not enantiomers) 283. Britannica. Diastereoisomer | Definition, Example, & Facts: Britannica; 2023 [Available from: https://www.britannica.com/science/diastereoisomer.

partially treated, and thoroughly treated seafood products that have been substantially re-contaminated through contaminated utensils and hands, for example (70). In terms of the dose-response relationship, the probability of illness is relatively low (<0.001%) for consumption of 10,000 *V. parahaemolyticus* cells/ serving (equivalent to about 50 cells/ g oyster). Consumption of about 100 million *V. parahaemolyticus* cells/ serving (500 thousand cells/ g oyster) increases the probability of illness to about 50% (79).

Information on burden of foodborne disease caused by these bacteria in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT for *V. parahaemolyticus* were 48, 34 and 25 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of *V. parahaemolyticus* for the general population is low (4).

*6.4.1.1.2 V. cholerae*

*V. cholerae* is indigenous to fresh and brackish water environments in tropical, subtropical and temperate areas worldwide. Over 200 O serogroups have been identified for *V. cholerae*. Strains belonging to O1 and O139 serotypes possess the *ctx* gene (*ctx* +) and produce cholera toxin (CT), they are responsible for epidemic cholera. Epidemic cholera is confined mainly to developing countries with warm climates. Faeces from individuals infected with the cholera bacteria are the primary source of transmission in cholera epidemics. Contamination of food production environments (including aquaculture ponds) by faeces can indirectly introduce choleragenic *V. cholerae* into foods. The concentration of free-living choleragenic *V. cholerae* in the natural aquatic environment is low, but *V. cholerae* is known to attach and multiply on zooplankton such as copepods (70). Oysters are filter feeders and so may become contaminated with these bacteria through consumption of zooplankton.

Cholera can be introduced from abroad by infected travellers, imported foods and through the ballast water of cargo ships. The choleragenic strains of *V. cholerae* that

spread to different parts of the world may persist, and some factors may trigger an epidemic in the newly established environment. Detection frequencies of choleragenic strains of *V. cholerae* from legally imported foods have been very low and they have seldom been implicated in cholera outbreaks (70). It is unlikely that a cholera epidemic will be triggered in the UK unless sanitation levels decline significantly. This is because, as discussed above, cholera epidemics are predominantly due to waterborne transmission through faecal contamination of water supplies that are not properly treated.

Outbreaks of foodborne cholera have been noted often in the past 30 years; seafood, including bivalve molluscs, crustaceans, and finfish, are most often implicated in foodborne cholera cases in many countries (70).

*V. cholera* can produce enterotoxins which affect the regulation of water and electrolyte fluxes across the intestinal mucosa through the cyclic adenosine monophosphate (cAMP); cyclic guanosine monophosphate (cGMP); and calcium dependent pathways (74). Cholera is characterised by profuse watery diarrhoea and vomiting which can cause life threatening dehydration. Symptoms normally last between three and seven days (80). With adequate and timely rehydration, the case-fatality ratio is <1%. This is associated with O1 and O139 serotypes more commonly associated with waterborne transmission. Non- O1 and O139 serotypes are more commonly associated with raw or undercooked seafood consumption. Symptoms of infections with these serotypes may range from mild gastroenteritis to life-threatening necrotising fasciitis (81) (82).

According to the WHO burden of foodborne disease report, *V. cholerae* (strain not specified) was implicated in 763,451 foodborne illnesses and 1,722,312 years lost to DALYs worldwide due to long term effects on health (10).

Scores from the SRT for *V. cholerae* O1 and O139 strains (choleragenic) were 52, 32 and 17 for the uncontrolled state and the two controlled states, respectively. For non O1 and non O139 strains, scores were 67, 47 and 32, respectively. A consistent drop in scores was observed for both types, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply

chain. Impact was generally higher for non O1 and non O139 strains, illustrating their importance in the LBMs scenario.

According to the ICMSF, the severity of O1 and O139 (choleragenic) strains of *V. cholerae* for the general population is high. The severity of non-O1 and O139 strains of *V. cholerae* is low (4).

*6.4.1.1.3 V. vulnificus*

*V. vulnificus* can occasionally cause mild gastroenteritis in healthy individuals, but it can cause primary septicaemia in individuals with chronic pre-existing conditions, especially liver disease or alcoholism, diabetes, haemochromatosis and Human Immunodeficiency Virus (HIV)/ Acquired Immunodeficiency Syndrome (AIDS), following consumption of raw bivalve molluscs. This is a serious disease with the highest fatality rate of any known foodborne bacterial pathogen (83). The incubation period ranges from seven hours to several days, with the average being 26 hours (70). Of the three biotypes of *V. vulnificus*, biotype one is generally considered to be responsible for most seafood-associated human infection. Foodborne illness from *V. vulnificus* is characterised by sporadic cases and an outbreak has never been reported. *V. vulnificus* has been isolated from oysters, other bivalve molluscs, and other seafood worldwide (70).

The densities of *V. vulnificus* are high in oysters at harvest when water temperatures exceed 20°C in areas where *V. vulnificus* is endemic, although *V. vulnificus* multiplies in oysters at a temperature higher than 13°C. The salinity optimum for *V. vulnificus* appears to vary considerably from area to area, but highest numbers are usually found at intermediate salinities of 5 to 25 g/l (ppt: parts per thousand). Relaying oysters to high salinity waters (>32 g/l (ppt) was shown to reduce *V. vulnificus* numbers by 3–4 logs (<10 per g) within two weeks (70).

The dose of *V. vulnificus* required to cause gastroenteritis or septicaemia is not known. Estimates of $10^3$ and $10^4$ cells have been made for the infectious dose for people with pre-existing health conditions that make them more susceptible to infection (84).

Information on burden of foodborne disease caused by these bacteria in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT for *V. vulnificus* were 33, 23 and 18 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of *V. vulnificus* for the general population is high (4).

6.4.1.2 *Salmonella* spp.

*Salmonella* is a gram-negative, rod-shaped genus belonging to the Enterobacteriaceae family. Within two species, *Salmonella bongori* and *Salmonella enterica*, over 2500 different serotypes or serovars have been identified to date. *Salmonella* is a ubiquitous and hardy bacterium that can survive several weeks in a dry environment and several months in water (85). *Salmonella* is a zoonotic pathogen and its presence in marine and fresh environmental surface waters may be from one or multiple routes, such as wastewater treatment plant discharges, urban and/ or agricultural runoff pollution, overburdened septic systems, or contact with local and migratory fauna (86).

The presence of *Salmonella* in marine waters can result in contamination of seafood. For example, between 2015 and 2018, 11 recalls of live oysters were issued in Canada due to the presence of *S. enterica.* After which, a study was conducted to prove that *S. enterica* present in seawater was able to accumulate in oysters due to filter feeding (87). Additionally, a survey in Tucson, USA revealed that oysters served raw in restaurants can, in rare cases, be contaminated with *Salmonella* strains that may also be multidrug resistant (88).

The number of unspecified typhoidal and non-typhoidal *Salmonella* spp. infections that go unreported have been estimated to be between 20 and 100 times greater than the number of reported infections, resulting in an estimated 1% of the population infected each year according to Heinitz *et al*. (87). Furthermore, the Longitudinal Study of Infectious Intestinal Disease (IID2 study) by Tam *et al* provides

a ratio of 4.7 and 1.4 for community cases and cases presenting to a general practitioner (GP), respectively, compared to the number of cases reported to national surveillance. The objective of the study was to estimate the incidence of IID in the community, presenting to general practice (GP) and reported to national surveillance. It was a community cohort study and study of GP presentation conducted between April 2008 and August 2009. 88 GPs across the UK participated, and 6836 participants registered with those participating practices were involved in the community study. In the community cohort study, participants were contacted weekly for any symptoms of diarrhoea and/ or vomiting, for up to 52 weeks. In the GP presentation study, GPs were asked to refer all patients presenting with IID to the study nurse who administered a questionnaire and requested a stool specimen. For national surveillance, records of IID cases reported in each UK country were obtained over the study period from the UK national surveillance centre. A community case refers to a potential IID case present amongst participants of the study whilst a GP case refers to a case that was reported to the GP. In this study the type of *Salmonella* spp. reported were non-typhoidal only. This suggests that underreporting of *Salmonella* infection is also significant in the UK (89).

Analysis of outbreak data in Europe between 2015 and 2019 revealed that the most important food sources for salmonellosis outbreak were eggs, pork and other meat products. The contribution of fish and fish products decreased from 3% in 2015 to 0.4% in 2019 (90).

*6.4.1.2.1 Non-typhoidal Salmonella*

For non-typhoidal salmonellosis (NTS), the infectious dose is approximately $10^3$ organisms. Vulnerable patients such as those with depressed cell-mediated immunity, who are elderly or very young children, may become infected at a lower infectious dose. The infectious dose may also be dependent on the level of acidity in the patient's stomach (91). NTS serovars include Typhimurium and Enteritidis.

*Salmonella* spp. can produce enterotoxins which affect the regulation of water and electrolyte fluxes across the intestinal mucosa through the cAMP; cGMP; and calcium dependent pathways to affect the intestinal secretion of water and electrolytes. Patients with NTS have self-limiting, acute gastroenteritis and watery

diarrhoea, nausea, vomiting, abdominal pain, and fever. With NTS infection, symptoms generally appear six to12 hours after the ingestion of the pathogen and clinical symptoms last less than ten days (91).

The WHO report on the global burden of disease provides information on *S.* Paratyphi A and *S.* Typhi only (typhoidal *Salmonella* only), not NTS serovars (92).

Scores from the SRT for *Salmonella* spp. (NTS, such as *S.* Enteritidis*, S,* Typhimurium) were 71, 59 and 31 for the uncontrolled stated and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity for serotypes other than *S.* Typhi and *S.* Paratyphi *A* (NTS, such as *S.* Enteritidis*, S,* Typhimurium) for the general population is medium (4).

*6.4.1.2.2 Typhoidal Salmonella*

*S. enterica* serovars including Typhi, Sendai, and Paratyphi A, B, or C are collectively referred to as typhoidal *Salmonella* serovars and are the causative agents of enteric fever (also known as typhoid or paratyphoid fever if caused by serovar Typhi or Paratyphi, respectively). The infectious dose is about $10^5$ organisms by ingestion. Enteric fever caused by typhoidal serovars is different from the gastroenteritis associated with NTS. The average incubation period for typhoidal serovars is 14 days with symptoms persisting for up to three weeks. Patients generally present with a gradual onset of sustained fever (39–40°C). Frequent symptoms include chills, abdominal pain, rash, nausea, anorexia, diarrhoea or constipation, headache, and a dry cough (93).

The WHO report on the global burden of disease provides information on *S.* Paratyphi A and *S.* Typhi only. *S.* Paratyphi A was implicated in 1,741,120 foodborne illnesses and 855,730 years lost to DALYs worldwide due to long term effects on health. *S.* Typhi was implicated in 7,570,087 foodborne illnesses and 3,720,565 years lost to DALYs worldwide (10).

Scores from the SRT for *S.* Paratyphi A *and S.* Typhi (typhoidal *Salmonella*) were 66, 58 and 24 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of both *S.* Typhi and *S*. Paratyphi A (typhoidal *Salmonella*) for the general population is high (4).

6.4.1.3 *Escherichia coli*

*E. coli* is a bacterium that is commonly found in the gut of humans and warm-blooded animals. Most strains of *E. coli* are harmless. Some strains, however, produce toxins which can cause severe foodborne disease, these are known as Shiga-toxigenic *E. coli* (STEC). Transmission to humans is primarily through consumption of contaminated foods, such as raw or undercooked ground meat products, raw milk, and contaminated raw vegetables and sprouts (94). According to the WHO, STEC cases in Europe attributed to seafood between 1998 and 2017 were 1.7% of all cases in the Americas, Europe and Western-Pacific regions (95). *E. coli* is also considered within this risk profile as an indicator of faecal contamination (see section 6.4.1.8). As identified in the SRT article, the strain of *E. coli* was not specified, however it has been provided with an SRT impact score for the LBMs scenario. STEC has been considered in this risk profile because it is important in terms of foodborne disease.

Currently, there are six recognised pathogenic groups enterotoxigenic *E. coli* (ETEC), enteropathogenic *E. coli* (EPEC), enterohemorrhagic *E. coli* (EHEC), enteroinvasive *E. coli* (EIEC), enteroaggregative *E. coli* (EAEC), and diffusely adherent *E. coli* (DAEC). Of these, the ETEC, EPEC, EHEC and EIEC groups are known to be transmitted via contaminated food or water; EHEC, especially, are often implicated in major foodborne outbreaks worldwide. EHEC are a subset of STEC (96). *E.coli* O157:H7 is the predominant strain of the EHEC infections worldwide (96). According to Rahal *et al*. (2012), the infectious process of *E. coli* O157:H7 is initiated by the ingestion of a relatively small inoculum of 10–100 colony forming units (CFUs) (97). EHEC are a subset of STEC (96). The enterotoxins produced by

EHEC and EAEC interrupt the host cell protein synthesis to affect the intestinal secretion of water and electrolytes (74).

Symptoms of STEC tend to appear three to four days after infection and include abdominal cramps, watery and/ or bloody diarrhoea, fever and vomiting. Vulnerable people may go on to develop more severe complications such as haemolytic-uraemic syndrome (HUS) which can lead to kidney failure. This is more common in children under five years old and in those with a weakened immune system (98).

According to the WHO burden of foodborne disease report, EPEC (common serotypes of EPEC are O26:H- and H11) was responsible for 23,797,284 foodborne cases and 2,938,407 years lost to DALYs worldwide due to long term effects on health, whilst ETEC was responsible for 86,502,735 foodborne cases and 2,084,229 years lost to DALYs worldwide due to long term effects on health (10).

Scores from the SRT for *E. coli* (unspecified) were 54, 38 and 26 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of both EHEC and EAEC for the general population is high. The severity for EPEC and ETEC for general population is low (4).

6.4.1.4 *Shigella* spp.

There are four species of *Shigella*: *S. dysenteriae*, *S. flexneri*, *S. boydii*, and *S. sonnei* (also referred to as group A, B, C, and D, respectively). Several distinct serotypes are recognised within group A, B and C species. These species cause an acute infection of the intestines called shigellosis. Shigellosis is highly contagious, as few as ten organisms can cause infection. Humans are the primary natural reservoir, although non-human primates can also be infected. *Shigella* spp. are endemic to temperate and tropical climates. Shigellosis is caused predominantly by *S. sonnei* in high-income countries, whereas *S. flexneri* is prevalent in low- and middle-income countries. Infections caused by *S. boydii* and *S. dysenteriae* are less common

globally. *S. boydii* is mostly restricted to the Indian subcontinent, and *S. dysenteriae* accounts for most *Shigella* spp. isolated in sub-Saharan Africa and South Asia (99).

*Shigella* can produce enterotoxins which affect the regulation of water and electrolyte fluxes across the intestinal mucosa through the cAMP; cGMP; and calcium dependent pathways to affect the intestinal secretion of water and electrolytes (74).

In 2019, the CDC recorded a multistate outbreak of gastrointestinal illnesses linked to oysters imported from Mexico. The outbreak was believed to be caused by the consumption of raw oysters contaminated with *S. flexneri.* Furthermore, *S. flexneri and S. sonnei* were also implicated in separate disease outbreaks between 1969 and 2000 in France and the USA due to the ingestion of shrimp, mussels and oysters. Symptoms of illness include diarrhoea, stomach cramps or pain, nausea, vomiting and fever (100).

According to the WHO burden of foodborne disease report, *Shigella* was implicated in 51,014,050 foodborne illnesses and 1,237,103 years lost to DALYs worldwide due to long term effects on health (92). Among shigellosis cases worldwide, approximately 20–119 million illnesses and 6,900–30,000 deaths are attributed to foodborne transmission (92).

Scores from the SRT for *Shigella* (species not specified) were 24, 21 and 16 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of *Shigella* (species not specified) for the general population is medium (4).

#### 6.4.1.5 *Campylobacter* spp.

*Campylobacter* spp. are mainly spiral-shaped, “S”-shaped, or curved, rod-shaped bacteria. Currently, there are 17 species and six subspecies assigned to the genus *Campylobacter*, of which the most frequently reported in human diseases are *C. jejuni* and *C. coli*. Other species such as *C. lari* and *C. upsaliensis* have also been isolated from patients with diarrhoeal disease but are reported less frequently (101).

*Campylobacter* spp. are widely distributed in most warm-blooded animals. They are prevalent in food animals such as poultry, cattle, pigs, sheep and ostriches; and in pets, including cats and dogs. The bacteria have also been found in shellfish, including oysters, however the main routes of transmission are through the consumption of raw or undercooked meat (particularly poultry), and contamination within the kitchen through handling of these products (101). The only way of eliminating *Campylobacter* spp. is through bactericidal treatment such as heating, through cooking (to an internal temperature of 70°C for two minutes) (102) or pasteurisation or irradiation, and freezing (101).

The dose requirement for *Campylobacter* spp. to cause illness may vary according to strain and host immunity but is thought to be relatively low, in the order of hundreds or thousands of cells (103).

*Campylobacter* spp. are one of the four key global causes of diarrhoeal diseases. Apart from diarrhoea, other symptoms include abdominal pain, fever, headache, nausea, and or vomiting. The symptoms typically last three to six days. Death from campylobacteriosis is rare, it is confined to vulnerable groups such as very young children or elderly patients, or to those already suffering from another serious disease such as AIDS. Complications such as bacteraemia (presence of bacteria in the blood), hepatitis (infection of the liver), pancreatitis (infection of the pancreas), and miscarriage in pregnant women have been reported with varying degrees of frequency. Post-infection complications may include reactive arthritis (painful joint inflammation which can last for several months) and neurological disorders such as Guillain-Barré syndrome (GBS). GBS is a polio-like form of paralysis which can result in respiratory and severe neurological dysfunction in a small number of cases (101).

The high incidence of diarrhoea caused by *Campylobacter* spp. infection, as well as its possible complications, makes it highly important from a socio-economic perspective. In developing countries, *Campylobacter* spp. infections in children under the age of two years are especially frequent, occasionally resulting in death (101). The true incidence of *Campylobacter* spp. infection is poorly known due to under reporting. For example, the IID2 study by Tam *et al* provides a ratio of 9.3 and 1.3 for

community cases and cases presenting to a GP, respectively, compared to the number of cases reported to national surveillance (104). A description of the IID2 study is provided in section 6.4.1.2.

According to the WHO burden of foodborne disease report, *Campylobacter* spp. were implicated in 95,613,970 foodborne illnesses and 2,141,926 years lost to DALYs worldwide due to long term effects on health (92).

Scores from the SRT for *C. jejuni* were 31, 22 and 16 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of *C. jejuni* for the general population is low (4).

#### 6.4.1.6 *Staphylococcus aureus*

*S. aureus* are gram-positive bacteria that are cocci-shaped and tend to be arranged in clusters that are described as “grape-like” (105). Antibiotic resistance is a common trait in *S. aureus*, which can be divided into methicillin-resistant *S. aureus* (MRSA), methicillin-susceptible *S. aureus* (MSSA), vancomycin-intermediate *S. aureus* (VISA) and vancomycin-resistant *S. aureus* (VRSA), based on their antibiotic resistance profile (106). About 25% of people and animals have *S. aureus* on their skin and in their nose. It usually does not cause illness in healthy people, but it has the ability to produce enterotoxins that can cause food poisoning (107). Enterotoxins are heat-stable and resistant to proteolytic enzymes which allows them to transit intact through the digestive tract (108). Staphylococcal food poisoning is a gastrointestinal illness caused by eating foods contaminated with these toxins (109). Foodborne illness is typically associated with food handlers and poor hygiene, followed by storage of foods in conditions which allow pathogen growth and toxin production (107). *S. aureus* can grow in a wide range of conditions; temperatures of 7 to 48.5°C (optimum 30-37°C), a pH of 4.2-9.3 (optimum 7-7.5) and sodium chloride (salt) concentrations of up to 15% (110).

According to a literature review conducted by Vaiyapuri *et al*. on MRSA in seafood in 2019, fish and shellfish may be contaminated with MRSA from the environment

through harvesting or improper handling by fish handlers, processors or consumers, prior to consumption (111).

*S. aureus* is killed by cooking (to an internal temperature of 70°C for two minutes) (102), but the toxins are not destroyed and will still be able to cause illness. Foods that are not cooked after handling, such as sliced meats, puddings, pastries, and sandwiches, are especially risky if contaminated with these bacteria (109). *S. aureus* enterotoxins interrupt the host cell protein synthesis to affect the intestinal secretion of water and electrolytes. The infectious dose for this bacteria in humans is $10^4$ organisms (112) and symptoms of *S. aureus* food poisoning are characterised by a sudden start of nausea, vomiting, and stomach cramps. Most people also have diarrhoea. Symptoms usually develop within 30 minutes to eight hours after eating or drinking an item containing *S. aureus* toxin, and last no longer than one day. Severe illness is rare and the illness cannot be passed from one person to another (109). Food frequently involved in staphylococcal food poisoning are cooked or RTE foods handled by persons carrying *S. aureus* which are then temperature-abused (held at incorrect or varying temperatures) such as ham; fermented sausages; cereal-filled pastries; cheese; milk, salads, peeled crustaceans, bivalve molluscs, and mushrooms (107). This hazard is still considered here because its presence in oysters cannot be ruled out due to potential introduction during processing.

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

SRT scores for this bacterial hazard were unavailable because it was not identified within the SRT.

According to the ICMSF, the severity of *S. aureus* for the general population is low (4).

#### 6.4.1.7 *Yersinia enterocolitica*

*Y. enterocolitica* is a gram-negative bacillus shaped bacterium that causes a zoonotic disease called yersiniosis (113). Various strains (many not pathogenic to humans) of *Y. enterocolitica* are widely distributed across many environments, including within animal and aquatic reservoirs. Strains of *Y. enterocolitica* from

porcine reservoirs are considered the largest sources of yersiniosis in humans (114). However, *Y. enterocolitica* has been identified in fish and shellfish, including oysters in both wild and aquaculture settings (115). There are six biotypes of *Y. enterocolitica* (1A, 1B, 2, 3, 4, and 5), all of which are capable of pathogenicity. Biotype 1B is considered the most virulent and is more common in North America (strains within biotype 1B are classed as 'New-World' strains), biotypes 2-5 are less virulent and are more predominant in Europe and Japan (strains within biotypes 2-5 are classed as 'Old-World Strains') (116).

*Y. enterocolitica* can produce enterotoxins which affect the regulation of water and electrolyte fluxes across the intestinal mucosa through the cAMP; cGMP; and calcium dependent pathways to affect the intestinal secretion of water and electrolytes (74). Symptoms of yersiniosis can vary depending on the age of the person infected. In young children, some common symptoms are fever, abdominal pain and diarrhoea, which is often bloody. Symptoms for older children and adults may include fever and pain in the right side of abdomen. Symptoms typically develop four to seven days after exposure and may last one to three weeks or longer. Complications are rare and can include skin rash, joint pain, or spread of bacteria to the bloodstream (septicaemia) (117). According to the CDC, *Y. enterocolitica* causes almost 117,000 infection cases, 640 hospitalisations, and 35 deaths in the US every year (117). Within the EU in 2018, *Y. enterocolitica* was responsible for 58 cases, seven hospitalisations and zero case fatalities. (118). Infection with *Y. enterocolitica* requires an infectious dose of around $10^8$ CFU (119).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

SRT scores for this bacterial hazard were unavailable because it was not identified within the SRT.

According to the ICMSF, the severity of *Y. enterocolitica* for the general population is medium (4).

#### 6.4.1.8 Faecal indicators/ coliforms

Coliforms are aerobic or facultatively anaerobic, gram-negative, non-spore forming rod bacteria, occurring in different varieties and they are commonly found in soil and surface water and may occur on human skin (120) (121). For close to a century, coliforms have been used as indicator organisms in evaluating water for faecal contamination. Consumption of water contaminated with coliform bacteria does not necessarily cause illness. However, if disease causing bacteria are present, symptoms could include gastrointestinal upset and general flu-like symptoms such as fever, abdominal cramps, and diarrhoea (121).

Coliforms are a subgroup of Enterobacteriaceae. They are comprised mostly of the *Escherichia, Klebsiella*, *Citrobacte*r, *Enterobacter* and *Serratia* genera. Faecal coliforms are a subgroup of coliforms that have an ability to grow at high temperatures of 44.5ºC and retain their ability to grow at mammalian gut temperatures. More than 80% of a faecal coliform count is typically made up of *E. coli*, the pathogenic strains of which are discussed in section 6.4.1.3 (122).

Information on burden of foodborne disease caused by this hazard type specifically in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT for faecal indicators were 42, 38 and 18 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

Severity has not been discussed for this hazard group because bacteria included are indicator organisms, and where they are pathogens associated with oysters, they are discussed in other sections.

### 6.4.2 Viruses

Table 5 provides the SRT impact score for viral hazards (HH only) from the refined hazard list (section 5.2). Scores were derived as part of the SRT supplementary information using the SRT schema (see section 6.2). Scores were provided for the uncontrolled state in which no controls are applied; control one - the controlled state

where either standalone/non-accrued control measures are applied at discrete phases of supply; control two - the controlled stated where the benefit of controls applied at one phase are accrued in subsequent phases of supply.

Table 5: SRT application to viral human health hazards (1)

| Virus | Score | | |
|---|---|---|---|
| | Uncontrolled | Control 1 [a] | Control 2 [b] |
| Rotavirus | 38 | 26 | 19 |
| Norovirus | 64 | 52 | 33 |
| Hepatitis A | 92 | 72 | 37 |
| Hepatitis E | 21 | 21 | 18 |

a) Controlled state when hazards are controlled at discrete phases, they are standalone/non-accrued control measures.
b) Controlled state when hazards are controlled at discrete phases and the benefit of controls are accrued in subsequent phases of supply.

The change in impact score between the uncontrolled state and control one was most prominent for Hepatitis A, however it did have a higher impact score than other hazards in the uncontrolled state. No change in score was observed between the uncontrolled state and control one for Hepatitis E. Changes were observed for the other viruses listed for each control type, even if minor.

Viruses are microorganisms that differ in size, structure and biological characteristics from bacteria. Viruses are strictly host-dependent for their replication and have their own typical host range and cell preference (tropism). Viruses can be transmitted in different ways, for example, via respiratory or faecal-oral routes. Human viruses can be transmitted directly from person-to person, but also indirectly via virus-contaminated water, air, soil, surfaces or food. Some viruses (zoonotic viruses) are transmitted from animals to humans (123).

Viruses are comprised of the viral genome (RNA or DNA) and the virus-coded protein capsid which surrounds the genome. A non-enveloped virus contains only these two elements, while an enveloped virus contains an additional lipid bilayer membrane surrounding the protein capsid known as the envelope. Enveloped viruses are typically less virulent than non-enveloped viruses because they don’t always cause cell lysis during cell exit (after invading host cells), although cell death does often occur as a consequence of viral replication. Enveloped viruses use the host cell membrane during virus assembly and exit from host cells to assemble the

envelope. Enveloped viruses also tend to be more sensitive to conditions associated with control such as extreme pH, heat, dryness and simple disinfectants (124).

Some viruses transmitted by the faecal-oral route can persist for months in foodstuffs or in the environment (for example, in soil, water, sediments, bivalve molluscs or on various inanimate surfaces). Most foodborne viruses are more resistant than bacteria to commonly used control measures, (for example, refrigeration, freezing, pH, drying, UV radiation, heat, pressure, disinfection, etc.). Freezing and refrigeration temperatures preserve viruses and are believed to be important factors that increase the persistence of foodborne viruses in the environment. Heat and drying can be used to inactivate viruses, but there are virus-to-virus differences in resistance to these processes. The presence of organic matter, such as faecal material and the food matrix can influence relative resistance to heat and drying (123).

Viruses, such as norovirus, enter the marine environment through untreated human sewage and vomit. This may come from leaky septic systems, faulty wastewater treatment plants, discharges from boaters, or beachgoers (125).

#### 6.4.2.1 Rotavirus

Rotavirus is a genus of double-stranded RNA viruses belonging to the family Reoviridae. It is a non-enveloped virus with a characteristic wheel-like appearance under an electron microscope. Rotaviruses are classified into different species, with species A being the most common and significant human pathogen. Other species include B, C, D, E, F, and G, but their impact on human health is relatively less understood (126). The infectious dose of rotavirus is relatively low, estimated to be as few as 10-100 viral particles. This means that a small amount of the virus can be sufficient to cause infection in susceptible individuals. Rotavirus infections are primarily transmitted through the faecal-oral route, and contaminated food and water can serve as sources of infection. While rotavirus can potentially contaminate a variety of foods, it is commonly associated with fresh produce, shellfish, and other food items that may come into contact with contaminated water sources (127) (128) (129).

Rotavirus is resistant to many common food processing techniques, including heat treatment and freezing. It can survive in various environmental conditions and remain infectious on surfaces for extended periods. Therefore, proper hygiene, sanitation, and preventive measures are crucial to reduce the risk of contamination during food handling and processing (128). Rotavirus infection primarily affects the gastrointestinal tract, causing gastroenteritis. The typical symptoms include watery diarrhoea, vomiting, abdominal pain, and fever. Infected individuals, especially infants and young children, may also experience dehydration due to fluid loss. The severity of symptoms can vary, ranging from mild to severe. In some cases, hospitalisation may be required to manage dehydration and prevent complications (128). Rotavirus infections can be particularly severe in young children, especially in resource-limited settings with limited access to healthcare and proper nutrition. In these populations, rotavirus is a leading cause of severe diarrhoea, which can result in dehydration and potentially lead to life-threatening complications. However, the severity of the disease can be reduced through early detection, supportive care, and access to appropriate medical interventions (128) (130).

Before the introduction of rotavirus vaccines, rotavirus gastroenteritis was responsible for a significant burden of disease, hospitalisations, and deaths, particularly among children under the age of five. The prevalence of rotavirus infection varies across different regions and is influenced by factors such as sanitation practices, access to clean water, healthcare infrastructure, and vaccination coverage (130).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT for rotavirus were 38, 26 and 19 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

The ICMSF has not assigned severity to rotavirus (4). Information on DALYs per case for rotavirus was also not available from the WHO report (10). In this case, the

severity for rotavirus has been considered from other literature. Severity was assigned based on clinical manifestations and expert opinion in a risk ranking study of foodborne zoonoses by Sabine Cardoen *et al* (131). As a result, the severity of disease associated with rotavirus for the general population using the ACMSF's qualitative scale for the severity of detriments of foodborne risks (3) is considered low for the purposes of this risk profile.

#### 6.4.2.2 Norovirus

Norovirus (NoV) belongs to the *Caliciviridae* family of viruses. NoV is a non-enveloped virus and has a small (27 – 40nm) icosahedral shaped capsid that contains a 7.7kb single stranded RNA genome (132). When NoV particles are in the water, shellfish can accumulate the virus in their bodies because they are filter feeders, filtering seawater through their bodies. Affected shellfish include clams, geoducks, mussels, scallops and oysters. However, most illness outbreaks are linked to oyster consumption because they are typically consumed raw (125).

NoV infections occur year-round and causes gastroenteritis in people of all ages. Overall, illness is relatively mild, but can be more severe and may result in death in high-risk groups such as the elderly or people with underlying disease. The greatest public health impact from NoV outbreaks has been reported in institutions such as hospitals and nursing homes, where NoV outbreaks commonly occur due to the close proximity of patients in an enclosed environment (123). NoV has been well-documented as the leading cause of epidemic gastroenteritis in all age groups, causing >90% of non-bacterial and ≈50% of all-cause epidemic gastroenteritis worldwide (133). Outbreaks of this illness are usually more common in cooler winter months with most outbreaks occurring from November to April in countries above the equator, and from May to September in countries below the equator. However, in places closer to the equator, NoV may be less seasonal (134).

The incubation period is 12-72 hours; in most cases symptoms appear between 24-30 hours. The onset of symptoms after NoV infection is often characterised by sudden onset of one or several episodes of projectile vomiting and/ or by one to several days of diarrhoea. NoV-infected persons shed large amounts of infectious virus particles ($10^6$ -$10^{10}$ particles/g) in their stool while having symptoms, but this

may also occur before the onset of symptoms, and shedding may continue on average for two or more weeks after resolution of symptoms even in immunocompetent persons. The disease and shedding period may be longer in the case of immuno-suppressed individuals. Some NoV infections occur without resulting in apparent symptoms. A vaccine against NoV is not available at present (123).

According to the WHO burden of foodborne disease report, NoV was implicated in 124,803,946 foodborne illnesses and 2,496,078 years lost to DALYs worldwide due to long term effects on health (92).

Scores from the SRT for NoV were 64, 52 and 33 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of NoV for the general population is low(4).

#### 6.4.2.3 Hepatitis A

Hepatitis A virus (HAV) is primarily spread when an uninfected (and unvaccinated) person ingests food or water that is contaminated with the faeces of an infected person. The disease is closely associated with unsafe water or food, inadequate sanitation, poor personal hygiene and oral-anal sex (135). Oyster consumption has also been linked to HAV infection, as observed by Conaty *et al*. in their study investigating HAV outbreak from oyster consumption in New South Wales, Australia.(136). Therefore, eating raw or undercooked oysters can increase the risk of HAV infection. Historic data from a study conducted in 1988 in the US revealed a relationship between the consumption of raw oysters and HAV infection, with 61 patients identified across Alabama, Georgia, Florida, Tennessee and Hawaii (92).

HAV is a cause of acute viral hepatitis. The incidence of HAV infection varies considerably among and within countries. In countries where HAV infection is highly endemic (low- and middle-income countries), the majority of people are infected in early childhood, when the infection is asymptomatic in over 90% of children under five years of age. Virtually all adults in these areas are immune. In countries, where

HAV infections are less common (high income countries) as a result of increased standards of public health such as access to safe drinking water, sanitation and hygiene, very few persons are infected in early childhood, and the majority of adults remain susceptible to infection by HAV (123).

HAV infection is symptomatic in over 80% of infected people aged 40 years and above and may result in a more severe disease outcome. As a result, the potential risk of outbreaks of hepatitis A is increased in these regions. The incubation period for HAV is at least two weeks, to a maximum of six weeks, with an average of 28 days. The peak infectivity occurs in the two weeks preceding the onset of jaundice, i.e., the presence of yellow colouring of the skin and/ or mucous membranes. The virus is shed in large numbers ($10^6$ -$10^8$ particles/g) in faeces from the final two weeks of the incubation period up to five weeks into the symptomatic phase. In HAV endemic areas, children may be an important risk factor in the spread of HAV during primary production or food preparation activities. Some HAV infections occur without symptoms (123).

According to the WHO burden of foodborne disease report, HAV was implicated in 13,709,836 foodborne illnesses and 1,353,767 years lost to DALYs worldwide due to long term effects on health (92).

Scores from the SRT for HAV were 92, 72 and 37 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of hepatitis A for the general population is high (4).

#### 6.4.2.4 Hepatitis E

Hepatitis E is inflammation of the liver caused by the hepatitis E virus (HEV). Four different types of the virus are known: genotypes 1, 2, 3 and 4. Genotypes 1 and 2 have been found only in humans. Genotypes 3 and 4 circulate in several animals including pigs, wild boars and deer without causing any disease, and occasionally infect humans (137).

According to the French Agency for Food Environmental and Occupational Health and Safety (ANSES) the available data allows an indirect estimate of the 50% infectious dose (ID50) by the oral route in humans, which is considered to be at least $10^{5.5}$ genome equivalents(138).

HEV can be present in various types of food, including raw or undercooked meat, especially pork products (139), and shellfish (140). HEV can be present in various types of food, including raw or undercooked meat, especially pork products (139), and shellfish (140). Contamination of food can occur during the slaughtering or processing of infected animals.

HEV infection can range from asymptomatic or mild illness to a severe form of the disease. The incubation period is typically two to six weeks. Symptoms can include fatigue, nausea, abdominal pain, loss of appetite, jaundice (yellowing of the skin and eyes), dark urine, and pale stools. Most cases of acute HEV resolve on their own within a few weeks to months. However, in pregnant women, especially those in the third trimester, hepatitis E can lead to severe complications, including liver failure and death. Foetal loss and mortality may also occur (137).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10). However, according to the WHO factsheet, every year there are an estimated 20 million HEV infections globally, with an estimated 3.3 million symptomatic cases of hepatitis E. Furthermore, the WHO estimates that hepatitis E caused approximately 44,000 deaths in 2015. It also stated that HEV infection is more common in countries with limited access to water, sanitation hygiene and health services. The disease usually occurs as an outbreak or as sporadic cases. Outbreaks often follow larger scale or consistent faecal contamination of drinking water supplies, while sporadic cases are also often due to contaminated water, but on a smaller scale. Cases in these areas are most often through infection with genotype 1 and less frequently with genotype 2, as these are more commonly associated with the faecal-oral route. In areas with better sanitation and water supply, HEV infection is much less frequent and occasional, sporadic cases are more commonly from infection with genotype 3 originating in animals, usually through ingestion of undercooked meat (more

commonly pork). .The WHO attributes the most transmission to unsafe drinking water (137).

Scores from the SRT for HEV were 21, 21 and 18 for the uncontrolled state and the two controlled states, respectively. There was no change in score between the uncontrolled state and control one, showing that measures taken reduce the impact of the hazard are certain phases of supply may have a limited effect. However, the change in score for control two, indicates that benefits from controls may be accrued along the supply chain.

According to the ICMSF, the severity of hepatitis E for the general population is low (4).

### 6.4.3 Parasites

Table 6 provides the SRT impact score for parasitic hazards (HH only) from the refined hazard list (section 5.2). Scores were derived as part of the SRT supplementary information using the SRT schema (see section 6.2). Scores were provided for the uncontrolled state in which no controls are applied; control one - the controlled state where either standalone/non-accrued control measures are applied at discrete phases of supply; control two - the controlled stated where the benefit of controls applied at one phase are accrued in subsequent phases of supply.

Table 6: SRT application to parasitic human health hazards (1)

| **Parasites** | **Score** | | |
|---|---|---|---|
| | **Uncontrolled** | **Control 1** [a] | **Control 2** [b] |
| *Cryptosporidium* | 30 | 22 | 16 |
| *Giardia* | 24 | 18 | 16 |

a) Controlled state when hazards are controlled at discrete phases, they are standalone/non-accrued control measures.
b) Controlled state when hazards are controlled at discrete phases and the benefit of controls are accrued in subsequent phases of supply.

The parasites in this section include *Cryptosporidium, Giardia, Microsporidia,* and *T. gondii.*

A decrease in SRT scores was observed for both parasites from the uncontrolled state to control one, with a further decrease in scores (22 to 16 and 18 to 16

respectively) observed for control two. SRT scores were unavailable for *Microsporidia,* and *T. gondii* because they were not identified within the SRT.

The protozoan parasites *G. duodenalis* (synonyms: *G. lamblia, G. intestinalis*), *Cryptosporidium* spp. and *T. gondii* are commonly reported in humans and a wide range of domestic animals and wildlife worldwide. In the case of *G. duodenalis* and *Cryptosporidium* spp., transmission occurs through the ingestion of infectious stages known as cysts and oocysts respectively, either directly through contact with faecal material from an infected human or animal, or indirectly through contaminated water or foods (141). Oocysts of *Cryptosporidium* spp. and *T. gondii*, and cysts of *G. duodenalis*, have been directly or indirectly detected in a variety of foods worldwide, particularly fresh produce and bivalve shellfish. As these foods are very often consumed raw, contamination with the infectious stages of parasites represents a public health concern. While bivalve shellfish thrive in coastal marine environments due to the high nutrient levels, these habitats can also be contaminated with sewage and agricultural runoff (141).

#### 6.4.3.1 *Cryptosporidium* spp.

*Cryptosporidium* is a genus of microscopic parasites that belong to the phylum Apicomplexa. These parasites are responsible for causing a disease called cryptosporidiosis in humans and animals. There are multiple species within the genus *Cryptosporidium*, with *C. parvum* and *C. hominis* being the most common that affect humans (142) (143). The infectious dose of *Cryptosporidium* spp. is relatively low, meaning that a small number of oocysts (the infective stage of the parasite) can lead to infection. Ingesting as few as ten oocysts can cause illness in humans, making it highly contagious (144).

*Cryptosporidium* spp. can contaminate various food and water sources, including fruits, vegetables, and drinking water. The parasite can survive for long periods in the environment, especially in water sources, making it a potential risk for foodborne transmission (144). Oysters, particularly those harvested from contaminated waters, can be a source of *Cryptosporidium* spp. infection (145). In a study conducted by Srisuphanunt *et al*.(146) on the occurrence of *Cryptosporidium* oocysts in commercial oysters in southern Thailand, *Cryptosporidium* was detected in oysters

obtained from Thailand's southern Gulf coast. Willis *et al*.(147) also conducted a review of global detection of *Cryptosporidium* and *Giardia* in shellfish, with a focus on Canada where it was noted that *C. parvum* had been detected in various species of shellfish.

The parasite can accumulate in oysters and remain infectious if consumed raw or undercooked. Therefore, consuming raw or partially cooked oysters from contaminated waters poses a risk of cryptosporidiosis (148). According to the Irish Agriculture and Food Development Authority (Teagasc) (149), the normal recommended time and temperature for controlling bacterial food poisoning (cooking to an internal temperature of 70°C for two minutes) (102) will eliminate *Cryptosporidium* spp. (149).

Cryptosporidiosis primarily affects the gastrointestinal tract and commonly presents with symptoms such as watery diarrhoea, stomach cramps, nausea, vomiting, and fever. In individuals with a healthy immune system, the illness is usually self-limiting and resolves within a few weeks. However, people with weakened immune systems, such as those with HIV/ AIDS or undergoing chemotherapy, may experience severe and prolonged illness, which can be life-threatening (143).

According to the WHO burden of foodborne disease report, *Cryptosporidium* spp. were implicated in 8,584805 foodborne illnesses and 296,156 years lost to DALYs worldwide due to long term effects on health (92).

Scores from the SRT for *Cryptosporidium* spp. were 30, 22 and 16 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of *Cryptosporidium* spp. for the general population is low (4).

6.4.3.2 *Giardia* spp.

*Giardia* parasites are species of microscopic, single-celled protozoan parasites that belong to the genus *Giardia*. The most common species that infects humans is *G.*

*lamblia* (also known as *G. intestinalis*). *Giardia* parasites can be found in the intestines of infected humans and animals, and they are transmitted through the ingestion of contaminated food or water (150). According an article on the global occurrence of *Cryptosporidium* and *Giardia* by Willis *et al, Giardia* has been detected in a variety of shellfish species (151). The infectious dose of *Giardia* spp. is relatively low, with as few as ten to 25 cysts (the dormant and infective form of the parasite) being sufficient to cause infection in susceptible individuals (147).

The prevalence of *Giardia* spp. in food can vary depending on various factors such as the hygienic practices during food preparation and the quality of the water used. Contaminated water sources used for irrigation or washing of fruits and vegetables can introduce *Giardia* cysts onto the food, increasing the risk of infection (150). Oysters, specifically raw or undercooked oysters, can be a potential source of *Giardia* spp. infection. Oysters are filter feeders and can accumulate the parasite from contaminated water sources. With regards to processing, cooking food to an internal temperature of 70°C for two minutes (102) kills *Giardia* spp., reducing possibility of infection (150).

When *Giardia* spp. infect the human GI tract, it can cause a condition called giardiasis. The symptoms of giardiasis can vary and may include diarrhoea, abdominal pain, bloating, gas, nausea, vomiting, and weight loss. In some cases, individuals infected with *Giardia* spp. may be asymptomatic, showing no signs of illness (152).

Geographically, *Giardia* spp. infections are distributed worldwide, and the parasite is found in various regions, including North and South America, Europe, Africa, Asia (153)

According to the WHO burden of foodborne disease report, *Giardia* spp. were implicated in 28,236,123 foodborne illnesses and 26,270 years lost to DALYs worldwide due to long term effects on health (92).

Scores from the SRT for *Giardia* spp. were 24, 18 and 16 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was

observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

According to the ICMSF, the severity of *Giardia* for the general population is low(4).

6.4.3.3 *Microsporidia* spp.

*Microsporidia* spp. are small, unicellular eukaryotic, intracellular parasites. There has been some discussion amongst biologists over their classification, they have been described as “related to fungi” and also as “reclassified from protozoa to fungi”. They are obligate intracellular parasites, meaning they rely on a host cell to replicate. *Microsporidia* spp. have a highly specialised infective stage called the spore, which is the primary means of transmission. These spores are extremely resistant to environmental conditions, allowing them to survive in various habitats, including soil, water, and host tissues (154) (155) (156).

*Microsporidia* spp. can be found in various food sources, including fruits, vegetables, and seafood. However, their prevalence in food is relatively low compared to other pathogens, and the risk of foodborne transmission is generally considered to be low. Among the different food sources, oysters have been identified as a potential reservoir for certain *Microsporidia* spp. Oysters are filter feeders, and they can accumulate *Microsporidia* spores from contaminated water. Therefore, the prevalence of *Microsporidia* spp. in oysters can vary depending on the environmental conditions and the quality of the water they are harvested from (154). *Microsporidia* spp. are being increasingly recognised as opportunistic infectious agents worldwide. Efforts to characterise the global distribution of species and genotypes are ongoing. (157). The effect of processing on *Microsporidia* spp. varies depending on the specific species and the processing method employed. Heat treatments such as cooking or pasteurisation can inactivate some *Microsporidia* spores, reducing the risk of infection. However, certain resistant spores may survive processing, emphasising the importance of proper food safety measures (157).

Symptoms of *Microsporidia* spp. infection (microsporidiosis) include diarrhoea, myositis, keratitis, bronchitis and in rare cases encephalitis. Infections can also occur in the lung, kidney, brain, sinuses and eyes. *Microsporidia* spp. infection can also be

asymptomatic and this is more common in healthy individuals, it is considered uncommon for microsporidiosis to occur in immunocompetent people (154, 158).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

SRT scores for this hazard were unavailable because this hazard was not identified within the SRT.

The ICMSF has not assigned severity to *Microsporidia* spp. (4). Information on DALYs per case for *Microsporidia* spp. was also not available from the WHO report (10). In this case, the severity for the general population has been assigned based on clinical manifestations identified above using the expert opinion of the analyst. As a result, the severity of disease associated with *Microsporidia* spp. for the general population based on the ACMSF's qualitative scale for the severity of detriments of foodborne risks (3) is considered low for the purposes of this risk profile given the likelihood of asymptomatic infection for immunocompetent individuals discussed above.

6.4.3.4 *Toxoplasma gondii*.

*T. gondii* is a protozoan parasite that infects a wide range of warm-blooded animals, including humans. It has a complex life cycle involving both definitive and intermediate hosts. Cats are the definitive host, while various mammals and birds serve as intermediate hosts (159). The infectious dose of *T. gondii* can vary depending on the strain, route of transmission, and individual susceptibility. Ingesting even a few viable oocysts (infectious stage) can lead to infection (159).

*T. gondii* can be found in raw or undercooked meat, especially pork, lamb, and venison, which can serve as a source of infection for humans. The prevalence of *T. gondii* in food varies geographically and depends on factors such as animal husbandry practices, hygiene standards, and dietary habits. Prevalence rates can be influenced by factors such as climate, cultural practices, and the presence of definitive and intermediate hosts. Higher rates of infection are often found in regions with warm climates and where consumption of raw or undercooked meat is common (159). Oysters and other filter-feeding shellfish can become contaminated with *T.*

*gondii* through the deposition of oocysts in the water. The prevalence of *T. gondii* in oysters can vary depending on the level of contamination in their environment, such as coastal areas with contaminated waters (159).

Proper cooking (to an internal temperature of 70°C for two minutes) (102) can effectively kill *T. gondii*, reducing the risk of infection. Freezing at sub-zero temperatures (-12°C or lower) for a specific period can also inactivate the parasite. In healthy individuals, *T. gondii* infection often goes unnoticed or causes mild flu-like symptoms. However, it can pose serious risks to pregnant women and individuals with weakened immune systems. Congenital infection can lead to severe birth defects or foetal loss. In immunocompromised individuals, *T. gondii* can cause severe encephalitis or disseminated infection (160).

According to the WHO burden of foodborne disease report, *T. gondii* was implicated in 10,280,089 foodborne illnesses and 829,071 years lost to DALYs worldwide due to long term effects on health (92).

SRT scores for this hazard were unavailable because this hazard was not identified within the SRT.

According to the ICMSF, the severity of *T. gondii* for the general population is low (4).

## 6.5 Chemical hazards

Table 7 provides the SRT impact score for chemical hazards from the refined hazard list (section 5.2). Scores were derived as part of the SRT supplementary information using the SRT schema (see section 6.2). Scores are provided for the uncontrolled state in which no controls are applied; control one - the controlled state where either standalone/ non-accrued control measures are applied at discrete phases of supply; control two - the controlled state where the benefit of controls applied at one phase are accrued in subsequent phases of supply.

Table 7: SRT application to chemical human health hazards (1)

| **Hazard Type** | **Chemicals** | **Score** | | |
|---|---|---|---|---|
| | | **Uncontrolled** | **Control 1** [a] | **Control 2** [b] |
| Heavy metals | Cadmium | 35 | 33 | 19 |
| | Mercury | 35 | 33 | 19 |
| | Lead | 35 | 33 | 19 |
| | Arsenic | 14 | 20 | 12 |
| | Copper | 11 | 10 | 8 |
| Persistent organic chemicals/ pollutants (POCs/ POPs) | Polychlorinated Biphenyls (PCBs) | 20 | 18 | 13 |
| | Perfluorinated compounds (PFCs) | 20 | 14 | 12 |
| | Polybrominated diphenyl ethers (PBDEs) | 20 | 14 | 12 |
| | Polycyclic aromatic hydrocarbons (PAHs) | 20 | 13 | 13 |
| | Dioxins | 20 | 20 | 18 |
| Radiological contaminants | Radionuclides | 14 | 6 | 6 |
| Veterinary pharmaceuticals and personal care products | Antimicrobials | 23 | 20 | 12 |

a) Controlled state when hazards are controlled at discrete phases, they are standalone/non-accrued control measures.
b) Controlled state when hazards are controlled at discrete phases and the benefit of controls are accrued in subsequent phases of supply.

A decrease in SRT impact scores between the uncontrolled state and control one for all heavy metals except arsenic (which showed an increase for control one) was observed. A similar pattern was observed for PCBs, PFCs and PBDEs. The score for dioxins on the other hand remained constant for control one. In all cases, a decrease from control one to control two was observed, except for PAHs and radionuclides where the score remained the same. The increase in score for arsenic for control one could indicate that control of this hazard at a discrete phase is less effective or reflect an anomaly in the SRT data.

SRT impact scores were not provided for other chemical hazards characterised in this section (microplastics and High Production Volume (HPV) chemicals) as these hazards were not identified within the SRT.

### 6.5.1 Heavy metals

Heavy metals can cause adverse health effects in humans and food is the main source of exposure for the general population. Fish and seafood are regarded as one of the main food sources of cadmium (Cd), mercury (Hg) and lead (Pb) as they live in marine environments which may be contaminated by these ubiquitous chemicals. Marine environments can be prone to high distribution whether via anthropogenic or natural origin, and marine animals can bioaccumulate cadmium, mercury and lead in their tissue to a high level (161). Other heavy metals include methylmercury, arsenic (As) and copper (Cu) (1).

Information on burden of foodborne disease caused by heavy metals in the form of DALYs were unavailable in the WHO burden of disease report (10). However, information was available from an article by Gibb *et al* (Estimates of the 2015 Global and Regional Disease Burden from Four Foodborne Metals – Arsenic, Cadmium, Lead and Methylmercury). The results indicate that in 2015, ingestion of arsenic, methylmercury, lead, and cadmium resulted in more than one million illnesses, over 56,000 deaths, and more than nine million DALYs worldwide. All of the heavy metals had high DALYs per case in comparison with other foodborne disease agents, including infectious and parasitic agents. In particular, lead, arsenic, and methylmercury (162).

Heavy metals noted within the SRT are characterised further in the follow sections.

#### 6.5.1.1 Cadmium (Cd)

The highest cadmium levels are found in the kidney and liver of mammals fed with cadmium-rich diets and in certain species of oysters, scallops, mussels and crustaceans (163). In humans, chronic cadmium intake is responsible for different organ systems toxicity with reproductive and fertility impairments, skeletal damage, urinary and cardiovascular disorders, central and peripheral nervous deficiency, kidney disease and cancer (164).

The dose of cadmium required to cause illness varies depending on factors such as duration of exposure, route of exposure, and individual susceptibility. Chronic exposure to low levels of cadmium over a long period is concerning because cadmium can accumulate in the body. The WHO has established a provisional tolerable monthly intake (PTMI) of 25 µg per kg of body weight (bw) to protect against the adverse effects of cadmium (165). Processing techniques can have varying effects on cadmium levels in food, including oysters. Some studies have suggested that certain processing methods, such as boiling and steaming, can help reduce the cadmium content in oysters. However, the cooking time and temperature, can also influence the efficacy of reducing the presence of cadmium in the commodity during processing (166).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10). However, information was available from other literature and is noted above in the introduction to heavy metals.

Scores from the SRT for cadmium were 35, 33 and 19 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

#### 6.5.1.2 Lead (Pb)

Lead is responsible for extensive environmental contamination, human exposure and significant public health problems in many parts of the world. A review conducted by

Wang and Lu revealed that although global lead concentrations in oysters were <4 mg/g dry weight (dw), the Persian Gulf produced oysters with concentrations as high as 41 mg/g dw, due to possible contamination within the region (161).

Exposure to lead has serious health effects, even more so in children. Lead can accumulate in the body and may be distributed to the brain, liver, kidneys, and be stored in the teeth and bones. Lead stored in the bones can be released into the blood during pregnancy and become a source of exposure for the developing foetus. In children particularly, exposure to lead at high levels affects the brain and nervous systems, causing coma, convulsions and possible death. Lead poisoning has been linked to the incidence of neurodevelopment conditions and disorders. At lower levels, lead may cause no obvious symptoms, but can cause behaviour changes over time. Lead exposure also causes anaemia, hypertension, renal impairment, immunotoxicity and reproductive toxicity in all age groups. Neurological effects are thought to be irreversible (167). According to the WHO, nearly half of the two million lives lost to known chemicals exposure in 2019 were due to lead exposure. Lead is responsible for 21.7 million years lost to DALYs worldwide due to long-term effects on health, with 30% of the global burden of idiopathic intellectual disability, 4.6% of the global burden of cardiovascular disease and 3% of the global burden of chronic kidney diseases (168). The US Food and Drug Administration (FDA) stipulates interim reference levels (IRLs) levels of 2.2 µg per day for children and 8.8 µg per day for females of childbearing age of lead in food (169).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10). However, information regarding DALYs specifically for lead has been discussed above, and information was available from other literature and is noted in the introduction to heavy metals.

Scores from the SRT for lead were 35, 33 and 19 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

#### 6.5.1.3 Mercury (Hg)

Mercury exists in various forms, namely: elemental and inorganic and organic (for example, methylmercury, to which people may be exposed through their diet). These forms of mercury differ in their degree of toxicity and in their effects on the nervous, digestive and immune systems, and on lungs, kidneys, skin and eyes (170). Neurological and behavioural disorders may be observed after inhalation, ingestion or dermal exposure of different mercury compounds. Symptoms include tremors, insomnia, memory loss, neuromuscular effects, headaches and cognitive and motor dysfunction (170).

Wang and Lu's review on bivalve molluscs revealed study results suggesting that when oysters are exposed to copper and zinc (Zn), there is a significant bioaccumulation of mercury (161).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10). However, information was available from other literature for methylmercury and is noted above in the introduction to heavy metals.

Scores from the SRT for mercury were 35, 33 and 19 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

#### 6.5.1.4 Copper (Cu)

Copper is an essential trace element involved in various vital enzymes. The population is exposed to this element primarily via food and drinking water (171). According to an evaluation carried out by the International Agency for Research on Cancer (IARC) on copper (II) 8-hydroxyquinoline, copper was classified as non-carcinogenic (171). Furthermore, under CODEX General Standard for Contaminants and Toxins in Food and Feed, copper is not considered as a contaminant with public health significance hence there is no standard for copper (172). However, chronic exposure to high levels of this element could lead to liver damage and

gastrointestinal symptoms (for example, abdominal pain, cramps, nausea, diarrhoea, and vomiting) (173).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10). Furthermore, information available from other literature noted above in the introduction to heavy metals does not include copper.

Scores from the SRT for copper were 11, 10 and 8 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain. However, these are not significant changes compared with other chemical hazards, particularly as the initial impact score of 11 was relatively low.

#### 6.5.1.5 Arsenic (As)

Arsenic is a metalloid that occurs in different inorganic and organic forms found in the environment both from natural occurrence and from anthropogenic activity (174). It is generally accepted that inorganic arsenic compounds are more toxic than the organic compounds. In fish and seafood such as bivalve molluscs, inorganic arsenic in the form of arsenobetaine is the main form. Arsenobetaine is a compound considered as non-toxic since it is not metabolised in humans and is excreted intact (175) (176). According to the European Food Standards Authority (EFSA), “only 2% and 3.5% of the arsenic contained in fish and shellfish products, respectively, could be considered as toxic inorganic arsenic. By assuming these percentages, the estimated intake for inorganic arsenic would represent 0.42 µg/ day (2.94 µg/week) which is far below the most restrictive benchmark dose of 1% extra risk (Benchmark Dose Level$_{01}$ (BMDL$_{01}$)) for carcinogenic effects of inorganic arsenic. Taking into account that fish and shellfish provide a reduced amount of inorganic arsenic to the diet and that the arsenic concentrations found in this study were very low, it is assumed that the total arsenic intake from the fish species analysed would not be of health concern” (177). The EFSA has launched a public consultation on the draft scientific opinion on the update of the risk assessment of inorganic arsenic in food,

the consultation closes in September 2023, after the completion of this risk profile (178).

Inorganic arsenic is a carcinogenic, it has been linked with skin, bladder and lung cancer. Inorganic arsenic compounds (such as those found in water) are highly toxic while organic arsenic (such as those found in seafood) are less harmful. Symptoms of acute arsenic poisoning include vomiting, abdominal pain and diarrhoea, followed by later onset of numbness and tingling of the extremities, muscle cramping, and death in extreme cases. The first symptoms of chronic exposure to high levels of inorganic arsenic are usually observed in the skin. These include pigmentation changes, skin lesions and hard patches on the hands and feet. These are considered to occur after a minimum exposure of approximately five years and may be a precursor to skin cancer. Other adverse effects associated with chronic exposure include developmental effects, diabetes, pulmonary disease and cardiovascular disease. Arsenic-induced myocardial infarction can be a significant cause of mortality. Arsenic is also associated with adverse pregnancy outcomes and infant mortality, with exposure in utero and in early childhood linked with multiple cancers, lung disease, heart attacks and kidney failure (179).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10). However, information was available from other literature and is noted above in the introduction to heavy metals.

Scores from the SRT for arsenic were 14, 20 and 12 for the uncontrolled state and the two controlled states, respectively. The increase in score for control one could indicate that control of this hazard at a discrete phase is less effective or reflect an anomaly in the SRT data. However, the drop in score from control one to control two indicates that control measures taken at certain phases may reduce the impact of the hazard and for benefits to be accrued along the supply chain.

### 6.5.2 Persistent organic chemicals (POCs)

For SRT impact scores for POCs, refer to Table 7. The drop in scores for control one and two for Polychlorinated Biphenyls (PCBs), Perfluorinated compounds (PFCs)

and Polybrominated diphenyl ethers (PBDEs) indicate that the measures taken in controlling the chemicals are likely to reduce the impact of the hazard and for benefits to be accrued along the supply chain. On the other hand, the score for control one for dioxins did not change from the score in the uncontrolled state, indicating that control measures at a discrete phase may not be effective at reducing the impact of the hazard. Scores for Polycyclic aromatic hydrocarbons (PAHs) remained constant for control one and two, indicating that a similar effect could be achieved when both controlled states are applied. These changes in impact scores are less significant compared to other chemical hazards.

POCs, also known as persistent organic pollutants (POPs), are organic substances that persist in the environment, accumulate in living organisms and pose a risk to health and the environment. Previously, POCs were used in the manufacture of pesticides and industrial chemicals, which would later be released into the environment during chemical or agricultural processes (180). Examples of POCs include endosulfan, tetrabromodiphenyl ether (TBE), hentabromodiphenyl ether (PBE), Hexabromodiphenyl ether (HBE), heptabromodiphenyl ether (HBE), PCBs, PFCs, PBDEs, PAHs, perfluorooctane sulfonic acid (PFOS) and its derivatives. For the purpose of this risk profile, the focus will be on PCBs, PFCs, PBDEs, PAHs, dioxins and furans because they were identified within the SRT article.

A study investigated several POCs in Pacific oysters in San Diego Bay (181) with the following results: “PBDEs, benzyl butyl phthalate, and plastics were higher in winter. Contaminant levels were generally lower in Pacific oysters than mussels except for copper and zinc. Bay-wide PCB concentrations in oysters exceeded thresholds but individual samples (locations) also met or surpassed chlordane, PCB and PAH thresholds”.

Due to their lipophilic nature, POPs are often present in food, especially food of animal origin such as meat or fish. Additionally, shellfish are filter feeders, which means they filter seawater through their bodies to obtain food floating in the water. When POP particles are in the water, shellfish can accumulate the substance in their bodies. Although usually present at insignificant levels, there is the possibility that

they may reach levels potentially harmful to consumers, particularly as the result of an incident such as contamination of animal feed (182).

Some of the health effects of exposure to POCs include, increased cancer risk, reproductive disorders, alteration of the immune system, neuro-behavioural impairment, endocrine disruption, genotoxicity and increased birth defects (183).

#### 6.5.2.1 Polychlorinated Biphenyls (PCBs)

PCBs are a class of chemical compounds in which chlorine atoms replace some or all of the hydrogen atoms on a biphenyl molecule. PCBs are generally inert, resist both acids and alkalis and are thermally stable. PCBs are a group of synthetic organic compounds that were widely used in various industrial applications, including electrical equipment, hydraulic fluids, and as additives in paints and plastics. At high temperatures, PCBs are combustible, and the products of combustion may be more hazardous than the original compound (184). PCBs make their way into the marine environment due to accidental spills or leaks from industrial facilities. PCBs have been identified in fish and seafood, including oysters, and it is believed that recreational and subsistence fishers, who typically consume a large quantity are at a higher risk of exposure to PCBs than the general population (185).

Information on burden of foodborne disease caused by PCBs in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT for PCBs were 20, 18 and 13 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain. These changes in impact scores are less significant compared to other chemical hazards.

#### 6.5.2.2 Perfluorinated compounds (PFCs)

PFCs are a group of synthetic chemicals that have been used in many consumer products such as sofas, clothing and cookware. The structure of these chemicals makes them very stable, hydrophobic and oleophobic (186). Humans are mostly likely exposed by consuming PFC-contaminated water or food or by using products that contain PFCs. A study conducted in the US revealed that PFCs could be

present in shellfish if their environment is contaminated as they are able to accumulate PFCs due to their feeding method (187). Studies of laboratory animals given large amounts of PFCs have found that some PFCs may affect growth and development, reproduction, and injure the liver. However, more research is needed to assess the human health effects of exposure to PFCs (188).

Information on burden of foodborne disease caused by PFCs in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT for PFCs were 20, 14 and 12 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain. There was less of a reduction in the score between the two controlled states, suggesting that accrual of benefits along the supply chain may not be as high as for other chemical hazards.

#### 6.5.2.3 Polybrominated diphenyl ethers (PBDEs)

PBDEs are a group of man-made organobromine compounds which have been used as flame retardants in polyurethane foams in upholstery and in polymer resins and plastics used as components in electrical equipment (189). PBDEs bioaccumulate and biomagnify in food chains. They have been detected in birds and mammals, as well as fish, including shellfish. They also have potential adverse effects on aquatic life and humans, with a link to potential endocrine disrupting effects such as on the thyroid system, reproductive toxicity, and neurodevelopment toxicity in humans (189).

Information on burden of foodborne disease caused by PBDEs in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT for PBDEs were 20, 14 and 12 for the uncontrolled state and the two controlled states, respectively. A consistent drop in scores was observed, meaning that control measures may reduce the impact of the hazard and for benefits to be accrued along the supply chain. There was less of a reduction in the score between the two controlled states, suggesting that accrual of benefits along the supply chain may not be as high as for other chemical hazards.

#### 6.5.2.4 Polycyclic aromatic hydrocarbons (PAHs)

PAHs are a class of chemicals that occur naturally in coal, crude oil, and gasoline. They result from burning coal, oil, gas, wood, garbage, and tobacco and exposure can be through breathing contaminated air or consuming contaminated food (190). According to the FSA, bivalve shellfish accumulate PAHs from seawater and sediments, therefore, limits are applied to ensure that excessively-contaminated mussels or oysters do not enter the food chain (191). PAHs could also cause cancer, however, human health effects from indirect exposure to low levels of PAHs are unknown. The IARC Monographs Programme has reviewed experimental data for 60 individual PAHs. Of these only benzo[a]pyrene is classified as carcinogenic to humans (Group 1). Three PAHs reviewed by IARC (cyclopenta[cd]pyrene, dibenz [a, h] anthracene, and dibenzo[a,l]pyrene) were classified as probably carcinogenic to humans (Group 2A). Another 11 were classified as possibly carcinogenic to humans (Group 2B) (benz [ j] aceanthrylene, benz[a]anthracene, benzo[b]fluoranthene, benzo[ j]fluoranthene, benzo[k]fluoranthene, benzo[c]phenanthrene, chrysene, dibenzo[a, h]pyrene, dibenzo[a, i]pyrene, indeno[1,2,3-cd]pyrene, and 5-methylchrysene). The remaining 45 PAHs reviewed by IARC were determined to be not classifiable in regard to their carcinogenicity to humans (Group 3), because of limited or inadequate experimental evidence (192).

Information on burden of foodborne disease caused by PAHs in the form of DALYs were unavailable in the WHO burden of disease report(10).

Scores from the SRT for PAHs are 20, 13 and 13 for the uncontrolled state and the two controlled states, respectively. A drop in scores was observed, meaning that control measures may reduce the impact of the hazard but that benefits may not be accrued along the supply chain. These changes in impact scores are less significant compared to other chemical hazards.

#### 6.5.2.5 Dioxins

Dioxins, also known as 2,3,7,8- tetrachlorodibenzo para dioxin (TCDD) are a group of chemically-related compounds that are POPs (193). Dioxins are mainly by-products of industrial processes but can also result from natural processes, such as

volcanic eruptions and forest fires (193). Amongst other foods, dioxins have also been known to accumulate in oysters (194). Short-term exposure to high levels of dioxins in humans may result in skin lesions, such as chloracne (a form of acne specific to dioxin exposure) and patchy darkening of the skin and altered liver function. Long-term exposure is linked to impairment of the immune system, the developing nervous system, the endocrine system and reproductive functions. Finally, chronic exposure of animals and humans to dioxins has resulted in several types of cancer (193).

The Joint FAO/WHO has set a PTMI of 70 picograms (pg) of dioxins and dioxin-like PCBs (183).

According to the WHO burden of foodborne disease report, dioxins were implicated in 193,447 foodborne illnesses and 240,056 years lost to DALYs worldwide due to long term effects on health (92).

Scores from the SRT for dioxins were 20, 20 and 18 for the uncontrolled state and the two controlled states, respectively. The score for control one did not change from the score in the uncontrolled state, indicating that control measures at a discrete phase may be less effective at reducing the impact of the hazard. However, there was a slight drop in scores between the two control states, suggesting that measures applied at a specific phase may result in benefits being accrued along the supply chain. These changes in impact scores are less significant compared to other chemical hazards.

#### 6.5.2.6 Furans

Furans and the related compounds 2- and 3-methylfurans are chemical contaminants that naturally form during heated food processing, including cooking and they have always been present in cooked or heated foods (195). Furans are generally associated with processed foods, and oysters are generally not highly processed even in cases where they are cooked or smoked (195).

According to EFSA, liver damage and liver cancer are the major health effects of exposure to furans via food. There are some knowledge gaps about the toxicity of furans, therefore it’s possible that health risks have been overestimated (195).

Information on burden of foodborne disease caused by furans in the form of DALYs were unavailable in the WHO burden of disease report (10).

SRT impact scores for furans was not available as this hazard was not identified within the SRT.

### 6.5.3 Radiological contaminants

Radionuclides, also known as radioactive materials or radioactive isotopes, are unstable forms of elements that emit radiation as they undergo radioactive decay (196). Isotopes of a particular atom retain the same chemical properties but have different masses. They can be found naturally in the environment or can be generated through human activities, such as nuclear power generation and nuclear weapon testing. The presence of radionuclides in food, including oysters, can pose health risks if consumed in excessive amounts. However, it's important to note that the prevalence, effects, and severity of radionuclide contamination can vary depending on the specific radionuclide and the geographical location (197). Processing methods such as cooking, canning, and freezing do not significantly reduce the levels of radionuclides in food. However, strict regulatory limits are in place to ensure that food products, including oysters, do not exceed permissible radioactivity levels. The prevalence of radioactive contamination in the environment and food varies depending on historical nuclear activities, accidents, and local monitoring practices (198). Examples of radionuclides include caesium, cobalt, iodine, ionising radiation, plutonium, radium, radon, strontium, thorium and uranium and their respective isotopes (196).

Consuming food contaminated with radionuclides increases the amount of radioactivity in the body and could increase the health risks. For example, if radioactive iodine is ingested with contaminated food or drink, or inhaled with contaminated air, it will accumulate in the thyroid gland and increase the risk of thyroid cancer, particularly in children. Generally, exposure to radionuclides can result in an increased risk of certain types of cancer. Cancer types and target organs depend on the radionuclides (198).

Information on burden of foodborne disease caused by radiological contaminants in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT were for radionuclides generally and not provided individually, they were 14, 6 and 6 for the uncontrolled state and the two controlled states, respectively. The drop in score from the uncontrolled state to the two controlled states indicate that measures may be effective in reducing the impact of the hazard. However, the same score for the two controlled states indicates that measures applied may not be accrued along the supply chain, or that further reduction of the impact of the hazard would not be possible.

For the purpose of this risk profile, further detail will be provided on strontium-90, polonium-210, caesium-137, plutonium isotopes and naturally occurring isotopes and radium-226 because they were identified within the SRT article. It is not possible to characterise all potential radionuclides within the risk profile given the possible breadth of different types, therefore these five are prioritised here.

#### 6.5.3.1 Strontium-90

Strontium-90 is a radioactive isotope of strontium, with a half-life of approximately 29 years and emits beta particles during radioactive decay. The specific dose of strontium-90 required to cause illness can vary depending on factors such as exposure route, duration of exposure, and individual susceptibility. However, strontium-90 is primarily a concern due to its long-term effects of radiation exposure, including an increased risk of cancer and bone diseases (199).

Strontium-90 can contaminate the food chain through various pathways, such as deposition from nuclear fallout (199). Oysters are filter feeders that can accumulate contaminants, including radioactive isotopes like strontium-90, from their surrounding environment (200).

#### 6.5.3.2 Polonium-210

Polonium-210 is a radioactive isotope of polonium, which is a silvery-grey metal. It has a half-life of approximately 138 days, meaning that over time, half of the polonium-210 sample will decay into other elements. It emits alpha particles, which are highly energetic and can cause damage to living cells. It is considered one of the

most toxic substances known, with a lethal dose estimated to be around 1-3 Giga-becquerel (GBq) if ingested or inhaled (201) (202).

The significance of natural radionuclides, polonium-210 in particular and its bioaccumulation in marine and terrestrial foodstuffs has been known for some time. However, recently, it's concentration in fish and shellfish has been of greater interest due to its radiotoxicity to human cell structure and DNA (203). Symptoms include nausea, anorexia, hair loss, low white blood cell count, diarrhoea and bone marrow damage (204).

Oysters, particularly those harvested from certain regions, can accumulate polonium-210 from the water and sediments. The prevalence of polonium-210 in oysters can vary depending on the specific location and environmental factors. It is naturally found in the environment and higher concentrations have been reported in regions with specific geological characteristics. Studies have reported varying concentrations of polonium-210 in oysters from different regions, highlighting the need for monitoring and regulation. Processing methods such as cooking, or heat treatment do not significantly reduce the levels of polonium-210 in contaminated food. Exposure to polonium-210 can lead to acute radiation sickness and an increased risk of developing certain types of cancer, particularly lung cancer when inhaled or ingested (205) (206).

#### 6.5.3.3 Caesium-137

Caesium-137 is a by-product of nuclear fission and can remain in the environment for a long time, it has a half-life of 30.17 years (207) . It emits both gamma and beta radiation, making it hazardous to human health. Caesium-137 can accumulate in marine organisms, including oysters, through filter feeding in contaminated environments (208). This also depends on their proximity to potential sources of contamination. The dose of caesium-137 required to cause illness depends on various factors such as duration of exposure, route of entry, and individual susceptibility. Acute exposure to high doses can lead to severe radiation sickness, while chronic exposure to lower doses increases the risk of developing radiation-related health issues, including cancer (198).

Processing techniques such as cooking, canning, or freezing do not significantly affect the levels of caesium-137 in contaminated food. Caesium-137 is a persistent radionuclide that does not readily degrade or dissipate with standard food processing methods. Geographical distribution of caesium-137 contamination is directly linked to nuclear accidents and nuclear weapons testing. The most notable incidents involving caesium-137 include the Chernobyl disaster in 1986 and the Fukushima Daiichi nuclear disaster in 2011 (209).

#### 6.5.3.4 Plutonium

Plutonium is a silvery-grey metal that is highly toxic and radioactive. It is primarily produced as a by-product of nuclear reactions and has various applications in the nuclear industry, such as in the production of nuclear weapons and as a fuel in certain types of reactors. It's most common isotopes include plutonium-239, plutonium-240, and plutonium-241 (210).

Oysters and other seafood are not known to accumulate significant amounts of plutonium. Therefore, the prevalence of plutonium isotopes in oysters is considered negligible. Plutonium is highly resistant to chemical changes, so conventional food processing techniques have limited effects on its concentration or availability (210).

Chronic exposure to plutonium may increase the risk of developing cancer, particularly lung cancer. Other potential health effects include radiation sickness (likely to be caused by acute doses of radiation and not consumption of oysters naturally contaminated with plutonium), organ damage, and increased risk of genetic mutations. Geographical distribution of plutonium contamination can vary, depending on the specific incidents and local conditions (210).

#### 6.5.3.5 Radium-226

Radium-226 is a highly radioactive element that emits alpha particles, gamma rays, and some beta particles. It has a half-life of approximately 1,600 years. Radium-226 is a silvery-white metal that is chemically similar to calcium. Studies have shown that oysters collected from certain areas with naturally occurring elevated levels of radium-226 can contain higher concentrations of this radionuclide (211).

Processing methods, such as cooking or canning, do not significantly affect the levels of radium-226 in food, including oysters. Acute radiation sickness may occur due to exposure, with symptoms such as nausea, vomiting, diarrhoea, fatigue, and in severe cases, damage to the bone marrow and internal organs. Prolonged exposure to radium-226 can increase the risk of cancer, particularly bone cancer (osteosarcoma), as well as other bone disorders. The prevalence of radium-226 in different regions depends on local geological factors. Some areas, particularly those with certain types of rock formations, may have higher levels of radium-226 in the soil and water (211) (212).

### 6.5.4 Veterinary pharmaceutical and personal care chemicals

Veterinary pharmaceutical and personal care chemicals enter the environment by a number of different pathways at different stages of the product lifecycle (213). It has also been highlighted that during the treatment of fish with medicated feed pellets, some of these can enter the environment and are therefore accessible to wild fish, shellfish and crustaceans. Other routes into the sea include through wastewater treatment plants, agricultural runoff, and industrial discharges (213). Oysters are filter feeders, which means they filter seawater through their bodies to obtain food floating in the water. When these chemicals are in the water, oysters can accumulate them in their bodies.

Previous studies have shown the presence of antibiotics, for example oxytetracycline in fish after a period of treatment (213). An example of azithromycin and other pharmaceuticals being detected in oysters was in the Ebro delta in Spain (214). Antibiotics may be used in aquaculture to treat bacterial infections in farmed fish and if these are not properly managed, there is a risk of transfer to other organisms, which might include oysters (213). The high volume of antibiotics in other food-producing animals also contributes to the development of antimicrobial-resistant bacteria. These bacteria can be transmitted from animals to humans via direct contact between animals and humans, or through the food chain and the environment, such as sewage. These antimicrobial-resistant bacteria in the food supply can transfer to humans through ingestion, this can lead to more serious infections with longer illness, increased frequency of hospitalisation, and treatment failures which may result in death or long-term health effects (215). Antibiotic

residues could also accumulate in foods like oysters, leading to human exposure where they may cause allergies (penicillin and its derivatives) and induce other severe pathologies, such as cancers, anaphylactic shock, nephropathy, bone marrow toxicity, mutagenic effects, and reproductive disorders (216). However, given the amount of the drugs which are likely to be accumulated and the amount of oyster consumption, many of these symptoms may be considered unlikely.

The uptake of hormones by oysters from contaminated water is a topic of concern in environmental and aquatic science. Hormones, such as oestrogen, progesterone, and testosterone, can enter water bodies through various sources, including wastewater treatment plants, agricultural runoff, and industrial discharges. A study conducted by Dan *et al*. (217) revealed the presence of endocrine disrupting chemicals in fish in a shallow Chinese freshwater lake, also likely to house oysters. The study considered natural and synthetic oestrogens, in addition to other Endocrine Disrupting Compounds (EDCs). Excessive intakes of hormones through food may cause possible impact on human development and health (218) (219).

Examples of hormonal or hormonally active growth promoters used in farm animals worldwide are the natural hormones 17β-oestradiol, testosterone and progesterone, and the synthetic substances zeranol (oestrogenic activity), trenbolone acetate (TBA) (androgenic activity) and melengestrol acetate (MGA) (gestagenic activity). The EU banned the use of these substances in 1981 (Directive 81/602/EEC); the ban includes Member States and imports from third countries (Directive 96/22/EC as amended by Directive 2003/74/EC) (220) (221). As a Member State at the time, the UK was also subject to this law. However, the Medicines (Hormone Growth Promoters) (Prohibitions of Use) Regulations 1988 are also in place in the UK. This prohibits the use of any hormone growth promoters with oestrogenic, androgenic or gestagenic action (222).

In terms of the effects of accumulated 17β-oestradiol in humans, in women it can induce growth and development of the reproductive tract and breasts. The IARC have concluded that 17β-oestradiol is a Group I human carcinogen in that it has sufficient evidence for carcinogenicity in humans. In long-term studies of carcinogenicity in mice, rats and hamsters, increased incidences of tumours were

observed in multiple systems included mammary and pituitary glands; the uterus, cervix, vagina, and testicles; lymphoid organs and bones; and kidneys. 17β-oestradiol is also considered a genotoxic carcinogen. Progesterone, however, has shown no evidence of genotoxicity and the IARC have concluded that there is limited evidence to suggest carcinogenicity in experimental animals and no evaluations of carcinogenicity in humans. The main effects of progesterone are changes in the human uterus, its common use is as a contraceptive in women and in hormone replacement therapy (HRT) for menopausal women. In humans, the main effects of testosterone are developmental, with different effects in men and women. For example, in men, it affects libido, fat distribution, muscle mass, and the production of blood cells and sperm. In women, testosterone affects growth, maintenance and repair of reproductive tissues and bone mass. In human medicine, testosterone is used to treat testicular dysfunction in men and as HRT in menopausal women (in combination with oestrogen) (221).

Zeranol and it's derivative zearalenone (ZEA) are reproductive and developmental toxicants in humans. It has been reported to disrupt the endocrine system, potentially affecting the uterus, mammary glands, bones, liver and brain by inhibiting secretion of steroid hormones (223). TBA is also an endocrine disruptor and side effects can include elevated blood pressure and cholesterol levels, severe acne, premature balding, reduced sexual function and testicular atrophy. In men, abnormal breast development may occur, and in women it may have a "masculinising" effect (224). Finally, MGA has been recognised as having no genotoxicity relevant to human health, however adverse effects have been observed including mammary gland hyperplasia (increased cell production), endometrial hyperplasia and a lack of corpora lutea (leading to abnormal formation of ovarian follicles). MGA is considered as a reproductive and developmental toxicant (225).

There are also other types of growth promoters which may be used in farm animals which are not hormones or hormonally active. Examples include the beta-agonists ractopamine used in pigs and cattle, zilpaterol used in cattle and clenbuterol used in pigs, cattle and horses. Beta-agonists enhance growth efficiency by stimulation of beta-adrenergic receptors on cell surfaces (226). Ractopamine is banned in the EU (EC Directive 96/22/EC) and in the UK (within UK Legislation - the Animals and

Animal Products Regulations 1997 restricts the use of beta-agonists). Similarly, zilpaterol and clenbuterol are banned in the EU and the UK under the same legislation (227) (228) (229) (230). Potential adverse effects of ractopamine (if exposure were at a sufficiently high level) include tachycardia, muscle tremors and increased airway inflammation (231). Ractopamine is not considered genotoxic. Zilpaterol and clenbuterol have similar effects to ractopamine (232) (233).

Ibuprofen belongs to a class of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs) and it can enter ecosystems through different routes, of which wastewater effluents are the main one, including aquifer effluents from veterinary facilities, domestic premises, hospitals, and drug-production factories (234). Due to the feeding nature of oysters, it is possible for them to accumulate these drugs. Harmful effects may emerge generally from the presence of NSAIDs, other than and including ibuprofen, in fishery products for human health. Other NSAIDs which may be present include diclofenac, paracetamol and naproxen as they have a high usage by humans (235, 236, 237). Although there is a large amount of evidence of pharmaceuticals exerting negative effects on aquatic organisms, there is limited information available on the bioaccumulation and effects of NSAIDs on marine organisms (236). Diclofenac, ibuprofen and naproxen are among the top ten persistent pollutants, accounting for more than 15% of all pharmaceuticals detected in the aquatic environment. These pharmaceuticals have a stable chemical structure and biological activity which make them resistant to biodegradation. Oral NSAIDs have negative side-effects on human health such as increased risk of adverse events in the GI tract and, rarely, the cardiovascular system, the liver and the kidneys. NSAIDs are also contraindicated in the third trimester of pregnancy, meaning it is recommended that they are not used from the 28$^{th}$ week of pregnancy. This is because there is potentially an increased risk of premature constriction of the ductus arteriosus (connects the pulmonary artery to the aorta) in the foetus which can result in pulmonary hypertensions in the foetus and newborn infant. There also may be an inhibitory effect on labour, resulting in delayed onset of, or prolonged, labour (238). It is currently unclear exactly what the direct human health risks would be following transfer from aquatic organisms through ingestion, although potential risks cannot be excluded if NSAIDs are allowed to accumulate in aquaculture (235).

Feed additives are substances, micro-organisms or preparations (other than feed materials and premixtures) which are intentionally added to feed or water to meet the animals' nutritional requirements, improve the quality of feed, the quality of food from animal origin (for example, meat, fish, milk, eggs) and to improve the animals' performance and health in farming. These may enter the aquatic environment via wastewater and agricultural runoff (239). It is possible that these substances could be accumulated in oysters during the feeding process. However, very little to no research is available on their presence or effects on oysters or humans.

Recreational drugs are chemical substances taken for enjoyment rather than for medical reasons. These could include alcohol, tobacco, cannabis, cocaine, ecstasy, methadone, methamphetamine and magic mushrooms, amongst others. Although not much research has been conducted on the presence of these substances in oysters, an article in the New Scientist (240) highlighted that as methamphetamine levels in freshwater streams increase, due to pollution from wastewater, so does the increase in fish addiction to this drug. Due to the feeding nature of oysters, it is possible for them to accumulate such drugs and therefore pose a threat to humans through their consumption. Health effects of recreational drugs range from dizziness, vomiting or blackouts to instant death, depending on the drug (241). It is considered that the information from this study could be applicable to many recreational drugs. However, given the amount of the drugs which are likely to be accumulated and the amount of oyster consumption, this may be unlikely, depending on the drug, particularly effects such as instant death.

Sertraline is a type of antidepressant known as a selective serotonin reuptake inhibitor (SSRI). It's often used to treat depression, and also sometimes panic attacks, obsessive compulsive disorder (OCD) and post-traumatic stress disorder (PTSD). It works by increasing the levels of a mood-enhancing chemical called serotonin in the human brain. Effluents from wastewater treatment plants are the main contributors to the presence of sertraline in the environment. It has also been detected in surface waters, sediments, biosolids and biota (242). When sertraline is in water, oysters may accumulate it in their bodies, thereby posing a risk to consumers. Side effects of sertraline include nausea, headaches, lack of sleep, diarrhoea, dizziness and weakness (242). Due to the feeding nature of oysters, it is

possible for them to accumulate such drugs and therefore pose a threat to humans through their consumption. Side effects of sertraline include nausea, headaches, lack of sleep, diarrhoea, dizziness and weakness (243). This may be unlikely given the amount of sertraline likely to be accumulated and the amount of oysters likely to be consumed.

Tamoxifen is a hormone therapy drug used to treat breast cancer in women and men (244). It is also sometimes called endocrine therapy. Tamoxifen is one of the drugs identified as being present in aquatic ecosystems with the source being urban effluents, pharmaceutical plants and domestic livestock breeding and aquaculture (245). When tamoxifen is in water, oysters may accumulate it in their bodies and therefore pose a risk to consumers. Common side effects include hot flushes and sweats, fluid build-up, nausea, tiredness, skin rash and depression. Furthermore, tamoxifen is an IARC category 1 carcinogen, based on increased risk of endometrial cancers, despite it reducing the risk of breast cancer (246). Tamoxifen is also a reproductive and developmental toxicant, which is contraindicated for use during pregnancy, and it is also advised to stop use three months prior to attempts to conceive due to its long half-life. Effects on the foetus may include malformation, however the effects on the foetus and course of pregnancy are not fully understood (247) (248). This may be unlikely given the amount of tamoxifen likely to be accumulated and the amount of oysters likely to be consumed.

Salicylic acid is a simple phenolic compound synthesised in a wide range of prokaryotic and eukaryotic organisms, including plants (249). It is used in the preparation of aspirin and other pharmaceuticals. Salicylic acid can be used topically on the skin to loosen dry, scaly skin, making it easier to remove. Salicylic acid is a hazardous substance encountered in wastewaters mainly through by-products, human and veterinary drugs, paper milling and cosmetic industries (250). When salicylic acid is in water, oysters may accumulate it in their bodies and therefore pose a risk to consumers. Common symptoms of salicylic acid are recorded as topical side effects because it is available only in topical applications. Data from human studies on toxicity from oral ingestion include gastric irritation and reduced mass at birth for babies born to women who have ingested salicylate for long periods during pregnancy. An increased risk in prenatal mortality, anaemia, antepartum and

postpartum haemorrhage, prolonged gestation and complicated deliveries have been recorded during the third trimester (251) (252). This may be unlikely given the amount of salicylic acid likely to be accumulated and the amount of oysters likely to be consumed.

Processing methods such as cleaning, shucking and cooking can affect the presence of some of the described substances. However, it depends on factors like the cooking method (such as boiling or steaming), initial concentration of the substance, processing duration and temperature (253).

Information on burden of foodborne disease caused by veterinary pharmaceutical and personal care chemicals in the form of DALYs were unavailable in the WHO burden of disease report (10).

Scores from the SRT were not provided for veterinary pharmaceuticals and personal care products as a whole group, they were only provided for antimicrobials. The scores for antimicrobials were 23, 20 and 12 for the uncontrolled state and the two controlled states, respectively. The drop in score from the uncontrolled state to the two controlled states indicates that measures may be effective in reducing the impact of the hazard. However, the same score for the two controlled states indicates that measures applied may not be accrued along the supply chain, or that the impact of the hazard cannot be reduced any further.

### 6.5.5 Microplastics

Microplastics are small plastic particles within the size range of 0.0001 - 5 mm and are found in the environment, including in the oceans, freshwater bodies, and in the air. They can be categorised into two main types. Primary microplastics are intentionally produced as small particles for various purposes such as use in cosmetics and industrial applications. Secondary microplastics are formed by the breakdown of larger plastic items over time due to weathering, ultraviolet (UV) radiation, and mechanical action such as microfibers shedding from synthetic clothing, and opening of water bottle lids (254) (255).

Primary microplastics enter the aquatic environment through household sewage discharge or spillage of plastic resin powders or pellets such as those used for air

blasting in watercourses. Secondary microplastics are introduced to aquatic environments by wind dispersal, soil erosion or surface runoff (255). Microplastics have been found in various food sources, including seafood, water, salt and honey. The prevalence of microplastics in food can vary depending on the source and processing methods. Seafood, particularly shellfish like oysters, mussels, and clams, have been found to contain microplastics due to their filter-feeding nature. Oysters, in particular have been shown to accumulate microplastics in their tissues (256).

Processing methods, such as cooking, can have varying effects on microplastics. Information exists to suggest that some forms of processing may be effective in reducing microplastics in fish (257), however, it is not clear if these take into account the effects of processing (such as heat) on the release of chemicals from the plastics or the potential for additional sources of microplastics from processing (such as from cooking utensils). Other studies have reported no significant change. Further research is needed to understand the impact of different processing techniques on microplastic concentrations. Given oysters are often consumed raw, this information may not always be relevant in relation to oyster consumption. According to the FAO report on Microplastics in Fisheries and Aquaculture (258), there is no evidence that microplastics ingestion has negative effects on populations of wild and farmed aquatic organisms. A worst-case estimate of exposure to microplastics after consumption of a portion of mussels (225g) would lead to ingestion of 7µg of plastic, which would have a negligible effect (less than 0.1% of total dietary intake) on chemical exposure to certain bioaccumulative and toxic contaminants and plastic additives.

Nanoplastics (NPs) have also been identified in oysters. There are several definitions to define these, but NPs are most recently defined as particles of a size between 1 and 1000nm which result mainly from degradation of larger plastic particles. According to EFSA (259), microplastics smaller than 150 µm may translocate across the gut epithelium causing systemic exposure. The absorption of these microplastics is expected to be limited (≤0.3%). The smallest fraction (size<1.5 µm) may penetrate deeply into organs. However, the data is limited on the toxicokinetic fate of orally ingested microplastics in mammalian species, and very little data exists about NP toxicity, in a similar way to microplastics, and even less on

how NPs have resulted from fragmentation of larger plastic particles in the environment. The most significant data gap is the lack of appropriate and harmonised analytical methods for the detection and quantification of NPs (258). Therefore, the potential health risks from exposure to NPs is not yet clear. Although association between NPs and pathogenic organisms (such as *Vibrio* spp., *Pseudoalteromonas* spp. and *Aeromonas salmonicida*) has been demonstrated in research it is difficult to assess the impact of microbiologically contaminated NPs in the food chain due to significant data gaps and lack of research in this area (260).

The symptoms and diseases associated with microplastic ingestion in humans are not well-defined. Some studies suggest that microplastics may pose several toxicity concerns, including acute (cytotoxicity, respiratory, gastrointestinal and reproductive toxicity) and chronic toxicity (cytotoxicity, immunotoxicity and reproductive toxicity), carcinogenicity, and developmental toxicity (261).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

SRT scores for this hazard were unavailable as it was not identified within the SRT.

### 6.5.6 High production volume (HPV) chemicals

High production volume (HPV) chemicals were defined by the Organisation for Economic Cooperation and Development (OECD) as chemicals with a production of over 1000 tonnes/ year and by the US Environmental Protection Agency (EPA) as compounds produced at a minimum of 500 tonnes/ year. The list of chemicals was intended to prioritise chemicals for creation of data for risk assessments. This is large list of chemicals so only those noted in LBMs or oysters in a review of analytical methods by Castro *et al* have been characterised here (262).

As described elsewhere in this risk profile, oysters can bioaccumulate chemicals from their environment due to their physiology (as filter feeders), hence HPV chemicals may be of concern.

Organophosphate esters (OPEs), phthalate esters (PAEs), benzothiazoles (BTs), and benzotriazoles (BTRs) are some of the compound families included in the list of

HPV chemicals. Other families included benzotriazole UV light stabilisers (BUVS) and synthetic phenolic antioxidants (SPAs). These compounds are used as fire ignition preventors (which contain OPEs), plasticisers (which contain PAEs and OPEs) and corrosion inhibitors, UV light stabilisers, or antifungal agents (which contain BTRs and BTs). The widespread usage of these compounds in every day commodities has led to widespread contamination, with reports in air, dust and water. Their release through domestic and industrial discharges means that they are a major issue for aquatic environments, where species are directly exposed to these contaminants. Marine animals such as LBMs are susceptible to these contaminants and therefore, they represent a major source via dietary intake for humans. According to the review, compounds such as dibutyl phthalate (DBP) and Di(2-ethylhexyl) phthalate (DEHP) are confirmed to have development and reproductive adverse effects in laboratory animals. While other compounds such as di-n-butyl phthalate (DnBP) or benzyl butyl phthalate (BBP) have been linked to steroid-hormone reduction (such as testosterone (263) and progesterone (264)). OPEs exposure has been linked to potential adverse effects, with tris(2-carboxyethyl) phosphine hydrochloride (TCEP) and tris (chloroisopropyl) phosphate (TCPP) thought to be potentially mutagenic, carcinogenic and endocrine disruptors. Toxicity of BTs and BTRs has been reported by several studies to have respiratory irritant effects and cause dermal sensitisation (262).

The review of analytical methods by Castro *et al* states that it “intended to comprise the most recently used analytical methodologies for the determination of these compounds in seafood samples, focusing on their extraction and clean-up strategies.” The authors presented an overview of the occurrence in different studies globally and “the exposure and risk assessment calculations performed by several studies”. Seafood can be analysed as the whole organism or divided into different parts or organs, the review states that it focused on methods using only the edible parts of the seafood because its aim was to review the analytical methods which could provide the data necessary to perform exposure and risk assessment calculations for the ingestion of compounds via dietary intake. From the review it is clear that PAEs, OPEs and BTRs of different types were observed in molluscs, or oysters specifically, at varying levels and in varied locations (262). Therefore, these

compound families have been characterised further here as it is not possible to characterise all potential chemicals in this large group.

OPEs are derivatives of phosphoric acid and are widely used as flame retardants and plasticisers, their use has increased rapidly due to the prohibition of PBDEs. OPEs are mostly added to various materials by physical mixing so are therefore easily released into the environment via volatilisation, leaching and abrasion during production, use, transportation and after disposal. OPEs can enter the human body via ingestion, inhalation, and dermal contact. Toxicological studies have indicated that OPEs can cause various adverse toxic effects, such as acute, reproductive and developmental toxicity, neurotoxicity, genotoxicity, nephrotoxicity, and endocrine disruption. Long-term exposure to OPEs is thought to cause serious health problems such as increased incidence and severity of urinary bladder hyperplasia. Chlorinated-OPEs (Cl-OPEs) such as TCEP, tris-(chloroisopropyl) phosphate (TCiPP), and tris-1,3-dichloro-isopropyl (TDCiPP) have shown carcinogenic properties and can accumulate in the liver and testes where they can induce tumours. This information on TDCiPP comes mostly from carcinogenicity studies in animals (rats) (265). Neurotoxic effects have been observed for TCEP, tri-n-butyl phosphate (TnBP), and tri-phenyl phosphate (TPhP). And TPhP has been shown to have contact allergy effects and effects on fertility. Finally, it has been demonstrated that TDCiPP is associated with the change of hormone levels and may reduce semen quality (266).

PAEs are also widely used as plasticisers in industrial sectors to enhance the properties of polymers. They are not covalently bound, but simply mixed, in a similar way to OPEs, with the plastic polymer they are being used to enhance. Therefore, they are also easily released into the environment via volatilisation (267). Due to endocrine disruption properties, the US EPA has classified six PAEs as priority pollutants, including dimethyl phthalate (DMP), diethyl phthalate (DEP), DBP, BBP, DEHP and di-n-octyl phthalate (DNOP). PAEs have a direct effect on the reproduction of marine animals, particularly fish. Generally, PAEs can mimic normal hormone functions and disturb the oestrous cycle, which is mediated by two oestrogen receptors (ERs). Numerous studies have shown the oestrogenic binding activities of PAEs with human ERs and rainbow trout ERs. Previously, various

animal models have been used to evaluate in vivo toxicity of PAEs, however, most of the studies have been focused on the individual effects of PAEs, so it has been difficult to determine the combined toxicity potential of PAEs. Overall, it is considered that the main effects of PAEs are as endocrine disruptors, exposure to them can cause reproductive deformities, disrupt the oestrous cycle and decrease steroidogenesis (268). DEHP is considered the most prominent problematic PAE, both in literature specific to the toxicity of PAEs and in the HPV chemical review (268) (262).

BTR and its derivatives (collectively referred to as BTRs) are commonly used as corrosion inhibitors in de-icing fluids for aircrafts, automotive antifreeze formulations, household detergents, and industrial cooling systems. Common BTRs include 4-OH-BTR, 5-OH-BTR, xylyl triazole (XTR) and methylated tolyltriazoles (TTR) (269). Humans can be exposed to BTRs through multiple sources such as air, dust, drinking water and food. BTRs are respiratory tract irritants and dermal sensitisers, they are also associated with genotoxicity and carcinogenicity (270).

Chemicals considered as HPV chemicals may cross over with sections on POCs (6.5.2), veterinary pharmaceuticals and personal care products (6.5.4) and microplastics (6.5.5). Furthermore, this section is not considered a comprehensive review of all HPV chemicals but intended to characterise potential hazards associated with oysters specifically. Hence three main chemical groups have been described.

DALYs from the WHO burden of disease report have not been provided due to the general nature of this hazard category.

SRT scores for this hazard were unavailable because it was not identified within the SRT.

### 6.5.7 Natural biotoxin hazards

Table 8 provides the SRT impact score for marine biotoxins from the refined hazard list (section 5.2). Scores were derived as part of the SRT supplementary information using the SRT schema (see section 6.2). Scores are provided for the uncontrolled state in which no controls are applied; control one - the controlled state where either

standalone/non-accrued control measures are applied at discrete phases of supply; control two - the controlled stated where the benefit of controls applied at one phase are accrued in subsequent phases of supply.

Table 8: SRT scores for natural biotoxins (1)

| **Marine biotoxin** | **Score** | | |
|---|---|---|---|
| | **Uncontrolled** | **Control 1** [a] | **Control 2** [b] |
| Paralytic shellfish toxins (saxitoxins - STX) | 42 | 32 | 19.5 |
| Lipophilic toxins (okadaic acid - OA, azaspiracid - AZA) | 50 | 38 | 12.5 |
| Amnesic shellfish toxins (domoic acid - DA) | 50 | 42 | 16 |
| Brevetoxins (BTX) | 33 | 23 | 15.5 |
| Palytoxin (cyanobacterial) (PITX) | 33 | 23 | 15.5 |

a) Controlled state when hazards are controlled at discrete phases, they are standalone/non-accrued control measures.
b) Controlled state when hazards are controlled at discrete phases and the benefit of controls are accrued in subsequent phases of supply.

According to Table 8, okadaic acid (OA), azaspiracid (AZA group) and domoic acid (DA) had the highest impact scores in the uncontrolled state, followed by saxitoxins (STX group), brevetoxins (BTX group) and palytoxin (PITX group). There was a decrease in the scores for all marine biotoxins provided with SRT scores in the controlled states. SRT scores were not provided for other toxins included in this section because they were not identified within the SRT article (cyclic imines (CIs), pectenotoxin (PTX), yessotoxin (YTX) and tetrodotoxin (TTX)).

It should be noted that purification is not effective in the control of marine biotoxins in oysters. It is therefore important that controls are implemented early in the supply chain via the selection and monitoring of the growing area, and via testing methods to remove contaminated commodities from the supply chain. See section 7 for information on recommended control measures. For example, characteristics of the growing area including sea temperatures, sea water salinity, occurrence of biotoxins and seasonality are considerations when selecting and classifying growing areas. Continued monitoring is also discussed. The SRT notes that chemical hazards had less impact on early-life and grow-out phases of production, but impact harvesting and processing more, for example where concentrations of biotoxins exceed safe

limits (1). This is because of removal from the supply chain at these points if detected to be above safe limits. This is the only control measure in the latter part of the supply chain for these hazards as they cannot be removed via purification. Information on unsafe biotoxin concentrations is discussed in the following sections.

Marine biotoxins, also known as phycotoxins, are produced by certain species of naturally occurring marine algae such as dinoflagellates. Most phycotoxins are thermostable and therefore resistant to cooking, including those in this section (1). Therefore, consumption of raw or cooked oysters does not make a difference to the risk. Different algae lead to formation of different biotoxins (271). Over 4,000 species of marine algae exist, but only 70-80 species (~2%) are known to produce toxins (272). When toxin-producing algae grow excessively in a body of water, a harmful algal bloom (HAB) occurs and humans can become ill from eating seafood contaminated with HAB-related toxins (273). As microscopic algae are a food source for filter feeding bivalve shellfish, including oysters, it is well known that marine toxins can accumulate in their tissues. Certain environmental conditions such as warmer sea temperatures and excessive nutrients from fertilisers or sewage waste can trigger HABs. As the Earth's climate is getting warmer due to climate change, it is expected that HABs may become more frequent, prolonged and severe in different areas of the world (273).

The adverse health effects and other characteristics of different groups of marine biotoxins (as shown in Table 1) are discussed in their respective sections.

#### 6.5.7.1 Azaspiracid (AZA) group

Azaspiracid (AZA) group toxins are produced by the dinoflagellate *Amphidoma languida* and *Azadinium spinosum* (274). Approximately 20 different analogues have been identified, of which AZA1, AZA2 and AZA3 are the most important based on occurrence and toxicity. After accumulation of these toxins in edible marine organisms and their subsequent consumption, humans develop a gastrointestinal syndrome referred to as azaspiracid shellfish poisoning (AZP) which is characterised by symptoms such as nausea, vomiting, diarrhoea and stomach cramps. This syndrome is very similar to diarrheic shellfish poisoning (DSP), with main symptoms appearing a few hours after consumption and including diarrhoea, vomiting, and

stomach cramps (275). DSP symptoms are reversible (276). A study on the heat stability of AZAs in shellfish tissues showed that temperatures above 100°C are required to decompose or rearrange AZAs. The mechanism of action of AZAs is not yet known (277). AZAs have been reported from several countries, including Morocco and much of Western Europe (278).

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) established an acute reference dose (ARfD) of 0.2 µg for AZA1 equivalents/kg bw based on the available human data. Due to insufficient data on the chronic effects of AZAs in animals or human, a tolerable daily intake (TDI) was not established. No data on genotoxicity have been reported for AZAs. The current maximum level for AZA1 in EU legislation is 160µg equivalents/kg shellfish meat. The CONTAM Panel noted that consumption of a 400g portion of shellfish meat containing AZAs at the current EU limit of 160µg AZA1 equivalents/kg shellfish meat would result in a dietary exposure of 64µg AZA1 equivalents. For a 60 kg adult this is approximately 1 µg AZA1 equivalents/kg bw. This figure is five-fold higher than the ARfD established by the CONTAM Panel. Therefore, it was concluded that adverse effects in susceptible consumers at this intake cannot be excluded (277). Susceptible consumers were not defined by the Panel.

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

The SRT score for lipophilic toxins (which include AZA) was 50 in the uncontrolled state. The SRT scores reduced to 38 for control one, and further to 12.5 for control two. This suggests that controls are effective in reducing the impact of the hazard both at discrete phases and where benefits are accrued through the supply chain. However, effective control measures would have to be applied early in the supply chain or include testing and subsequent removal of contaminated commodities from the supply chain.

#### 6.5.7.2 Brevetoxin (BTX) group

Brevetoxin (BTX) group toxins are mainly produced by the dinoflagellate *Karenia brevis* and cause neurological shellfish poisoning (NSP). Symptoms and signs of

NSP include nausea, vomiting, diarrhoea, paraesthesia, cramps, bronchoconstriction, paralysis, seizures and coma. BTX is resistant to heat and steam autoclaving. The mechanism of action of the BTX-group toxins is that they bind to and activate the voltage-gated sodium channels in cell walls, leading to uncontrolled sodium ion influx into cells and depolarisation of neuronal and muscle cell membranes. NSP appears to be limited to the Gulf of Mexico, the east coast of the USA, and the New Zealand Hauraki Gulf region (279). Many cases of NSP are associated with recreationally harvested shellfish collected during or post “red tide” blooms, also known as HABs (280).

The toxicological database for BTX-group toxins is limited. The EFSA CONTAM Panel could not establish an ARfD or TDI for BTX-group toxins (279). Due to the lack of occurrence data on shellfish or fish in Europe and the limited data on toxicity, the CONTAM Panel could not comment on the risk associated with the BTX-group toxins in shellfish that could reach the European market. Currently, there are no regulatory limits for BTX-group toxins in shellfish or fish in Europe. However, some countries in other regions of the world such as USA, New Zealand and Australia have set action levels or maximum levels for BTX-group toxins in shellfish (279).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

The SRT score for BTX was 33 in the uncontrolled state. The SRT scores reduced to 23 for control one, and further to 15.5 for control two. This suggests that controls are effective in reducing the impact of the hazard both at discrete phases and where benefits are accrued through the supply chain. However, effective control measures would have to be applied early in the supply chain or include testing and subsequent removal of contaminated commodities from the supply chain.

#### 6.5.7.3 Cyclic imines (CIs) group

The cyclic imines (CIs) group includes gymnodimine (GYMs), spirolides (SPXs), pinnatoxins, prorocentrolide and spirocentrimine. The presence of this group of compounds in shellfish was discovered because of their very high acute toxicity in mice upon intraperitoneal injections of lipophilic extracts. SPXs and GYMs are

produced by the dinoflagellates *Alexandrium ostenfeldii* and *Karenia selliformis*, respectively. GYMs and SPXs occur in microalgae and/ or bivalve molluscs from Canada, Denmark, New Zealand, Norway, Scotland, Tunisia and the USA (276).

The toxicological database for CIs group is limited. There have been no reports of adverse effects in humans. Similarly, there is no information on subacute or chronic toxicity of any of the CIs. The Joint FAO/ Intergovernmental Oceanographic Commission (IOC)/ WHO ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs has not established an ARfD or TDI for the CIs due to insufficient data (276). The EFSA CONTAM Panel concluded that current estimated exposure to SPXs does not raise concern for the health of the consumer based on very limited toxicity data. No conclusions can be drawn with respect to any possible risk to consumers for other groups of CIs due to insufficient data (281).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (92).

An SRT impact score was not available as these toxins were not identified within the SRT.

#### 6.5.7.4 Domoic acid (DA) group

Domoic acid (DA) group toxins are mainly produced by marine red algae of the genus *Chondria* and diatoms of the genus *Pseudo-nitschia*. They cause amnesic shellfish poisoning (ASP) in humans. Symptoms of ASP include gastrointestinal symptoms (vomiting, diarrhoea or abdominal cramps) and/ or neurological symptoms (confusion, loss of memory, or other serious signs such as seizure or coma) occurring within 24-48 hours after consuming contaminated shellfish. DA is heat stable and cooking does not destroy the toxin. Therefore, consumption of raw or cooked shellfish, including oysters, from areas with known DA contamination can pose a risk of poisoning (282).

DA is a recognised agonist of non-N-methyl-D-aspartate (non-NMDA) glutamate receptors, including both α-amino-3-hydroxy-5-methyl-4-isoxazolepropionate (AMPA) and kainate receptors. Glutamate is a major excitatory neurotransmitter in the brain,

and the action of DA on non-NMDA receptors perturbs neurotransmission. DA isomers have been detected in shellfish in Canada, the USA and in a number of European countries (282). The prevalence of DA in food, particularly shellfish, can vary depending on environmental factors, such as water temperature and nutrient availability, which affect the growth and abundance of the toxic algae. DA outbreaks are typically associated with periods of HABs, which can lead to shellfish contamination, and poisoning outbreaks in humans are often associated with the consumption of contaminated shellfish from specific regions or harvest areas because of this. In oysters it can vary depending on the geographic location and the specific time of year. These events tend to be more common in coastal areas with nutrient-rich waters, and their occurrence can be influenced by factors such as temperature, sunlight, and ocean currents (282).

The EFSA CONTAM Panel established an ARfD of 30 µg DA /kg bw based on the available human data. Due to insufficient data on the chronic effects of DA in animals and humans, a TDI was not established. The current maximum level for DA in EU legislation is 20mg /kg shellfish meat (SM) (282). The CONTAM Panel noted that consumption of a 400g portion of shellfish meat containing DA and epi-DA (diastereoisomer[9] of DA) at the current EU limit of 20mg DA/kg shellfish meat would result in a dietary exposure of 8mg DA (equivalent to about 130µg DA/kg bw for a 60kg adult). This is about four times higher than the ARfD of 30µg DA/kg bw (equivalent to 1.8mg DA per portion for a 60kg adult) and is considered to constitute a potential health concern (282).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (10).

The SRT score for DA was 50 in the uncontrolled state. The SRT scores reduced to 42 for control one, and further to 16 for control two. This suggests that controls are

[9] Diastereoisomer, also spelled diasteromer, either member of a pair of substances that differ with respect to the configurations of their molecules (i.e., stereoisomers) and that lack a mirror-image relationship (i.e., are not enantiomers) 283. Britannica. Diastereoisomer | Definition, Example, & Facts: Britannica; 2023 [Available from: https://www.britannica.com/science/diastereoisomer.

effective in reducing the impact of the hazard both at discrete phases and where benefits are accrued through the supply chain. However, effective control measures would have to be applied early in the supply chain or include testing and subsequent removal of contaminated commodities from the supply chain.

#### 6.5.7.5 Okadaic acid (OA) group

Okadaic acid (OA)-group toxins are produced by dinoflagellates *Dinophysis* spp. and *Prorocentrum lima*. OA toxins cause DSP, which is characterised by symptoms such as diarrhoea, nausea, vomiting and abdominal pain. These symptoms may occur in humans shortly after consumption of contaminated bivalve molluscs such as oysters. DSP symptoms are reversible (276). OA toxins are heat stable. The mechanism of action of the OA-group toxins is through inhibition of serine/ threonine phosphoprotein phosphatases (284). OA and DSP have been reported in various parts of the world, including Europe, North America, Asia, and Australia (285). The prevalence of OA in oysters can vary depending on factors such as the location, season, and environmental conditions. Monitoring programs are typically in place to assess the levels of OA and other shellfish toxins in oysters and other shellfish. Prevalence in oysters is influenced by climate, water quality, and HABs (285).

Based on the available toxicological data, the EFSA CONTAM Panel established an ARfD of 0.3µg OA equivalents/kg bw based on the available human data, however due to insufficient data on the chronic effects of OA in animals or humans, a TDI was not established. The current maximum level for OA in EU legislation is 160µg /kg SM (284). The CONTAM Panel noted that a 400g portion of shellfish meat containing OA-group toxins at the current EU limit of 160µg OA equivalents/kg shellfish meat would result in a dietary exposure of 64µg toxin. For a 60kg adult this is equivalent to approximately 1µg/kg bw. This figure exceeds the ARfD by approximately three-fold and this intake would be expected to exert effects in susceptible consumers (284). The Panel did not define susceptible consumers.

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (92).

The SRT score for lipophilic toxins (which include OA) was 50 in the uncontrolled state. The SRT scores reduced to 38 for control one, and further to 12.5 for control two. This suggests that controls are effective in reducing the impact of the hazard both at discrete phases and where benefits are accrued through the supply chain. However, effective control measures would have to be applied early in the supply chain or include testing and subsequent removal of contaminated commodities from the supply chain.

#### 6.5.7.6 Palytoxin (PITX) group

Palytoxin (PITX) group toxins have mainly been detected in soft corals of the genus *Palythoa* and in algae of the genus *Ostreopsis*. PITX-group toxins were first reported in Hawaii and Japan but are currently distributed worldwide. Signs and symptoms of PITX-group toxins intoxication are not well-defined, but include myalgia and weakness, possibly accompanied by fever, nausea and vomiting. Fatalities are reported as rare although there are reports of severe cases, in which patients died after about 15 hours. PITX group toxins are heat resistant. PITX causes membrane depolarisation in excitable and non-excitable cells, and contraction of muscle cells. Cases have been reported from consumption of crustaceans and fish rather than LBMs, however the EFSA opinion on Marine Biotoxins in Shellfish – Palytoxin group does not specify which shellfish (286) (287).

The toxicological database is limited, comprising only acute toxicity studies via several routes of administration in various animal species. Based on the available toxicological data, the EFSA CONTAM Panel established an ARfD using the lowest observed adverse effect level (LOAEL) for oral toxicity in mice of 200µg/ kg bw as the reference point. They established an ARfD of 0.2µg/kg bw in humans. This ARfD applies to the sum of PITX and ostreocin-D (a PITX analogue). Due to insufficient data on the chronic effects of PITX, a TDI was not established. There are no regulations on PITX-group toxins in shellfish, either in the EU, or in other regions of the world. To avoid exceeding the ARfD of 0.2µg/kg bw, PITX and ostreocin-D should not exceed levels of 30µg/kg shellfish or a 400g portion of shellfish should not contain more than 12µg of the sum of PITX and ostreocin-D (based on a 60kg adult) (286) .

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (92).

The SRT score for PITX was 33 in the uncontrolled state. The SRT scores reduced to 23 for control one, and further to 15.5 for control two. This suggests that controls are effective in reducing the impact of the hazard both at discrete phases and where benefits are accrued through the supply chain. However, effective control measures would have to be applied early in the supply chain or include testing and subsequent removal of contaminated commodities from the supply chain.

#### 6.5.7.7 Pectenotoxin (PTX) group

Pectenotoxins (PTXs) group are produced by the algae of the genus *Dinophysis* (288). The biotoxins have been detected in microalgae and/ or bivalve molluscs in Australia, Italy, Japan, New Zealand, Norway, Portugal and Spain (276) and accumulate in filter-feeding bivalve molluscs such as oysters and mussels (288). The presence of PTXs in shellfish was discovered due to their high acute toxicity in the mouse bioassay after intraperitoneal injections of lipophilic extracts (276).

The toxicological database for PTXs is limited. There is no evidence of an adverse effect of PTXs in humans. Acute toxicity observed in mice following intra-peritoneal administration. No data are available on its chronic toxicity. The Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs has not established an ARfD or TDI for PTXs due to insufficient data (276). However, although the oral toxicity is not well defined, the CONTAM Panel of EFSA considered it appropriate to establish an ARfD on the basis of a LOAEL of 250µg/ kg bw for intestinal toxicity of PTX 2 observed in mice. They established an of 0.8µg PTX 2 equivalents/kg bw in humans (288).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (92).

The SRT score was not available as these toxins were not identified within the SRT.

#### 6.5.7.8 Saxitoxin (STX) group

Saxitoxin (STX)-group toxins are mainly produced by dinoflagellates belonging to the genus *Alexandrium*: for example, *A. tamarensis*, *A. minutum* (syn. *A. excavata*), A. catenella, *A. fraterculus*, *A. fundyense* and *A. cohorticula*. They cause paralytic shellfish poisoning (PSP) in humans, characterised by symptoms varying from a slight tingling sensation or numbness around the lips to fatal respiratory paralysis. In fatal cases respiratory arrest occurs two to 12 hours following consumption of shellfish contaminated with STX-group toxins (289). Mild illness is readily reversible (276). STX-group toxins are heat stable in shellfish and therefore cannot be destroyed by cooking and steaming (about 100°C). The mechanism of action of the STX-group toxins is that they bind to voltage-gated sodium channels on the nerves and muscle fibres and consequently block ion conductance through these channels (289) (290). Specific areas known for STX-related issues include coastal regions of the US, Canada, Europe, Asia, and other parts of the world where HABs are prevalent (290). The prevalence of STX in oysters can vary depending on the specific location and the presence of HABs (290).

Based on the available toxicological data, the EFSA CONTAM Panel established an ARfD of 0.5µg STX equivalents/kg bw based on the available human data. No data on the chronic effects of STX-group toxins in animals or humans were available, so a TDI cannot be established. The current maximum level for STX in EU legislation is 0.8 mg/kg SM (289). The CONTAM Panel noted that consumption of a 400g portion of shellfish meat containing STX-group toxins at the current EU limit of 800µg STX equivalents/kg shellfish meat would result in an intake of 320µg toxin (equivalent to 5.3µg/kg bw in a 60kg adult). This intake is considerably higher than the ARfD of 0.5µg STX equivalents /kg bw (equivalent to 30µg STX equivalents per portion for a 60kg adult) and is a concern for health (289).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (92).

The SRT score for STX was 42 in the uncontrolled state. The SRT scores reduced to 32 for control one, and further to 19.5 for control two. This suggests that controls are

effective in reducing the impact of the hazard both at discrete phases and where benefits are accrued through the supply chain. However, effective control measures would have to be applied early in the supply chain or include testing and subsequent removal of contaminated commodities from the supply chain.

#### 6.5.7.9 Yessotoxin (YTX) group

Yessotoxins (YTX) are produced by the marine dinoflagellates *Protoceratium reticulatum*. Their presence in shellfish was discovered due to their high acute toxicity in mice after intraperitoneal injection of lipophilic extracts. They have been detected in microalgae and/ or bivalve molluscs in Australia, Canada, Italy, Japan, New Zealand, Norway and the UK (276).

The toxicological database for YTX is limited. There are no reports of human intoxications caused by YTX (276). In a series of acute toxicity studies following oral administration, no lethality and no clinical signs of toxicity were observed. Following oral administration, cardiotoxicity was observed by the use of light microscopy down to a single dose of 7.5mg/kg bw with a no effect level of 5 mg/kg bw (291). No data are available on the long-term toxicity, reproductive toxicity, carcinogenicity, or genotoxicity of YTX.

The Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs has established a provisional ARfD of 50µg YTX /kg bw based on animal studies in mice. The CONTAM Panel decided to use the dose of 5mg/kg bw as the most robust no-observed-adverse-effect level (NOAEL) for acute cardiotoxicity caused by YTXs as identified by light microscopy. They established an ARfD of 25µg YTX equivalents/kg bw (291). No TDI could be established due to insufficient data on the chronic effects of YTX, however a regulatory level of 1mg/ kg shellfish has been implemented in some countries (276).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (92).

The SRT score was not available as these toxins were not identified within the SRT.

#### 6.5.7.10 Tetrodotoxin (TTX)

Tetrodotoxins (TTX) are produced by bacteria that can be found in certain fish species but also marine gastropods and bivalves. Human cases are more commonly associated with specific fish hosts, however TTX have been more recently detected in wider ranging aquatic hosts, including molluscs. 25 naturally occurring analogues of TTX have been detected and many of these have also been shown to have toxicity potential. Symptoms of acute TTX intoxication include perioral numbness and paraesthesia, lingual numbness, early motor paralysis, incoordination, slurred speech to generalised flaccid paralysis, aphonia and fixed/ dilated pupils to hypoxia, hypotension, bradycardia, cardiac dysrhythmias and unconsciousness and eventually death. Death is caused by respiratory failure and cardiac collapse. There is no antidote against TTX poisoning. TTX toxins are heat stable, and therefore will not degrade during cooking. The mechanism of action of TTX consists of the extracellular blockade of the sodium channel pore by binding, hence inhibiting sodium conductance. TTX effects both action potential generation and impulse conduction. The result is the blockade of the neuron action potential and muscle paralysis (292).

While several studies on geographical occurrence of TTX have been conducted, there is a lack of knowledge about the distribution of the toxin within and between bivalves (293).

There are no HBGVs for TTX worldwide and also no maximum levels of TTX in seafood in the EU. The EFSA CONTAM Panel decided to derive an ARfD considering human data, extrapolation from data on STX and the use of animal data. They established a group ARfD of 0.25µg/kg bw applying to TTX and its analogues. A concentration below 44µg TTX equivalents/kg shellfish meat, based on a large portion size of 400g, was considered not to result in adverse effects in humans (292).

Information on burden of foodborne disease caused by this hazard in the form of DALYs were unavailable in the WHO burden of disease report (92).

The SRT score was not available as these toxins were not identified within the SRT.

## 6.6 Summary

For the three hazard categories identified by the SRT (CH, AH and HH), six groups were identified for CH, five for AH and three for HH, with multiple hazards identified for each group. The CH groups were heavy metals (CH1), POCs (CH2), radiological contaminants (CH3), natural biotoxins (CH4), veterinary pharmaceuticals and personal care products (CH5), allergens (CH6). The AH groups were viral pathogens (AH1), bacterial pathogens (AH2), protistan pathogens (AH3), metazoan pathogens (AH4), syndromes (AH5). Finally, the HH groups were environmental pathogens (HH1), anthropogenically derived pathogens (HH2), zoonotic pathogens (HH3).

As discussed in section 5, the hazard list was refined before being carried forwards for hazard characterisation in consideration of the risk profile scope. AH hazards were not included unless also considered under HH, as the scope of this risk profile is to consider hazards associated with oysters which may pose a public health risk. Allergens and physical hazards were also excluded because they were considered to be present in all types of oysters and not related specifically to import, and hence there was no requirement for characterisation. Additional hazards were identified via a literature review outside of the SRT and included in the refined hazard list, as per section 5.

The refined hazards list was organised into two main categories for hazard characterisation: microbiological hazards and chemical hazards (including natural biotoxin hazards). Other microbiological hazards were removed from the list to be taken forwards for hazard characterisation when it became clear that they were not associated with oysters or were more commonly associated with other routes of transmission. For microbiological hazards, eight bacterial hazard groups, four viral hazards and four parasitic hazards were characterised. For chemical hazards, seven hazard groups were characterised, five identified by the SRT (allergens were excluded) and two additional groups identified from other literature: microplastics and HPV chemicals. Natural biotoxin hazards were presented within the chemical hazards category, with ten marine biotoxin groups characterised. Bacterial biotoxins were characterised under their respective bacteria.

In most cases, the hazards were well-defined in terms of health effects and composition. Where hazards were less well-defined it was usually due to limited information on severity of illness (high, medium or low severity of illness not assigned by ICMSF), geographical prevalence of the hazard and disease prevalence. Where possible, information from the WHO on DALYs was included to indicate the global prevalence of disease caused by the hazard. This was not possible in all cases, particularly for chemical hazards and for microbiological hazards where high, medium or low severity had not been assigned by the ICMSF. In cases where severity could not be assigned using the ICMSF assignation, information on DALYs lost per case, other literature sources or the expert opinion of the analyst was used.

SRT impact scores were also presented where possible, they were not provided in cases where hazards had been identified using sources other than the SRT article. Generally, SRT impact scores indicated where controls may reduce the impact of hazards and where these controls could have effects to reduce the impact later on in the supply chain. This is considered to show where it would be worth investigating control methods for certain hazards further within the SRT in order to ensure control. It is important to note that control measures implemented within different stages of the supply chain will vary with hazard type. For example, marine biotoxins cannot be removed by purification and cannot be controlled post-harvest except for removal of contaminated commodities from the supply chain.

Of the 16 individual microbiological hazards characterised, there was limited information on presence of *S. aureus* in oysters because these are mostly associated with contamination during processing. However, this hazard was still characterised because it could not be ruled out due to potential introduction during the processing of oysters in the supply chain. Of the chemical hazards discussed the toxicity of microplastics was not well-defined. Furthermore, the POC, veterinary pharmaceutical and personal care products, and HPV chemical groups are potentially extremely large groups of chemicals which could not all be fully characterised. It should be borne in mind that these groups may continue to expand and that information around the toxicity and prevalence of the chemicals within them is likely to be dynamic and could become quickly out of date. Finally, of the marine

biotoxins discussed, yessotoxin, pectenotoxin and cyclic imines were not well-defined in humans.

# 7 Risk mitigation and management options

This section summarises key risk mitigation and management options set out in internationally recognised standards and guidelines. This is intended to support auditors within the process of market access requests in determining what evidence may be expected during an audit. The guidance set out here has been used to create a proposed checklist for auditors in appendix 14.7. This is not an exhaustive list of all points to be considered by UK auditors and is not intended to replace any current checklists or programs used by UK auditors. It is intended as an additional information point to aid the efficiency of auditing when considering oysters specifically.

## 7.1 Seafood Risk Tool (SRT)

The SRT has been used and described in the hazard identification and characterisation (sections 5 and 6). The three different control states from the application of the SRT (uncontrolled; control one – control measures are applied at discrete phases of supply; control two – where the benefit of controls applied at one phase are accrued in subsequent phases of supply) are set out there, as is the scoring method. This section is a summary of what the SRT recommends as risk mitigation and management options.

According to the SRT article, the application of the SRT to an uncontrolled state can directly support decisions to progress or amend an aquaculture scenario plan and provides a baseline to which a Risk Mitigation Matrix (RMM) can be applied. An RMM is a bespoke inventory of measures aimed at reducing risk associated with specific hazards impacting specific supply chain phases (1).

Table 9 is adapted from the SRT article and illustrates the application of the RMM to the LBM scenario. This is not specific to oysters; however, measures applied to LBMs generally would, in many cases, be effective in risk mitigation and control for oysters. The table compares SRT impact scores for the uncontrolled state, control one and control two. These may differ from those presented in section 6, because they are summary impact scores for the entire hazard categories.

Table 9: Adapted from Figure 3 of the Seafood Risk Tool (SRT): RMM applied to bivalve mollusc aquaculture scenario where live animals are destined for export market to be consumed raw (1)

| Hazard category [a] | Early life | Grow out | Harvest | Processing | Trade | Consumption | Uncontrolled | Control 1 | Control 2 |
|---|---|---|---|---|---|---|---|---|---|
| CH1 (heavy metals) | NA [c] | NA[c] | Initial site-selection (based on risk assessment), site-catchment level monitoring and action post-monitoring. | Product-level monitoring (food safety criteria) [f] | Regional/national legislation (EU, CODEX) | NA | 28.72 | 21.76 | 15.24 |
| CH2 (POCs) | NA[c] | NA [c] | Initial site-selection (based on risk assessment), site-catchment level monitoring and action post monitoring [d] | Product-level monitoring (food safety criteria) [f] | Regional/national legislation (EU, CODEX) | NA | 23.2 | 18.28 | 13.52 |
| CH3 (radiological contaminants) | NA [c] | NA [c] | Initial site-selection (based on risk assessment), site-catchment level monitoring and action post monitoring [d] | Product-level monitoring (food safety criteria) [f] | Regional/national legislation (EU, CODEX) | NA | 14 | 6 | 6 |
| CH4 (natural biotoxins) | NA [c] | NA [c] | Initial site-selection (based on risk assessment), | Product-level monitoring (food safety criteria) [f] | Regional/national legislation (EU, CODEX) | NA | 41.38 | 32.19 | 16.07 |

| Hazard category [a] | Early life | Grow out | Harvest | Processing | Trade | Consumption | Uncontrolled | Control 1 | Control 2 |
|---|---|---|---|---|---|---|---|---|---|
| | | | site-catchment level monitoring and action post monitoring [d] | | | | | | |
| CH5 (veterinary pharmaceuticals and personal care products) | NA [c] | NA [c] | Initial site-selection (based on risk assessment), site-catchment level monitoring and action post monitoring [d] | Product-level monitoring (food safety criteria) [f] | Regional/national legislation (EU, CODEX) | NA | 28 | 20 | 12 |
| CH6 (allergens) | NA | NA | NA | Product-level monitoring (food safety criteria) [f] | Regional/national legislation (EU, CODEX) | NA | 8 | 8 | 7 |
| AH1[b] (viral animal pathogens) | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | NA | WOAH (international) and/or regional and national controls [i] | NA | 25.5 | 22.5 | 15 |
| AH2[b] (bacterial animal pathogens) | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | NA | WOAH (international) and/or regional and national controls [i] | NA | 28 | 20 | 16 |
| AH3[b] (protistan animal pathogens) | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | NA | WOAH (international) and/or regional and national controls [i] | NA | 24.18 | 21.55 | 16.65 |

| Hazard category [a] | Early life | Grow out | Harvest | Processing | Trade | Consumption | Uncontrolled | Control 1 | Control 2 |
|---|---|---|---|---|---|---|---|---|---|
| AH4[b] (metazoan animal pathogens) | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | NA | Regional and national controls [i] | NA | 14 | 12 | 10 |
| AH5[b] (animal syndromes) | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | WOAH Code, PMP-AB, on-farm biosecurity and BAP [h] | NA | Regional and national controls [i] | NA | 7 | 6 | 6 |
| HH1 (environmental human pathogens) | NA | NA | Initial site-selection (based on risk assessment), site-catchment level monitoring and action post monitoring [d] | Application of food safety or process hygiene criteria [e] | Regional/national legislation (EU, CODEX) | Cold chain measures, good hygienic practice, education at point of sale (consumers, staff) and product labelling [g] | 34.5 | 24.25 | 18.13 |
| HH2 (anthropogenically derived human pathogens) | NA | NA | Initial site-selection (based on risk assessment), site-catchment level monitoring and action post monitoring [d] | Application of food safety or process hygiene criteria [e] | Regional/national legislation (EU, CODEX) | Cold chain measures, good hygienic practice, education at point of sale (consumers, staff) and product labelling [g] | 44.25 | 33.99 | 23.26 |

| Hazard category [a] | Early life | Grow out | Harvest | Processing | Trade | Consumption | Uncontrolled | Control 1 | Control 2 |
|---|---|---|---|---|---|---|---|---|---|
| HH3 (zoonotic pathogens) | NA | NA | Initial site-selection (based on risk assessment), site-catchment level monitoring and action post monitoring [d] | Application of food safety or process hygiene criteria [e] | Regional/national legislation (EU, CODEX) | Cold chain measures, good hygienic practice, education at point of sale (consumers, staff) and product labelling [g] | 7.22 | 6 | 6 |

a) See hazard category definitions in appendix 14.2.
b) AH hazards are not characterised within this risk profile unless they fall within the scope of public health hazards. They have been included here as part of the SRT RMM application because the SRT considers all hazards.
c) Site pre-selection (covering CH, AH and HH hazards) offers the best risk mitigation measure that may be accrued during all subsequent supply phases.
d) Actions include suspension of harvest, 'relaying' animals at clean sites or otherwise informing onward processing requirements.
e) Purification through re-immersion of molluscs in clean water (for example, depuration and relay) or other mechanical interventions where criteria for efficacy of intervention are measurable (for example, irradiation).
f) Product monitoring either by official services or food businesses informed by application of Hazard Analysis Critical Control Point (HACCP) plans (including batch release measures).
g) Good hygiene practices (GHP) and education of workers to avoid cold chain breach, contamination of seafood by staff and consumption by 'at risk' groups; labelling and traceability are critical.
h) Application of Progressive Management Pathway, supported by appropriate national biosecurity tools, on-farm biosecurity plans, application of Best Agricultural Practices (BAP) or similar, application of measures in World Organisation for Animal Health (WOAH) Code for listed pathogens and generic chapters (surveillance and biosecurity) for other pathogens.
i) Application of WOAH standards for international trade as recognised by the World Trade Organisation (WTO), including more stringent national/ regional controls where justified by risk assessment, and meeting other criteria (equivalence) set out in the WTO Sanitary and Phytosanitary (SPS) agreement.

For anthropogenically derived CH and HH hazards, it is possible to increase the benefits of controlling hazards through the supply chain by using sites which have been comprehensively characterised environmentally. Interventions during harvest include suspension of harvest, transfer of live animals to cleaner sites ('relaying') or altering onward processing requirements. Interventions during processing include purification through re-immersion in clean water (for example, depuration) or other mechanical interventions (for example, irradiation for denaturing of potential human pathogens in the final product). These are really only applicable in the context of hygiene and not for the presence of biotoxin hazards, for example. These methods will also have limited effects on certain pathogens. Additionally, product monitoring during the processing phase may either occur at the official services level and/ or by the food business operator (FBO) informed by the application of HACCP plans, including batch release measures. During the consumption phase, labelling and traceability; GHP; general education of workers (such as cold chain breaches and contamination by staff with GI symptoms) and advice on avoidance of consumption of raw products by 'at risk' groups are critical measures for reducing risk.

AH hazards have not been characterised within this risk profile unless they fall into the scope of HH as well. For AH hazards, interventions during the production phase may be essential. This includes initiatives such as: the Progressive Management Pathway for Aquatic Biosecurity (PMP-AB) approach supported by appropriate national biosecurity tools, on-farm biosecurity planning (determined by government biosecurity policy/ practice) and application of BAP approaches from organisations like the Global Aquaculture Alliance (GAA). During the trading phase, application of the WOAH Code is relevant for listed pathogens, with generic chapters (surveillance and biosecurity) also contributing to reducing the risk of disease outbreaks from non-listed taxa. Most producer and trading countries are WOAH members, with standards for international trade recognised by the WTO. More stringent national/regional controls can also be implemented if justified by risk assessment and meeting other criteria (equivalence) set out in the WTO SPS agreement. For the LBM scenario, the largest reductions in risk were where controls were applied in early supply chain phases and accrued at subsequent phases. For some hazards (for example, CH6 - allergens), the application of available controls did not reduce

risk; for allergen hazards, avoidance of a product by susceptible consumer groups was the most relevant measure to reduce risk.

The SRT article states that aquatic animal health and seafood safety are public goods, as they cannot be easily purchased in the marketplace and thus require government intervention to ensure they are enacted. It goes on to say that state-level responsible authorities designated to oversee aquaculture production and trade must be supported by official control laboratories able to apply quality-assured surveillance, analytical and diagnostic tools with respect to animal health (for example, WOAH, the PMP-AB and National Biosecurity Plan (NBP)), anthropogenic and natural contaminants, and pathogens threatening seafood safety (for example, CODEX Alimentarius codes of practice and standards). International guidance is discussed in subsequent sections of this risk profile.

Known hazards (where regulatory requirements exist) can be controlled by industry, such as at farm-level by best management practice and application of HACCPs to production and processing. This must be supported by formal responsible authority monitoring, and surveillance activities and audit functions. Consumer behaviour such as a preference for cooked seafood may confer additional protection against the impact of microbial hazards present but will have less effect at mitigating the risk of chemical threats. For example, many marine and bacterial biotoxins are heat stable, so cooking will not mitigate the risk. Furthermore, oysters are commonly consumed raw, so this is not likely to be a major mitigation route for this type of commodity.

In terms of export, regulations for primary production and final products are frequently in place and audits by importing countries or by trading blocs such as the EU often take place. This helps to mitigate risks of identified hazards in final products for consumers within those markets. The desire for trade is a primary motive for nations producing seafood to deploy controls. However, understanding hazards at each supply chain phase in the country or region of production, which may vary geographically, is vital irrespective of whether the product is destined for export or domestic markets. For all seafood production, quality and safety standards should be designed to control risks within that region and intended use of the product, with export regulatory requirements applied as an addition.

The SRT considers those hazards with potential for greatest impact on supply of seafood from different aquaculture sectors, and the interventions that may be required to mitigate them. It also provides a flexible framework to which novel emerging chemical and pathogen hazards may be added, potentially including those hazards that do not directly impact aquatic animal health or seafood safety but may significantly impact supply chains. For enactment, national strategies for aquaculture growth must include or interact with comprehensive policies to protect aquatic habitats from diverse pollution sources, to protect the biodiversity upon which future aquaculture will rely.

## 7.2 Characteristics of the commodity affecting risk management options

As filter feeders, oysters are susceptible to accumulating chemical (including biotoxins) and microbiological contaminants from the environment, often at levels much higher than those observed within the environment (294). Oysters have been associated with multiple foodborne outbreaks, particularly norovirus. This virus usually enters the oyster at primary production and can present a particular risk to consumer safety as oysters are often consumed raw. Norovirus and consumption are discussed in more detail in sections 6.4.2 and 9 of the risk profile, respectively (295).

Oysters can be grown ‘naturally’ on the seabed and harvested or 'farmed’. Oyster aquaculture includes a wide range of grow-out techniques in inter-tidal or sub-tidal waters: suspension of oysters in the water column via rafts, floats, racks or trestles, or bottom culture where oysters are grown directly on the seabed (296). Water quality has a large impact in oyster farming with contaminants (such as pesticides), phytoplankton (release of biotoxins), agricultural run-off (faecal bacteria, pesticides, veterinary pharmaceuticals) and particularly sewage (faecal bacteria, viruses, chemicals) all potentially impacting oyster quality. More information on potential hazards is provided in section 6.

Growing areas are classified as detailed in Table 11 in section 7.3.1.4 of this risk profile which summarises summarising growing area classification. Oysters can be relayed or depurated to reduce contamination and make them safer to eat, as

discussed in further detail in section 7.3.2 of the risk profile. However, these methods cannot mitigate all hazard types.

## 7.3 Control

### 7.3.1 Growing area

The FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes suggests that a growing area risk profile is produced. This is the first stage in establishing a monitoring program and includes acquisition, recording and assessment of available information in the area. It then recommends that a growing area assessment is performed with further monitoring over a period of time to classify growing areas, followed by continuous management and review.

The following sections provide summary information on what is included within the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes. This may be subject to change if the guidance is updated. The guidance should be consulted for full detailed information.

#### 7.3.1.1 Growing area risk profile

The FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes should be consulted for full detailed information on what a growing area risk profile should include and how it should be produced. The following is a summary list of FAO recommendations for information that should be included within a growing area risk profile:

- Geographical location and growing area.
- Scope: for example, intention for international or domestic sales.
- Existing legal framework - current food safety regulations and standards which might affect the growing area sanitation programme.
- Jurisdictions and responsible authorities - authorities responsible for the application of the sanitation program and associated enforcement and monitoring activities.

- Interactions between food safety bodies and other bodies: for example, sewage treatment works can be run by national or regional authorities or private companies.
- Current industry situation, current resources and available resources.
- Location of LBM resources - the location and extent of occurrence of each species under the program.
- Cultivation and harvest practices - wild or aquaculture.
- The location in the water column - sediment, seabed, rocks, artificial structures.
- Harvesting methods – mechanical, handpicking by diving etc.
- Relaying, conditioning or wet storage conditions[10].
- Distance to landing site from growing areas.
- Industry capabilities.
- Seasonality of harvest.
- Growing area production capability.
- Seasonal air and water temperatures.
- The extent of the assessment area.
- Epidemiological data - regional, national and international data relevant to the LBM species of interest.
- Use of products and consuming population.
- Other relevant information - contamination sources, for example, sewage discharges, farm animals, watercourses, hydrology, seawater temperature.
- Hazards to be considered - microbiological, radiological, chemical and marine biotoxins.
- Program capabilities and capacities.

[10] Relaying - the removal of LBMs from a contaminated growing area into a non-contaminated area for enough time to reduce the contamination to a level acceptable for consumption. Conditioning - the act of putting LBMs in tanks, floats or natural sites to remove sludge. Wet storage - the temporary storage of LBMs after harvest before sale or processing.

- Laboratories - should be ISO70125[11] accredited, meaning they have met general requirements for competence, impartiality and consistence in laboratory operation (297).
- Documentation of growing area risk profile.

7.3.1.2 Growing area assessment

The growing area assessment takes into account data and information from the risk profile including shoreline observations and information based on the growing area identified. It assesses a wide range of hazards including enteric pathogens identified within the growing area risk profile and should be tailored to the outputs of the risk profile. For example, if the outcome of the growing area risk profile or policy decision stated that biotoxins or a single biotoxin was the only hazard of importance, then other hazards would not be considered in the growing area assessment.

The growing area assessment involves the acquisition of much more detailed data than the growing area risk profile. The FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes should be consulted for full detailed information on what should be included within a growing area assessment, and how it should be carried out. The following is a summary of the main stages of completing a growing area assessment which are set out in the guidance:

1. Additional data collection - detailed information on the hazards identified in the growing area risk profile: factors that affect the occurrence and impact of the hazard, and sources of contamination or environmental factors identified in the growing area risk profile. This is summarised in Table 10. Figure 1 is taken from the FAO Technical Guidance for the Development of Growing Area Aspects of Live Bivalve Mollusc Sanitation Programmes and depicts the relationship between the additional data collection considerations.

[11] ISO - International Organisation of Standardisation.

Table 10: Additional data collection: sources of contamination, recommended data collection and explanation (23).

| Contamination source | Data collection required | Explanation/summary |
|---|---|---|
| Untreated sewage discharge. | Permitted and actual levels, permits, flow rates and discharge location. | In some countries raw sewage can be discharged which poses a greater risk of contamination of LBMs, such as informal discharges from shanty towns. |
| Sewage treatment works. (Covers farm, mining, food processing and industrial waste as well as sewage treatment works). | Permits, type of effluent, flow, microbial content or quality of discharges, location, microbial content, and times of discharges. | Discharges may contain multiple hazard types (chemical, enteric pathogens) compliance with permit. |
| Sewage collection systems. | The location of pumping stations, storm water storage tanks and combined sewage overflows, including information on the permitted operation of intermittent discharges. | In areas where there are intermittent discharges there will be frequent human faecal contamination of the aquatic environment. |
| Private sewage works and handling facilities including septic tanks. | Septic tanks and cesspit emptying frequency and destination. | These can be significant sources of human faecal contamination and be linked to norovirus outbreaks in oysters. |
| Direct human defecation and nightsoil spreading. | Nightsoil spreading on arable land is practice in some countries, knowledge of local habits and number of people using the systems should be considered. | Faecal indicator bacteria and enteric bacteria can enter marine and estuarine waters. |
| Shipping and boating activity. | Identify if any boating activities discharge human waste, consider seasonality, number of people using boats and moorings. | There are recognised standards (298, 299) for marine sanitation devices for larger vessels, but smaller vessels can directly or indirectly impact the growing area through faecal discharge, it should be determined whether holding tanks are required on smaller vessels and if fishing boats adhere to practices; the discharge of ballasts can introduce toxic algal species and chemical |

| Contamination source | Data collection required | Explanation/summary |
|---|---|---|
| | | contaminants; fuel spillages can introduce chemical contaminants. |
| Land use and agricultural activity. | Ascertain the mining activities, livestock locations and effluent, feedstock locations, abattoirs and slurry disposal, artificial fertiliser application locations and timings. | Mining activities can contribute to high levels of chemical contaminants that can enter watercourses directly or indirectly. |
| Other human activities. | Industrial and solid waste and refuse disposal information should be found, volume, concentration and contaminants. Radioactive discharges, salt pan and salt mine, marine sediment dredging, and marine dumping activities should be ascertained, and environmental monitoring data obtained. | Effluent from food factories and timber mills contain high numbers of faecal indicator bacteria, seafood processing plants can contain high numbers of *Vibrio* spp. and bacteria contaminants. |
| Wild animals and birds. | Populations can be increased around feeding sites or landfill sites and this should be considered, seasonality should also be considered. | Wild animals contribute faecal indicator pathogens and bacteria into the environment, birds scavenging human waste can pick up pathogens. |
| Watercourses. | Identify the location of all watercourses in the assessment area, preliminary judgement of the impact on the LBM area will be needed. | Watercourses act as conduits for contaminants this affects the concentration rate and the volume rate of discharge of the contaminant. |
| Meteorological, environmental and geographical factors. | Identify principal rocks in the area and soil type, and the topography. | Geology can influence the chemical hazards that are naturally present, topography influences the fate of contamination and flow of watercourses. |
| Bathymetry and stratification. | Determine tidal characteristics, depth of water and hydrodynamics (currents) and stratification (differences in conditions at different depths). | Tides and depth of water will affect the contaminants and the path they take, tidal path software and hydrodynamic modelling can be used. |
| Weather | Rainfall, severe storms, sunshine, wind. | Rainfall and snow/ice melt effects water flow in the watercourses, wind effects currents and the ability of contaminants to reach the LBMs, sunshine effects the UV inactivation of bacteria, but this declines with water depth. |
| Seawater temperature and salinity | Seawater temperature and salinity should be considered and seasonal variations of this assessed. | Effects the ability of faecal indicator bacteria to survive. |

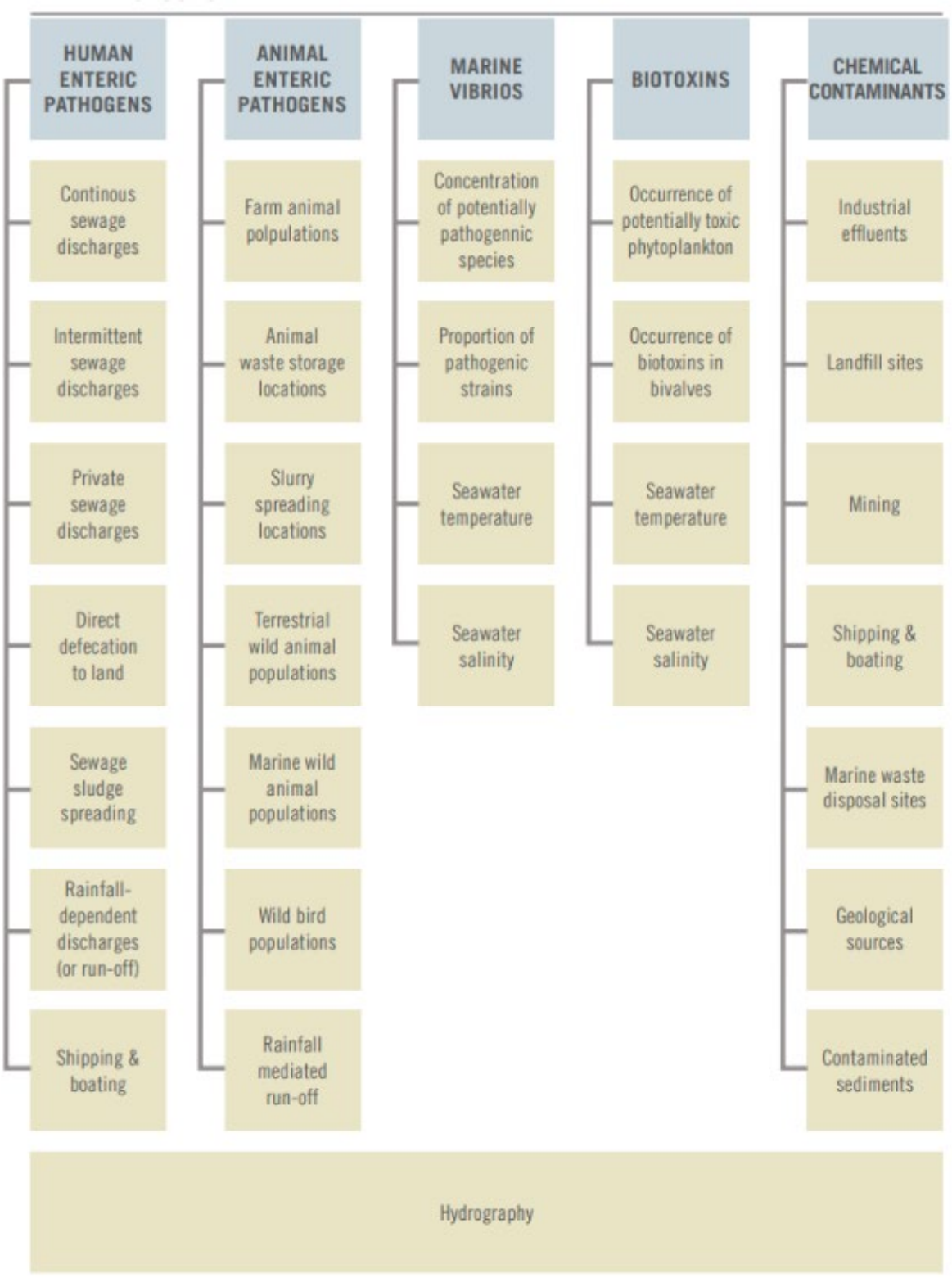


Figure 1: A summary of source and factor considerations for the major hazard groups taken from the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes (23).

2. Shoreline survey - a physical inventory of the actual and possible sources of contamination. Health and safety, access, daylight, tides, and weather should all be considered when planning a survey. The following information should be obtained, along with photographs, and collection and analysis of samples of hazards identified in the risk profile.
    a. Location of the LBM resource.
    b. Location of sewage or wastewater discharge points.
    c. Visual evidence of any malfunctioning systems (for example, septic tanks).
    d. Occurrence of human defecation to land.
    e. Agricultural activities.
    f. Wild animals and birds.
    g. Sea traffic.
    h. Watercourse movements.
3. Indicator / hazard survey – determine whether required as part of the growing area assessment. If required undertake the survey with sampling and laboratory analysis. Sampling locations should be chosen based on the growing area assessment and be expected to reflect the worst-case scenario of occurrence across the area.
4. Data analysis – qualitative or semi quantitative.
    a) Qualitative source estimation: sources of contamination relating to each hazard or group of hazards is determined based on expert judgement.
    b) Semi quantitative assessment (source estimation): depending on the hazard being considered, the contaminants should be ranked from 0 to 4, with 4 representing continuous impact and 0 representing no impact. They should also be scored 0 to 4 for proximity, the maximum transport distance is divided into four with each quartile representing distance to the source, 0 would be beyond the maximum transport distance and 4 would be closest to it. A semi-quantitative approach allows some comparison of the possible impacts of sources with respect to hazards.
5. Data analysis - quantitative assessment:

a) Quantitative source estimation: estimation of the contribution of various sources to a hazard, for example, faecal coliform loading (bacteria per day) can be used to quantify hazards from a combination of sources for example, sewage discharge, animal feedlot.
b) Quantitative transport estimation: calculations can be done on tidal streams, hydrodynamic modelling, dilution based on the water volume (these approaches are time consuming and costly and have uncertainties).
c) Quantitative impact estimation: estimates the quantitative impact of the hazard or indicator at the assessment point average concentration and variability of the hazard for a range of conditions.

6. Outcomes - the extent of the classified growing area should be determined and given a national grid format. Anticipated impacts across the assessment area should be defined, for example if two different parts of the growing area are subject to different hazards, the growing area should be subdivided into two with two separate monitoring requirements. Therefore, if recall is required, for example, only one subsection of the growing area would need to be included.
7. Recommendations for primary monitoring - usually targeted at the growing area itself with the range of hazards identified related to the risk area profile.
8. Documentation of the growing area assessment.

7.3.1.3 Growing area monitoring

Monitoring provides additional evidence but is not a substitute for the growing area risk profile and growing area assessment. The FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes should be consulted for full detailed information on recommendations for growing area monitoring. This section summarises the recommendations from the guidance on how growing area monitoring should be performed.

Monitoring considers microbial pathogens and faecal indicator organisms but no other hazards such as biotoxin and chemical hazards. The primary monitoring of the growing area provides information on the level of contamination with the outcome used to modify and refine the sampling plans for ongoing monitoring.

It should be determined whether monitoring is performed directly on the LBMs or on the water, or both (i.e., the sample matrix), the approach can include monitoring for faecal indicator bacteria (faecal coliforms or *E. coli*) or male specific coliphage (MSC) and pathogens. Faecal indicator bacteria monitoring will be dictated by the laboratory capabilities and existing regulations. If there are no constraints, the recommendation is to undertake monitoring through water sampling with limited LBM monitoring. MSC is recommended to be used when the growing area risk profile indicates a high risk of human enteric viruses, this is not always required but can be used to supplement sewage treatment efficiency verification. Monitoring for pathogens is performed when pathogens are identified as a primary hazard in the growing area risk profile and then should be directly on the LBMs.

Consideration should be given to:

1. The sampling site: worst-case scenario with one or more sampling sites.
2. The sampling strategy: random sampling or adverse pollution condition sampling (for worst case scenario).
3. Sampling frequency: random sampling (at least two weekly sampling at each site is recommended), adverse pollution condition sampling (requires targeted sampling to ascertain whether a pollution event affects the growing area).
4. Ongoing monitoring: used to reflect the presence of hazards relevant to the growing area in order to inform the risk management process, the indicator pathogens should be associated with the sampling plans and growing area matrices and based on the growing area review.
5. General sampling considerations: samplers should be adequately trained. For LBM sampling, it is recommended to either separately monitor each species or use an indicator species for the growing area. If using an indicator species parallel monitoring should show that the indicator species yield results as high as those it represents. Laboratories undertaking the testing should be ISO 17025 accredited (meaning they have met general requirements for competence, impartiality and consistency in laboratory operation (297)). Internationally recognised methods should be used for detection and enumeration of pathogens, these are usually referenced in

the CODEX Code of Practice. Methods for pathogenic *Vibrio* spp. is under review with guidance published by the FAO and WHO (2016).

#### 7.3.1.4 Classification of growing area

The FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes should be consulted for full detailed information on classifying growing areas. This section summarises the recommendations from the guidance for classifying growing areas.

Classification is based on the outcome of the primary monitoring and growing area assessment; it provides a broad risk characterisation for the area so that common risk management procedures can be applied. When defining the final classification area consideration should be given to:

- the growing area risk profile with respect to hazards in the growing area.
- growing area assessment, with respect to sources of hazard and their impact on the growing area.
- results from primary monitoring presence of indicators or hazards in the growing area.

It should be defined whether the requirements for classification are stipulated in any national or international regulations. Trade requirements may apply to certain growing areas to be approved for export. The conditional growing area must be deemed to conform to the classification at a specific level for example, environmental factors, rainfall or river flow. The types of classification are generally related to the risk from enteric pathogens as reflected by faecal indicator monitoring results. However, risk from other hazards (such as chemicals) should be considered. Conditional classification can apply for example when a growing area is subject to varied conditions such as the season or rainfall which takes it back into acceptable hazard conditions, in this instance the growing area can either be given two classification levels or be given the worst-case classification for all of the time. The conditional classifications can be:

1. Seasonal classifications.
2. Rainfall related classifications.

3. Treatment work related classifications.
4. Other hazards.

The boundaries of the growing area should be defined using geographical coordinates. If one growing area has varied hazards and the harvest and monitoring of LBMs can be in separate parts then they can be managed separately. Consideration should be given to designing separate growing areas for different classifications. Any areas that are unsuitable for harvest (for example the presence of chemical contaminants such as biotoxins above acceptable levels) should be explicitly identified.

The determination of buffer zones around point sources or discharges should be determined so there is acceptable hazard level across all of the growing area, buffer zone determination can be categorised as follows:

1. Buffer zones around point sources - average loading hazard and variability in loading in each point discharge.
2. Buffer zones around marinas or other boating areas.

The classification status should be formally documented and updated following the growing area review.

The categories, classification criteria and analyses required are summarised in Table 11. Chapter I of REUL Regulation 2019/627 (300) sets out the classification of production and relaying areas for LBMs for GB. These are designated as Class A (areas where LBMs may be collected for direct human consumption), Class B (areas from which LBMs may be collected and placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet health standards detailed under Class A) and Class C (areas from which LBMs may be collected and placed on the market only after relaying over a long period so as to meet the health standards detailed under Class A). Additional detail is given within the Regulation.

Table 11: Classification of growing area adapted from the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes (23)

| **Category** | **Type of classification** | **Classification criteria** | **Analysis** |
|---|---|---|---|
| Category I; fit for direct human consumption. | Hazards identified in the risk profile should either be absent or at acceptable levels. | Faecal indicator monitoring should comply with requirements and contain no hazards deemed a risk to human health, as defined by the CODEX Standard for Raw and Live molluscs (301). The CODEX standard applies to maximum levels of pesticides and veterinary pharmaceuticals (301). | The analysis should be performed to a most probable number (MPN) method specified in ISO 16649-3 (301). ISO 16649-3 sets out the method for the enumeration of beta-glucuronidase positive *E.* coli. It recommends that where the microbiological criteria are not met, actions should be taken by the competent authority. Countries monitoring water usually use a system based on the National Shellfish Sanitation Program (NSSP) Alternative methods may be used if they are validated against this reference method in accordance with the criteria in ISO 16140. ISO 16140 sets out standards for validation and verification of microbiological methods (302). This corresponds with Class A under REUL. |
| Category II; need for depuration or short-term relay. | LBMs with relatively low levels of faecal contamination can be subject to depuration or relaying to reduce levels however it should be noted that the *Vibrio* and enteric virus risk is not reduced through this process, nor is the risk from some chemical hazards like biotoxins in the short-term. | LBMs should not contain hazards that are a risk to human health after depuration or short-term delay. | When there are no existing regulatory requirements, the faecal indicator concentration can be determined from the water or LBM flesh and should represent 90$^{th}$ percentile faecal indicator concentration less than or equal to the acceptable value. Alternatively the US NSSP (USNSSP) criteria (303) based on faecal coliforms in water, or EU criteria for class B (Commission |

| Category | Type of classification | Classification criteria | Analysis |
|---|---|---|---|
| | | | Implementing Regulation (EU) 2019/627) can be used (40). This corresponds with Class B under REUL. |
| Category IIIa; need for long term relay. | Long term relay, for example of two months, can reduce levels to those acceptable for human consumption. It is usually used for reduction of faecal contamination. Chemical and biotoxin contamination reduction may take six months or longer. | LBMs should not contain hazards that are a risk to human health after post-harvest processing or long-term delay. | When there are no existing regulatory requirements, it is recommended to use the risk profile to identify hazards that need to be addressed by long term relay and determine the processes to be used.<br>The faecal indicator concentration can be determined from the water or LBM flesh and should represent 90$^{th}$ percentile faecal indicator concentration less than or equal to the acceptable value, alternatively EU criteria for Class C (Commission Implementing Regulation (EU) 2019/627) can be used (40). This corresponds with Class C under REUL. |
| Category IIb; need for post-harvest treatment (canning, cooking, freezing) | This is used as an alternative or in addition to relay. High pressure treatment, cooking and canning will inactivate *Vibrio* spp. and viruses. Freezing will reduce the concentration of pathogenic *Vibrio* spp. | LBMs should not contain hazards that are a risk to human health after post-harvest treatment. | The same analysis applies as in Category IIa but in addition if hazards are identified in the risk profile that are not reduced to an acceptable level they should be addressed by additional monitoring and management (closures or additional processing requirements). |
| Category IV; not fit for human consumption. | Growing areas should be designated as prohibited for harvesting LBMs for human consumption, the responsible authority may allow gathering from buffer zones (zones near sewage discharge) for the purpose of removal of microbial hazards. | The category IV areas are demonstrated not to meet the requirements of category I, II or III and are deemed subject to more hazards than are acceptable. | The same analysis applies as in Category IIa but in addition if hazards are identified in the risk profile that are not reduced to an acceptable level they should be addressed by additional monitoring and management (closures or additional processing requirements). |

#### 7.3.1.5 Growing area management

The FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes should be consulted for full detailed information on growing area management. This section summarises the recommendations from the guidance for managing the growing area.

The responsible authority will have the ability to monitor and assess changes for the status of growing areas with respect to identified hazards, these capabilities may be shared with other regulatory bodies where it is defined in regulations or binding agreements such as Memoranda of Understanding (MOU). The responsible body should publish the boundaries and classification status for each growing area, along with criteria for any classifications or imposition of other closures, the closure status should be communicated directly to harvesters, stakeholders and wholesalers. Where there are a permanent category IV closures, authorities should ensure no harvesting takes place. The authority can utilise low level monitoring to see if the hazard status has changed, a growing area review must be done before reclassification of conditions have changed.

Category I, II and III growing areas require management plans, the content of which varies dependent on several factors, including complexity of the growing area the number of fisheries and the hazards. Expected and unexpected events may occur.

Expected event management plans should be established to cover events in the growing area assessment which are predictable. This is a written plan to define the possible events, closure triggers and subsequent actions. Where hazard monitoring management actions for category I, II and III may be closure and post-harvest processing requirements, for some pathogens, especially *Vibrio* spp. management, they can include time and temperature.

Unexpected events management is more complicated and may involve investigative action and risk assessment. The management plan should be established to define the investigation and assessment of unexpected events. The plan of management should outline how to identify when an event has occurred, for example through communication with responsible bodies such as environmental regulators. The risk

assessment should determine if risk management is required. Elements of the plan of management will vary depending on the hazard but may include growing area investigation, epidemiological investigation, sampling and analysis and risk communication, risk management and follow up (review of the risk assessment during and after the event).

Examples of unexpected events include:

- Abnormal weather such as hurricanes, which affects bacteria, viral, protozoal and chemical hazards related to sediment.
- Failure or breakage of sewage plants and pumping stations affecting bacterial, viral and protozoal pathogens of human origin.
- Spills of animal waste stations affecting bacterial, viral and protozoal pathogens of human origin.
- Outbreaks related to established pathogens such as *Salmonella*, *Vibrio* spp. or *Cryptosporidium* spp.
- Oil spillage or discharge associated chemical contaminants.

When an unexpected event occurs, all interested parties should be notified. Interested parties should be notified if the growing area is closed, if the LBMs are subject to greater post-harvesting controls and if export to certain countries will not be allowed. The responsible authority should also consider public health warnings for recreational harvesters if required.

The responsible authority should have a written plan detailing the growing area surveillance (patrol and enforcement) activities to be undertaken in the growing area both when its open and closed.

7.3.1.6 Growing area review

The FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes should be consulted for full detailed information on performing a growing area review. This section summarises the recommendations from the guidance on reviewing the growing area.

The growing area review involves ongoing assessment of the relevance of the growing area risk profile and growing area assessment. A review period should be defined for each element of the risk plan, it will usually be short term (annual), medium term (three to five years) or long term (every ten years). The review period can be modified according to the review area. A review should be initiated outside of the scheduled cycle time if there is evidence that the levels of illness or inputs relevant to the growing area have changed, an unexpected event has occurred, or the frequency of unexpected events has changed.

There can be more than one periodic review, for example an annual review could consider monitoring over the year whereas a longer-term review could be a fully comprehensive update of the original growing area assessment. Both types of review should address:

1. Sampling - considering if sampling was targeted appropriately, was timely, etc.
2. Monitoring results - if there were unexpected or unusual results that needed further exploration.
3. Expected and unexpected events: occurrence, reaction, reporting, and any public health emergencies.
4. Surveillance - review of the surveillance for activity, findings and actions.
5. Pollution sources review.
6. Review of ongoing monitoring data.
7. Conclusions of the review.
8. Recommendations of the review.

### 7.3.2 Surveillance and control after the growing phase

This section summarises the international guidance for the surveillance and control of oysters after the growing phase, i.e., during processing, transit and retail. Full details are in the original standards and guidance. Information is subject to change if these are updated by the relevant international organisations.

#### 7.3.2.1 Hygiene

Measures for control are set out in the CODEX Standard for Live and Raw Bivalve Molluscs (301). This Standard is referenced in the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes discussed in the previous section. The CODEX Standard for Live and Raw Bivalve Molluscs applies to LBMs and to raw bivalve molluscs which “have been shucked and/ or frozen, and/or processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs. Raw bivalve molluscs are marketed either in a frozen or chilled state. Both live and raw bivalve molluscs may be intended for direct consumption or further processing. The Standard does not apply to scallops when the final product is the adductor muscle only.”(17).

Part one of the code applies to LBMs and part two applies to raw bivalve molluscs.

Part one defines the product (LBMs) as products alive immediately prior to consumption and the process as harvested alive from a harvesting area either approved for direct human consumption or classified to permit harvesting for an approved method of purification, for example, relaying or depuration, prior to human consumption. These would be Class A and B growing areas respectively under REUL. Both relaying and depuration must be subject to appropriate controls implemented by the official agency having jurisdiction. Any presentation is permitted provided that all requirements for labelling and the standard are met. The section then goes on to set out potential contaminants, including marine biotoxins and microbial contaminants. The limitations of depuration should be noted when considering this as an appropriate control. Additives are not permitted.

The section of part one regarding hygiene sets out recommendations for compliance with the appropriate sections of the General Principles of Food Hygiene (CXC 1 – 1969), the Code of Practice for Fish and Fishery Products (CXC 52-2003) and other relevant CODEX codes. These are discussed later in this section. It also recommends compliance with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of

Microbiological Criteria Related to Foods (CXG 21-1997). Furthermore, it states that growing area monitoring programs, irrespective of the type of indicator bacteria used, must ensure that LBMs destined for direct human consumption meet the *E.coli* limit when tested in accordance with an MPN method specified in ISO 16649-3 or equivalent (304). ISO 16649-3 sets out the microbiology of the food chain and the method for *E. coli* enumeration. The CODEX Standard for Live and Raw Bivalve Molluscs recommends that where the microbiological criteria are not met, actions should be taken by the competent authority.
The labelling sections of part one are set out in section 7.3.2.3 of this risk profile.

The sampling section of part one sets out the method for sampling LBMs specifically, including how to take the sample and how many should be analysed. In particular, it sets out recognised methods for hygiene and chemical sampling, and the criteria for analysing the samples to detect the presence of microbes and chemicals.

Part two is homologous with part one in the sections set out. The difference is that raw bivalve molluscs are defined as products that were alive immediately prior to the commencement of processing and comply with part one in relation to harvesting, purification and relaying. Other sections are set out and mostly refer to part one for their standards, however, given that raw bivalve molluscs may be frozen, there are additional details on freezing and thawing.

The CODEX General Principles of Food Hygiene provide a framework for producing safe and suitable food, it outlines the principles that FBOs should follow and understand to ensure food safety, the guidance is for all stages of food processing. Chapter one covers GHP, and chapter two covers the HACCP system and guidelines for its application.

Chapter one (GHP) is not specific to any food type but is applicable as guidance for procedures to ensure there is no compromise to food safety, for example, through ensuring personal hygiene. An overview of the sections in chapter one considered relevant to LBMs is as follows:

1. GHP: introduction and control of food hazards, an assessment of the suitability of water and good agricultural practice (GAP).

2. Primary production: environmental control; hygienic production; handling, storage and transport; cleaning, maintenance and personal hygiene.
3. Establishment of design of facilities and equipment: location, layout, cleaning, temperature, storge and food control monitoring equipment.
4. Training and competence: awareness, training and supervision, instruction programmes and refresher training.
5. Maintenance, cleaning, disinfection and pest control: general maintenance and cleaning, disinfection methods and procedures, monitoring of effectiveness, pest control systems, prevention, harbourage and infestation, monitoring and control of pest infestation. Waste management,
6. Personal hygiene: health status, cleanliness and behaviour.
7. Control of operation: product description, process description, effectiveness of GHPs, verification, microbial contamination, physical contamination, chemical contamination, allergen management, recall procedures.
8. Product information and consumer awareness: lot identification and traceability, product information, product labelling.
9. Transportation: requirements and use and maintenance.

Surveillance is not explicitly set out in the General Principles of Food Hygiene but is inferred by the reference to monitoring and verification. Section 3.3.2 (food control and monitoring) describes FBOs and food handlers using and calibrating suitable equipment to monitor conditions such as temperature humidity and airflow. Section 5.1.3 relates to monitoring and review of cleaning and disinfection measures including inspection, audit and microbiological sampling. While section 7.1.5 describes verification of GHP procedures, monitoring, corrective action and assessment of the efficacy of cleaning.

Chapter two of the General Principles of Food Hygiene outlines the seven principal stages of HACCP with guidance on how this can be applied by FBOs. The chapter also describes barriers to the effective application of HACCP to small and less developed food businesses. It details the steps of design and implementation of a HACCP system. Step 3.3.2 outlines monitoring of food control and equipment so that deviation from CCP can be detected, it suggests that monitoring of ‘measurable critical limits’ such as temperature should be continuous whereas other limits such

as moisture level or preservative concentration cannot be monitored continuously. Section 3.11 outlines HACCP verification procedures, stating that verification of the procedures should be carried out by someone other than the person carrying out the monitoring to ensure the HACCP system is effective (19).

The CODEX Code of Practice for Fish and Fishery Products is a comprehensive guidance document for all stages of fish growing, harvesting and processing.

Table 12 summarises the sections that describe hygiene surveillance procedures within the Code of Practice, which are applicable to LBMs.

Table 12: Hygiene surveillance recommendations applicable to LBMs, adapted from the CODEX Code of Practice for Fish and Fishery products (18).

| **Section of the CODEX Code of Practice for Fish and Fishery products.** | **Summary of surveillance intervention** |
|---|---|
| 3.4 Hygiene control programme | Reference to surveillance of hygiene control: 'the efficiency of cleaning should be controlled as appropriate'. |
| 5.3.1 Application of HACCP | Verification (of HACCP) involves application of methods, procedures and tests to determine the effectiveness of HACCP. |
| 5.3.6 and 5.3.8 monitoring and verification | Monitoring and verification of HACCP and CCPs, including quality assurance. |
| 7 Processing of LBMs | Details growing areas, harvesting, relaying, depuration, processing, shucking and documentation. All subsections include information regarding hygiene. |
| 12.4.11 Processing operations, molluscan shellfish | All steps of processing encompassing hygiene (for example, 'products should be protected from dehydration, dirt and contamination'). |
| 21.Transportation | This section does not give any detail on hygiene control for LBMs. |
| 22 Retail | This section does not give any detail on hygiene control for LBMs. |

Section 7 of the Code of Practice also refers to other CODEX guidance such as the Guidelines on the Application of the General Principles of Food Hygiene to Control Viruses in Food (123) and the Guidelines on the Application of the General Principles of Food Hygiene to Control Pathogenic *Vibrio* Species in Seafood (21). Both of these outline hygiene verifications and have a homogeneous layout in terms

of sections presented. Section three details primary production and harvesting areas and the hygiene of the environment, food sources, transport, and persons. The section states that it is the responsibility of the FBO to ensure the facilities meet appropriate hygiene standards (21, 123).

Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997) encompasses surveillance for microbiological criteria, however section 1.4. states that 'since the criteria for monitoring of the food processing environment cannot be defined as specifically as microbiological criteria for food, they generally are not used in defining the acceptability of food, and therefore they are not in the scope of the document, despite their utility in managing food safety'. The guidance sets out general principles to supplement HACCP with regard to microbiological criteria. Section 4 outlines general considerations of criteria, section 5 outlines methods and limits and section 6 outlines sampling plans. The guidelines are not specific to LBMs but are applicable in some phases of supply.

*7.3.2.1.1 Depuration*

Depuration is a process whereby shellfish are treated to purge bioaccumulated contaminants (305). Depuration is used to reduce microbial contamination of LBMs, to levels acceptable by legislation for human consumption, by keeping LBMs in tanks with clean seawater (305). Four main water disinfection methods are used in depuration; ozone, UV, chlorine and iodophors, this varies from country to country. Depuration times must be long enough for the LBMs to release pathogens from their GI tract but minimum times can be set by individual countries (305, 306). There are different types of purification systems; small scale shallow tank purification, medium scale multilayer, large scale multilayer, vertical stack, bulk bin systems and purification systems of non-standard design (13).

Depuration is primarily intended to remove microbial contamination. It is effective at clearing many types of faecally derived bacteria and some viruses from shellfish but is less effective at removing norovirus and hepatitis A. Depuration cannot reliably remove *Vibrio* spp., marine biotoxins, microscopic algae, lipophilic chemicals or heavy metals. The seawater used in depuration must conform to the definition of

‘clean seawater’ (as defined in relevant CODEX/ FAO/ REUL documentation) and the type used can also vary with natural seawater, artificial seawater and saline borehole water all being used by different countries and systems (307).

The hygiene monitoring and surveillance requirements after depuration (permitted levels of *E. coli*) are summarised in the FSA’s shellfish classification pages (294). In GB all LBMs intended for export to the EU and destined for human consumption require an export health certificate (EHC). As a third country, LBMs cannot be directly landed by GB fishing vessels into the EU. They must be exported to arrive via a border control point. LBMs including oysters can continue to be exported to the EU if they are harvested from Class A waters or from Class B waters following depuration within GB and if they have cleared end product testing (ready for human consumption). These can be exported using the EHC for LBMs for direct human consumption, Local Health Authorities (LHAs) issue these certificates. The European Commission (EC) has indicated that un-depurated (unpurified) LBMs from Class B waters cannot be exported from GB into the EU for the purpose of depuration (purification), this includes both wild harvested LBMs and those from aquaculture (308).

In GB only shellfish harvested from category B (or A where necessary) can be depurated. Responsibility for approval for depuration systems in England and Wales lies with local authorities. Cefas can offer advice to local authorities to assist with this approval process (309). Section 7.5 of the CODEX Code of Practice for Fish and Fishery Products outlines technical guidance for depuration approval, it does not outline hygiene verification but does state that it should be overseen by the official agency having jurisdiction (309) (18). REUL Regulation (EC) 853/2004, Annex III, Section VII sets out the legal requirements for LBM harvesting and relaying/ depuration. Chapter IV covers the hygiene requirements for purification centres, the regulation also lays out that all LBM FBOs must be approved by a competent authority (41).

#### 7.3.2.2 Chemical and biotoxin contaminants

Chemical contamination can come from both environmental contaminants in the growing environment (for example, naturally such as biotoxins from HABs) or

anthropogenically such as from agricultural run-off leading to contamination with veterinary pharmaceuticals) or from chemical cross-contamination during food processing (for example, surface cleaner contaminants).

Chemical and biotoxin surveillance is set out in section 1.8 (determination of biotoxins) of the CODEX Standard for Live and Raw Bivalve Molluscs Guidance (17). This recommends that the methods selected are chosen on the basis of practicability and preference should be given to methods which have applicability for routine use. The guidance sets out criteria for determination of toxin analogues by chemical methods and contains extensive information on the minimum applicable range for sampling and the limit of detection (LOD) and limit of quantification (LOQ) criteria. The guidance states that internationally scientifically validated toxicity equivalency factors (TEFs) must be used. Current internationally validated TEFs can be found on the FAO website (17, 310).

Chemical surveillance is also set out in section 1.5 (contaminants) of the CODEX Standard for Live and Raw Bivalve Molluscs Guidance (301). This sets out the maximum level per kg of flesh allowed for biotoxins of the STX, OA, DA, BTX and AZA groups. The standard also states that LBMs destined for direct human consumption should comply with the CODEX General Standard for Contaminants and Toxins in Food and Feed, this guidance comprehensively covers contaminant[12] maximum levels (MLs)[13]. The guidance details multiple chemical contaminants however most areas are not specific to LBMs or oysters, except for cadmium where an ML for LBMs is explicitly noted (311).

[12] Contaminants are defined as: “any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter”.

[13] MLs are defined as the maximum concentration of a contaminant in a food or feed commodity that is legally permitted in that commodity.

The CODEX General Principles of Food Hygiene set out general HACCP principles which encompass measures to ensure chemical contamination of food does not occur from the perspective of cross contamination for example, from food surfaces into food, handling, storage and transport. Section 2.4. sets out cleaning design and recommendations but does not specify any chemicals. Section 3.11.2. sets out monitoring and verification of HACCP and GHP, not detailing specific chemicals (19).

The Joint FAO/WHO Guidance on Toxicity Equivalency Factors for Marine Biotoxins Associated with Bivalve Molluscs sets out guidance for the characterisation of TEFs and their detection methods. It is not specific to aquaculture (312).

Information from the Codex Code of Practice for Fish and Fishery products relevant to LBM surveillance is summarised in Table 12 in section 7.3.2.1. There is little detail regarding chemicals.

The FSA website contains guidance for LBM chemical contaminant monitoring, this includes levels for heavy metals, PAHs and dioxins (313).

7.3.2.3 Labelling

REUL Regulation (EC) 853/2004, Annex III, Section VII, Chapter VII sets out that LBMs must be accompanied by a waterproof label including the identification mark (bearing the approval number of the establishment), species of bivalve (common and scientific name) and the date of packing. It also requires that the retailer keep this label for at least 60 days after opening the package (41).

The CODEX General Standards for Labelling of Prepackaged Food is general guidance outlining labelling requirements (i.e. name of the food, net contents and drained weight, name of manufacturer, importer, distributor or vendor, country of origin, lot number, date marking and storage instructions and instructions for use) (314).

Labelling is set out in section 1.7 and 2.7 of the CODEX Standard for Live and Raw Bivalve Molluscs Guidance (17), which recommends that labelling should comply with the standards set out in the CODEX General Standards for Labelling of Prepackaged Food. Additionally, these sections also set out the labelling

requirements for LBMs. This includes the name of the food, content declaration, storage instructions, and labelling of non-retail containers. Section 1.8 sets out surveillance and sampling of the LBMs; section 1.8.3 states that “weight per unit weight or volume should be verified”. Sections 2.2 and 2.7 set out the description and state that “name of food should be declared on the label along with the common name of the species in accordance with the law in that country”.

The CODEX General Principles of Food Hygiene set out general HACCP principles which encompass measures to ensure contamination of food does not occur from the perspective of cross contamination for example, allergen contamination from insufficient packaging. Chapter 3 sets out monitoring and verification of GHP and chemical contamination, but with nothing specific to labelling or packaging (19).

Information from the CODEX Code of Practice for Fish and Fishery Products that is relevant to LBM surveillance is summarised in Table 12 in section 7.3.2.1, labelling is not specifically noted.

## 7.4 Summary

The SRT provides a flexible framework which considers those hazards with potential for greatest impact on supply of seafood from different aquaculture sectors and potential novel emerging hazards, as well as the interventions that may be required to mitigate them. The SRT largely aligns with the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Molluscs Sanitation Programmes and CODEX, FAO and WHO standards and guidelines set out in this section. In particular, the RMM applied to the LBM scenario, noted in section 7.1 of this risk profile, sets out processing and trade measures which quote FAO, WOAH and CODEX Guidance, and EU legislation, with scores for uncontrolled and controlled states. It is clear that these internationally accepted measures reduce the risk in multiple areas of the supply chain. The guidance is set out in more detail in section 7.3.1 of the risk profile, illustrating the specific areas for the growing phase and then subsequent stages of the supply chain. The conclusions drawn from the SRT analysis can be interpreted as follows: measures applied early on the in the supply chain, i.e., at the point of growing area selection and management, may reduce the impact of the hazard in the latter phases. Therefore, in many cases, they

may reduce the requirement for additional control measures outside of the general hygiene measures set out in CODEX guidance. Furthermore, it is important to note that the types of controls required and their potential for success depend on the type of hazard and the way in which they are applied (for example, at which supply chain phase). There are, however, options for when the growing area is under a classification that is not ideal for risk mitigation, such as in situations where oysters are harvested from Class B waters and require purification to allow safe human consumption. Depuration and short-term relay are options in these circumstances. However, their limitations (also noted within that section) should be considered, for example, depuration will not remove marine biotoxins.

Given that EU legislation is referenced in the SRT, it is noted that it is in line with the FAO and CODEX guidance and that GB law is also in line with this due to the current status of REUL.

The guidance set out here has been used to create a proposed checklist for auditors in appendix 14.7.

# 8 Legislation and control

## 8.1 GB domestic legislation and GB import controls

At the time of writing, legislation governing the hygiene rules for domestic production of LBMs (which include oysters) and the import of Products of animal origin (POAO) and specifically oysters into GB are contained within REUL. Under the Windsor Framework, goods moved from GB to NI can meet GB public health standards. Hence this section is within the context of GB legislation.

### 8.1.1 GB domestic Legislation

FBOs placing LBMs on the market in GB must meet the requirements in Regulation (EC) 178/2002 (315) which lays down the general principles and requirements of food law, Regulation (EC) 852/2004 (316) on the hygiene of foodstuffs and Regulation (EC) 853/2004 (317) which lays down specific hygiene rules for food of animal origin.

LBMs can only be harvested from a production or relaying area which has been classified and monitored in accordance with the requirements in Title V of Regulation (EU) 2019/627 (318).

Regulation (EC) 853/2004 (317) supplements the requirements of Regulation (EC) 852/2004. It sets out general obligations on FBOs and when establishments require registration or approval. Annex I sets out requirements for identification marking. Annex II, Section VII sets out specific hygiene rules for LBMs which includes hygiene requirements for:

- harvesting and handling of LBMs,
- dispatch and purification centres (including structural requirements),
- wrapping and packaging (including specific requirements for oysters),
- Identification marking and labelling.

Specific health standards which must be met before being placed on the market for human consumption are laid down in Chapter V and summarised in Table 13 (317).

Table 13: Health Standards for LBMs (317)

| Health Standards | Legislation or guidance contained within |
|---|---|
| Meet the microbiological criteria for LBMs. | Regulation (EC) 2073/2005, Annex I, Chapter 1. |
| Organoleptic characteristics associated with freshness and viability. | Regulation (EC) 853/2004, Section VII, Chapter V (1). |
| Marine biotoxins in total quantities (*) that exceed for PSP, 800µg per kg. | Regulation (EC) 853/2004, Section VII, Chapter V, 2(a). |
| Marine biotoxins in total quantities (*) that exceed for (ASP), 20mg of DA per kg. | Regulation (EC) 853/2004, Section VII, Chapter V, 2(b). |
| Marine biotoxins in total quantities (*) that exceed for OA, dinophysistoxins and PTX together, 160µg of OA equivalents per kg. | Regulation (EC) 853/2004, Section VII, Chapter V, 2(c). |
| Marine biotoxins in total quantities (*) that exceed for YTX, 3.75mg of YTX equivalent per kg. | Regulation (EC) 853/2004, Section VII, Chapter V, 2(d). |
| Marine biotoxins in total quantities (*) that exceed for AZA, 160µg of AZA equivalents per kg. | Regulation (EC) 853/2004, Section VII, Chapter V, 2(e). |

(*) Measured in the whole body of the LBM or any part edible separately.

The classification of production and relaying areas is not required in relation to harvesting of Pectinidae, marine gastropods and Holothuroidea which are not filter feeders (Article 11 of Regulation (EU) 2019/624) (319). This is when official controls to verify compliance with the health standards (Chapter V) and the specific requirements for such animals (Chapter IX) as set out in Regulation 853/2004 (317) are carried out by the competent authorities in fish auctions, dispatch centres and processing establishments.

### 8.1.2 GB Import Controls

Imports of LBMs into GB must meet certain requirements. As per Article 11 of Regulation (EC) 178/2002, any food and feed imported into GB for placing on the market within GB must comply with the relevant requirements of food law or conditions recognised by GB or be at least equivalent thereto (320).

With regards to the hygiene of imported food, the relevant requirements in Article 11 of Regulation (EC) 178/2002 (320), shall also include the requirements in Article 3-6 of Regulation (EC) 852/2004 (316).

Regulation 2017/625 (321) lays down requirements for the performance of official controls in third countries (Article 1(d)) and applies to the official controls performed for the verification of compliance with the rules in the areas of food safety (Article 2(a)) and where such rules are applicable to animals and goods entering GB (Article 3).

Regulation (EU) 2019/625 (322) supplements Regulation (EU) 2017/625 (321) with regards to requirements for the entry into GB of consignment of certain animals and goods intended for human consumption. It also provides for consignments entering GB to be accompanied by an Official Certificate (Article 13) (323).

LBMs must only be imported into GB if they come from a third country or region authorised under Article 8 and listed in Annex I of Regulation (EU) 2019/626 (324) and accompanied by an official certificate. Third countries must also have a veterinary residue plan approved under Decision 2011/163 (323). This must cover the commodity being imported and be included on the list of trading partners with approved residue monitoring control plans for products of animal origin (325). For oysters this would only apply to aquaculture LBMs.

They must also be harvested from production areas and dispatched from, and obtained or prepared in, establishments that appear on a list drawn up in accordance with Article 127 of Regulation (EU) 2017/625 (321).

In accordance with Article 47(1) of Regulation (EU) 2017/625 (321), oysters are subject to official controls at border control posts at first arrival into GB from a third country.

The FSA’s Guidance on safely importing fishery products or bivalve molluscs into GB, summarises criteria required for entry of LBMs (326).

## 8.2 International legislation

It is not possible to summarise the legislation for the control of oysters, both domestically and those intended for export, for all countries in the world. Therefore, this section summarises the key legislation for certain countries or states. These have been selected using a varied combination of the following criteria.

- Contributions to international guidance considered throughout this risk profile, particularly in section 7 (EU).
- Noted production for a variety of, or specific species of oysters, as per section 10 (all).
- Large world powers (all).
- Available information (all).

### 8.2.1 EU

The FAO and CODEX guidance are set out in section 7 of this risk profile. In 2019, in the UK, Cefas was designated as the FAO Reference Centre for Bivalve Mollusc Sanitation, it supports the FAO to ensure bivalve shellfish safety and trade. The centre is funded by the FSA and Defra (327). Cefas provides information and guidance on the following:

- international guidance(328)
- seafood safety, legislation and international codes of practice (329)
- protocols and technical guidance (330)
- proficiency testing and quality assurance (331)

Regarding the hygiene requirements for domestic production of bivalve molluscs, EU regulations remain broadly similar to REUL in GB. Under Windsor Framework arrangements, businesses importing POAO into NI from third countries will continue to follow EU rules. Since 1 October 2023, the Windsor Framework allows GB public health standards to apply for pre-packed retail goods moved via the new NI retail movement scheme (332) and placed on the NI market. Therefore, goods moving via this route containing GB authorised POAO will be able to be placed on the NI market. Chapter 32 of Commission Regulation (EU) 2020/2235 (333), covers the

entry of LBMs (intended for human consumption) into the EU, the chapter encompasses competent authorities certifying officer checks, which ensure verification of their own checks on certification and harvesting. Chapter 32 ensures that, while being transported, there is verified documentation issued by the competent authorities in place, which authorise the transport, attesting to the nature and quantity of the product, production area of origin and establishment of destination. Chapter 31 of commission regulation 2020/2235 (333) contains a model animal health certificate for LBM entry into the EU. This document covers transport requirements, health information and requirements, labelling and veterinary checks. It also covers requirements for LBMs that are to be processed within the EU before consumption.

The EU and USA permit reciprocal trade of bivalve molluscs for human consumption from two US States (Washington and Massachusetts) and two EU Member States (Spain and the Netherlands) (334).

### 8.2.2 Australia

Food standards Australia and New Zealand (FSANZ) follow the Food Standards Code which are legislative instruments under the Food Standards Act of 2003 (335). The Food Code 4.2.1 sets out the production and processing standards for seafood in Australia but not New Zealand, this standard requires primary producers and processors of certain bivalve molluscs to implement a food safety management system. This requirement also extends to manufacturing activities relating to bivalve molluscs. For primary producers and processors of bivalve molluscs, the food safety management system incorporates conditions on the areas from which the product may be harvested or harvested for depuration or relaying, along with conditions on the water used for wet storage (336). Legislative instrument standard 4.2.1, division two covers the general food safety requirements including hygiene, traceability, handling, packaging, storage and transportation of LBMs (337).

The Australian Government Department of Fisheries Agriculture, Fisheries and Forestry (DAFF) has a food safety recognition agreement with various countries including the USA, however this agreement excludes raw bivalve molluscs (338). Australian exporters have to comply with the Export Control Act (2020) (339), this

Act sets out the overarching legal framework for the regulation of exported goods, including food and agricultural products, from Australia. It enables the Secretary of the DAFF (the Secretary) to make rules that detail the requirements and establish conditions for exporting certain goods from Australia. It has streamlined and consolidated the export requirements included in more than 20 Acts and 40 legislative instruments into one Act, making the requirements to export easier to understand and comply with (340). LBMs are listed in the Imported Food Control Order (2019) (341) as medium or high public health risk (342) with the requirements for a foreign government certificate arrangement to be in place when importing LBMs into Australia. The Export Control Rules (2021) (The Rules) do not apply to LBMs (343).

From November 2023 in Australia any imports of LBMs including oysters must be covered by a foreign government certificate under a government-to government certification arrangement which ensures equivalence (344). The competent authorities websites do not specifically note following FAO or CODEX guidance however point four of the Eligibility Criteria for the Foreign Government Certificate for Imports into Australia states that '(the competent authority) verifies and enforces compliance with national standards, government controls and export conditions for bivalve molluscs and bivalve mollusc products' (345). The DAFF also states that it participates in CODEX and Australia hosts and chairs the CODEX Committee on Food Import and Export Inspection and Certification Systems (CCFICS) (346). The DAFF also states that it has a compliance agreement with the FAO (347).

In South Australia processors and manufacturers of LBMs require a Food Safety Management System (FSMS) as per Legislative Instrument Standard 4.2.1 (345), these are verified and audited by the Government of South Australia Food and Controlled Drugs Branch (SA Health) (348). SA Health use the DAFF for exports of agricultural products including LBMs. The DAFF is responsible for regulating export establishments and the specific products for export (349).

Within the government of South Australia Economic Development Agency (EDA) is a department of Primary Industries and Regions South Australia (PIRSA) which accredits LBMs fisheries and carries out the South Australian Shellfish Quality

Assurance Program (SASQAP). The SASQAP monitors the water quality in shellfish harvesting areas of the state, processes requests to farm and harvest LBMs and accredits those farmers. All holders of aquaculture or fishery licences authorising the farming or taking of bivalve molluscs, who harvest or grow for human consumption, must be accredited. It is a requirement of accreditation for businesses to implement a Food Safety Arrangement. This includes a HACCP plan covering activities accredited to be undertaken on site (350).

Under the Primary Produce (Food Safety Schemes) Act 2004, The South Australian Primary Produce (Food Safety Schemes) (Seafood) Regulations 2017 (351) is the statutory instrument for the seafood regulations, with part three containing obligations relating to LBMs production.

Australia and New Zealand align with international guidelines for contaminants and toxins, under schedule 19 of the Australia and New Zealand Food Standards Code (352).

### 8.2.3 New Zealand

New Zealand shares some joint food standards and legislation with Australia and some standards that are specific to New Zealand (353). FSANZ follow the Food Standards Code which are legislative instruments under the Food Standards Act of 2003 (335). In 2002 New Zealand adopted the Australia New Zealand Food Standards Code, and all of its amendments, as joint food standards (except for the Australia-specific chapters and standards).

The Ministry for Primary Industries (MPI) is responsible for the implementation of the Code in New Zealand, including compliance policy. Unless otherwise noted in the Code, all Standards apply in New Zealand, however the LBM related food code legislation discussed in section 2 for Australia does not apply in New Zealand. This includes those for high-risk imported foods or export requirements relating to destination markets, other than Australia (353).

The MPI in New Zealand (353) ensures that producers and growers of LBMs meet food safety requirements. The requirements are laid out in the two main legislative instruments which come under the Animal products Act 1999, section 167(2) and section 38(2)(a) (354); The Animal products (regulated control scheme- live bivalve molluscs) Legislation 2006 (355) and the Regulated Control Scheme - Bivalve

Molluscan Shellfish for Human Consumption Legislation (356). These regulations cover classified areas for harvesting LBMs, processing and harvesting requirements. The MPI oversees food safety in New Zealand and provides guidance for LBM harvesters and producers, they must adhere to seafood safety operational codes (357).

The New Zealand Customs Service administers the Customs Export Prohibition (strategic goods) Order of 2021, under section IV chapter 16, paragraph 1 LBMs export is covered (358). All domestically produced food sold in New Zealand or intended for export must comply with the requirements in the MRL Food Notice, this is enforced by the MPI (353). MRLs are listed in the Maximum Permissible Levels (MPLs) Product Animal Notice (359).

The MPI also sets out guidance for FBOs on how to register to be an exporter, this includes applying for an animal products e-certificate, checking the destination market requirements, registering as a seafood exporter and applying for a seafood export certificate (360). The MPI has an extensive list of registers on its website, for example harvesters, growing areas and sorting sheds (361). The MPI also has country listings for the EU and GB approved premises for market access requirements (362, 363). The MPI website states that “New Zealand follows international food safety standards, which are coordinated through the CODEX Alimentarius Commission” (364).

### 8.2.4 United States of America (USA)

In the USA, the FDA regulates seafood safety. The FDA has guidance and documents on its webpages which includes research, inspection, compliance, enforcement, outreach, regulations and guidance (365). The FDA webpages lists numerous regulations relating to seafood, the primary articles of relevance are the provisions of the Federal Food, Drug and Cosmetic Act, Title 21, Volume 2, Chapter I, Subchapter B, Subpart A, B and C which relates to oyster regulations including general provisions, labelling requirements, HACCP requirements and source controls (366). The FDA Amendments Act of 2007, Public Law 110-85, Section 1006 relates to molluscs inspection, and covers seafood inspection traceability and contaminants (367).

The NSSP is the federal/state cooperative program recognised by the FDA and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish

produced and sold for human consumption. The NSSP aims to promote and improve the sanitation of shellfish including oysters, moving in interstate commerce through federal/state cooperation and uniformity of state shellfish programs.

The FDA has equivalence with the EC standards. The FDA and the EC Directorate General for Health and Food Safety (DG SANTE) carry out periodic on-site evaluations or audits to verify that equivalence is maintained, and free trade is allowed between the USA and EU. In addition, FDA and DG SANTE will notify each other if they are planning to adopt, modify or repeal a food safety control measure applicable to raw bivalve shellfish or make substantive changes to their molluscan shellfish safety programs so that the other authority can determine whether those measures or changes are likely to affect its equivalence determination (368).

The export of shellfish from USA is subject to listing and certification requirements as a precondition for market access, this is managed by the FDA and National Oceanic and Atmospheric Administration (NOAA). The EU and UK maintain lists of establishments and growing areas from which LBMs are approved for export. All shellfish exported to the EU and UK must be harvested from growing areas and harvested by establishments that appear on these lists. Most shellfish products exported from the US to the EU and UK must also be accompanied by certificates issued by the NOAA's Seafood Inspection Program (369).
The FDA participates and exercises leadership in the CODEX Alimentarius Commission, by working closely with the US CODEX Office (USCO) at the US Department of Agriculture (USDA) (370). The FDA also has partnerships and cooperative arrangements (which include MOUs and similar documents), as well as confidentiality commitments with international partners (371).

### 8.2.5 Canada

Canada's legislative process involves all three parts of Parliament: The House of Commons (elected, lower Chamber), the Senate (appointed, upper Chamber), and the Monarch (Head of State, who is represented by the Governor General in Canada). These three parts work together to create new laws. Regulations are a form of law, sometimes referred to as subordinate legislation, which define the application and enforcement of legislation. Regulations are made under the authority of an Act, called an Enabling Act. Regulations are not made by Parliament but are

enacted by the body to whom the authority to make regulations has been delegated in the Enabling Act, such as the Governor in Council or a minister (372).

Health Canada (HC) is responsible for establishing standards for the safety and nutritional quality of all foods sold in Canada. It exercises this mandate under authority of the Food and Drugs Act and pursues its regulatory mandate under the Food and Drug Regulations. HC consults with the Canadian public, industry, non-governmental organisations and other interested parties in the development of these laws. HC also prepares guidelines in order to help interpret and clarify legislation and regulations (372).

The Canadian Food Inspection Agency (CFIA) is responsible for the administration and enforcement of other federal acts and regulations concerning animal and plant health, food packaging, labelling and advertising (373). Canada is a member of CODEX (374) and is part of the standardised monitoring and data acquisition system (the ‘shellfish monitoring network’) (375). The Canadian competent authority websites do not specifically cite following FAO and CODEX guidance, but they do have processes for export certification to the EU (376).

The CFIA oversees the Safe Food for Canadians Regulations (SFCR), SOR 2002-144 section 58 relates to LBMs and specifically labelling (377) and carries out inspection and enforcement activities. The Food and Drugs Act (The Act) is regulated by HC and is the overarching legislation under which other specific seafood legislation sits. Molluscs are regulated under the Food and Drug Regulations, part B, division 21 (b) (378), however the CFIA website states that it does not maintain the statutes under the Government of Canada Department of Justice (379). The CFIA has export certification, export regulations, and registers on its website (380) and is the regulator for seafood and LBM export (381). The CFIA also carries out phytosanitary audits of LBM growers under the Fish Inspection Act (382).

The Canadian Shellfish Sanitation Program (CSSP) is a federal food safety program jointly administered by the CFIA, Environment and Climate Change Canada (ECCC) (383) and Fisheries and Oceans Canada (DFO) (384). The goal of the program is to minimise the health risks associated with the consumption of contaminated bivalve

molluscan shellfish such as mussels, oysters and clams. Under the CSSP, the Government of Canada implements controls to verify that only shellfish that meet food safety and quality standards reach domestic and international markets (385).

### 8.2.6 China

In China, food safety governance is complex with multiple laws and regulations and governing bodies. The Peoples Republic of China (PRC) Food Safety Law of 2015, sets out comprehensive statutory requirements governing the production, circulation, recall and import/export of food products in China (386) (387). Exports are covered under Chapter VI (388).

The Food Safety Law of the PRC is regulated by the National People's Congress (NPC) and regulates most aspects of food safety (389).The Food Safety law of the PRC is regulated by the National People's Congress (NPC) and regulates most aspects of food safety (389). The product quality law of China (2018) was enacted to strengthen import and export quality (390).

No reference could be found on the Chinese competent authority websites to the CODEX or FAO guidance.

The China Food and Drug Administration (CFDA) established the Information Inquiry Platform for Food Safety Supervision and Inspection, which covers sampling information, published by the General Administration of Customs (GAC) in 2015, and is updated in real time based on sampling inspection. To aid the functioning of the CFDA, several platforms have been established. A typical example is the National Food Safety Traceability Platform, which is available for producer, government, and population. This platform was established by GS1 China, an affiliate of General Administration of Quality Supervision Inspection and Quarantine of the PRC (AQSIQ) (391). Most foods in China do not require an export permit, however LBMs do require a permit which is issued jointly by the Ministry of Commerce (MOFCOM) and the GAC, and is updated annually, and must be issued before export (392). AQSIQ is a ministerial administrative organisation directly under the State Council of the PRC in charge of national quality, metrology, entry-exit commodity inspection, entry-exit health quarantine, entry-exit animal and plant quarantine, import-export food safety, certification and accreditation, standardisation, as well as administrative

law-enforcement. The Ministry of Health coordinates food safety and inspections. There are numerous competent authorities in China that regulate food exports and specifically LBMs, these are summarised in Table 14.

Table 14: Summary of the legislation in China applying to export and control of seafood and LBMs.

| Law | Overseen by | Summary |
|---|---|---|
| PRC Food Safety Law 2015 (387). | CFDA. | Regulates food safety standards (chapter 3), production and distribution (chapter 4), monitoring and inspection (chapter 5), import and export (chapter 6). |
| GAC Decree No.249 (393). | GAC. | Chapter III covers exports including ensuring compliance with the country's standards (article 38), registration (article 39), customs procedures (article 40-43), traceability (article 44), packaging and transportation (article 46). |
| Agricultural Product Quality Safety Law (APQSL) (394). | NPC | Covers fisheries quality sales, production and supervision of agricultural law. |
| The product quality Law (2018). | NPC | Covers general provisions, supervision of product quality, obligations from sellers and penalties for non-compliance. |
| Export permit | Jointly by the MOFCOM and GAC. | Required for export or shipping of all goods outside of China. |
| Food product permits | CFDA. | Governs food production. |
| Administrative Measures for Food Trading Permits (2017). | CFDA | Governs online food trading. |
| Administrative Measures for Food Safety in Importation and Exportation (2011). | Issued by the PRC AQSIQ. | Covers import and export food safety including record filing by importers and exporters, quarantine and inspection, product labelling and including overseas facilities registration requirements. |

### 8.2.7 Japan

The competent authority in Japan is the Ministry of Agriculture forestry and fisheries (MAFF) (395). The MAFF has information relating to radionuclide monitoring in

fishery products but no other monitoring or information about compliance with international standards (396).

The main legislation that governs food quality and integrity in Japan is the Food Sanitation Act ("FSA")(298) and the Food Safety Basic Act (397). Under article 4, Part 6 of the “FSA”, food businesses that collect food from fisheries are excluded from the Act. The MAFF cooperates with CODEX and the FAO, stating that “the regional projects have contributed greatly to enhancing the capacity of recipient countries to contribute to CODEX standards setting and to implement adopted CODEX standards”. Currently, the project titled ‘Enhancing Capacity in CODEX for Effective Participation and Contribution of Selected Countries in Asia’ is in place (398). The MAFF website has multiple links to CODEX and EU legislation relating to molluscs, however many of the documents could not be translated (399).

Legislation that governs seafood in Japan is the Domestic Trade of Specific Marine Animals and Plants Act (‘The Act’), however this legislation was not available in English (400). Descriptions of the Act state that it mandates that the domestic fishery industry adopt a catch documentation scheme (CDS) and develop a traceability system and is concerned with illegal fishing rather than food safety (401).

# 9 UK consumption patterns

## 9.1 Consumption of oysters in the UK

### 9.1.1 Consumption estimates of oysters in the UK from survey data

Chronic consumption estimates for oysters have been estimated using the DNSIYC and NDNS for all age groups between four months and 95 years (9) (5). The DNSIYC includes infants and children between four and 18 months and was carried out in 2011 (published in 2013) (9). Whilst the NDNS includes participants from 18 months – 95 years, and data utilised here is from years one to 11 of the NDNS. The NDNS rolling programme is a continuous, cross-sectional survey designed to collect detailed, quantitative information on the food consumption, nutrient intake and nutritional status of the general population in private households in the UK. The survey covers a representative sample of around 1000 people per year. These data are presented in the tables below. Consumption data for women of child-bearing age is also presented, although it should be noted that pregnant women are not included in the NDNS survey (5, 6, 7, 8).

Table 15 presents consumption data for raw and processed (canned) oysters. These were the only types included within the surveys. Data is presented to show consumption for raw oysters (with and without the shell) alone, canned oysters alone and then both combined.

NDNS and DNSIYC food codes (and their definitions) used to estimate consumption are listed in Table 31 in appendix 14.4.

Table 15: Chronic consumption data for raw and processed (canned) oysters.

| Age group | Consumers (n)[a] | Mean (g/person/day) [b] | P97.5 | Mean (g/kg bw/day) [b] | P97.5 | Respondents in population group (n) |
|---|---|---|---|---|---|---|
| **Raw oysters with and without shell** | - | - | - | - | - | - |
| 4 – 18 months | 1 | 1.7 | 1.7 | 0.18 | 0.18 | 2683 |
| 1.5 – 3 years | 0 | 0 | 0 | 0 | 0 | 1157 |
| 4 – 10 years | 0 | 0 | 0 | 0 | 0 | 2537 |
| 11 – 18 years | 0 | 0 | 0 | 0 | 0 | 2657 |
| 19 – 64 years | 6 | 9.2 | 14 | 0.13 | 0.19 | 5094 |
| 65+ years | 0 | 0 | 0 | 0 | 0 | 1538 |
| Women of childbearing age (16 – 49 years) | 2 | 7.8 | 9.8 | 0.11 | 0.12 | 2556 |
| **Raw oysters (including with and without the shell) and canned oysters** | - | - | - | - | - | - |
| 4 – 18 months | 1 | 1.7 | 1.7 | 0.18 | 0.18 | 2683 |
| 1.5 – 3 years | 0 | 0 | 0 | 0 | 0 | 1157 |
| 4 – 10 years | 0 | 0 | 0 | 0 | 0 | 2537 |
| 11 – 18 years | 0 | 0 | 0 | 0 | 0 | 2657 |
| 19 – 64 years | 6 | 9.2 | 14 | 0.13 | 0.19 | 5094 |
| 65+ years | 0 | 0 | 0 | 0 | 0 | 1538 |
| Women of childbearing age (16 – 49 years) | 2 | 7.8 | 9.8 | 0.11 | 0.12 | 2556 |
| **Canned oysters none recorded in NDNS or DNSIYC** | - | - | - | - | - | - |

a) Consumption estimates made with a small number of consumers may not be accurate. If the number of consumers is less than 60, this should be treated with caution and may not be representative for a large number of consumers.
b) Rounded to 2 significant figures

According to the consumption estimates, adults (19-64 years) are generally the highest consumers of oysters in the UK, this is for raw oysters (with or without the shell). However, consumption estimates made with a small number of consumers may not be accurate. If the number of consumers is less than 60, this should be treated with caution and may not be representative for a large number of consumers. While this may not give an accurate representation of how many oysters and how often adults may consume oysters, this does illustrate that much of the population do not regularly eat them.

This is supported by Wave Five (2019) of the Food and You consumer survey where fewer people reported eating fish and shellfish than meat and poultry (402). More respondents ate cooked or smoked fish (41%) at least once a week than cooked shellfish (10%), which 42% of respondents said they never ate at all. 90% of respondents reported never eating raw oysters. Those who did report eating raw oysters more often (for example, at least once a day or five to six times a week) were very few and fell into the two higher household income brackets (403) (404). The Food and You survey is a consumer survey commissioned by the FSA to provide evidence on consumers' self-reported food-related activities and attitudes. The survey has been running on a biennial basis since 2010. The findings from Wave five are based on 2,241 interviews from representative samples of adults aged 16 and over across England, Wales and NI (402). The information on fish and shellfish above is from Chapter one – Cooking, Shopping and Eating and is provided in table 1.6 of the report as well as in a summary within the report. Table 1.6 in the Food and You survey report provides information on the age group; household size, children under 16 in the household; children under six in the household; employment status and household income. The data is split into male, female and all adults and the interview for this chapter includes questions and multiple-choice answers detailed within the report (404).

### 9.1.2 Portion size

According to the Shellfish Association of GB, a typical serving of raw oysters is 100g. To put this into context, oysters produced in the UK are not usually harvested until they weigh 75g or more (405). Therefore, it is assumed that 75g is the approximate weight of each oyster with its shell, and that the 100g serving quoted above refers to

oysters without the shell. Recipes on various websites and menus from restaurants suggest that raw oysters are typically served in multiples of three. Often for recipes, the serving is three per person, and in many restaurants the minimum order is one oyster, and then increments of three and six (406, 407, 408, 409).

### 9.1.3 Consumer behaviour

The Seafish Seafood Consumption Market Insight Analysis 2022 quotes the Defra Family Food Dataset for Consumption in and Out of the Home (410) (411). It states that the latest data released in 2022 shows that in 2020, total seafood consumption was 162.8g per person per week, which is up by 1.0% from the previous year. The Defra dataset is two years in arrears. Table 16 is adapted from the Market Insight Analysis and presents the total UK Seafood consumption for 2018-2020.

Market insight information from the Seafish database did not provide information on shellfish separately, therefore it could not be used to determine consumer behaviour in regard to purchasing and consumption of oysters, in and out of the home (412).

Table 16: Adapted from Seafish Seafood Market Insight Analysis: Total UK Seafood Consumption 2018-2020 (410) (411)

| Type of consumption | 2018 | 2019 | 2020 | Percentage change (2019 vs. 2020) |
|---|---|---|---|---|
| **Seafood consumption in home (g)** | 138.5 | 145.7 | 148.0 | 1.6 |
| **Seafood consumption out of home (g)** | 14.3 | 15.6 | 15.0 | -4.3 |
| **Total seafood consumption (g/person/week)** | 152.8 | 161.3 | 163.0 | 1.0 |
| **Portions/ person/ week (140g portion)** | 1.1 | 1.2 | 1.2 | 1.0 |

However, the Defra Family Food Dataset for UK Household Purchases in 2020 – 2021, shows that only an average of 11g of shellfish were purchased per person, with 7g for fresh or chilled shellfish and 4g for frozen shellfish (411). Furthermore, according to the Defra Family Food Dataset for UK Eating Out Purchases in 2020-2021, no shellfish (defined as shellfish without sauce or dressing (for example, prawns, shrimps, oysters, crab)) was consumed on average. This is drop from other years where 1g was recorded (411).

# 10 International trade and production

The FAOSTAT website was reviewed for data on UK and global oyster production. Data was present but could not be analysed to establish specific outputs for this (413).

## 10.1 UK

### 10.1.1 UK imports of oysters

Import data from UK His Majesty's Revenue and Customs (HMRC) extracted from the FSA Trade Visualisation Dashboard (414) shows that between 2016 and 2022, the UK imported on average approximately 350,000 kg of oysters per year. There was an approximate decrease in imports of oysters to the UK of 5% during this time period, with approximately 380,000 kg in 2016 and 360,000 kg in 2022.

Within this period, the countries the UK most commonly imported oysters from were France, Ireland, The Netherlands, Republic of Korea and New Zealand. UK import data for oysters is presented in Table 17. This provides the weight of oysters in kg imported by the UK each year from any country between 2016 and 2022. The data was extracted from the FSA Trade Visualisation Dashboard and analysed to provide sum and average calculations. Raw data was sifted according to year and within each year, the different oyster categories were identified and the sum of each was recorded. The oyster categories in Table 17 are presented according to commodity code definitions.

Out of nine categories, imports were observed for six: 'Live, fresh or chilled: Flat oysters…' (03071110); 'Live, fresh or chilled: Other' (03071190); 'Frozen' (03071200); 'Other: Smoked, whether in shell or not…' (03071900); 'Frozen, dried, salted or in brine' (03071990); 'Prepared or preserved' (16055100).

However, for the 'Frozen' (03071200) and 'Other: Smoked, whether in shell or not…' (03071900) categories imports were only observed for years 2017 – 2022. For the 'Frozen, dried, salted or in brine' (03071990) category, imports were only recorded in 2016 and not for later years.

Finally, there were no UK imports recorded at all during the time frame for ‘Live flat oysters/ *Ostrea* spp.’ (03071010); ‘Live, fresh, chilled, frozen, dried, salted or in brine’ (03071090); ‘Smoked, even in shell, even cooked but not otherwise prepared’ (03071910) between 2016 and 2022.

The majority of oysters imported into the UK during this time period were processed. The highest imported oyster categories in total were prepared or preserved (16055100) (697,594 kg), followed by smoked, dried, salted or in brine (03071900) (621,416 kg). However, during the time period of 2016-2022, there were significant imports of frozen and fresh oysters.

The commodity codes and their full definitions used to extract UK HMRC import data from the FSA Trade Visualisation Dashboard (414) are listed in Table 32 in appendix 14.5. The government trade tariff website was also used to inform the definitions (415).

Table 17: Oysters imported into the UK in weight (kg) between 2016 and 2022 (414).

| **Oyster category (commodity code)** | **2016 (kg)** | **2017 (kg)** | **2018 (kg)** | **2019 (kg)** | **2020 (kg)** | **2021 (kg)** | **2022 (kg)** | **Total (kg)** |
|---|---|---|---|---|---|---|---|---|
| Live flat oysters/ *Ostrea* spp. (03071010) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Live, fresh, chilled, frozen, dried, salted or in brine (03071090) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Live, fresh or chilled: Flat oysters (of the genus *Ostrea*), live and weighing (shell included) not more than 40g each (03071110) | 32,584 | 10,411 | 10,887 | 3,813 | 1,388 | 24,113 | 7,143 | 90,339 |
| Live, fresh or chilled: Other (03071190) | 65,986 | 84,510 | 24,830 | 5,607 | 1,276 | 15,786 | 217,368 | 415,363 |
| Frozen (03071200) | 0 | 75,747 | 81,172 | 87,598 | 53,768 | 104,789 | 86,207 | 489,281 |
| Other: Smoked, whether in shell or not, whether or not cooked before or during the smoking process, not otherwise prepared and other (03071900) | 0 | 188,828 | 291,329 | 93,384 | 44,327 | 1,850 | 1,698 | 621,416 |
| Smoked, even in shell, even cooked but not otherwise prepared (03071910) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Frozen, dried, salted or in brine (03071990) | 128,736 | 0 | 0 | 0 | 0 | 0 | 0 | 128,736 |
| Prepared or preserved (16055100) | 151,920 | 26,181 | 32,087 | 37,967 | 39,156 | 363,406 | 46,877 | 697,594 |
| **Total (kg)** | 379,226 | 385,677 | 440,305 | 228,369 | 139,915 | 509,944 | 359,293 | 2,442,729 |

Table 18 presents the percentage growth of oyster imports to the UK between 2016 and 2022. The only oyster category where percentage growth in imports was observed, between the years 2016 and 2022 was 'Live, fresh or chilled: Other' (229%). Some categories were not imported at all between 2016 and 2022 ('Live flat oysters/ *Ostrea* spp.'; 'Live, fresh, chilled, frozen, dried, salted or in brine'; 'Smoked even in shell, even cooked but not otherwise prepared').

For two categories, there were imports recorded between 2016 and 2022 but none recorded in 2016 so the percentage growth could not be calculated. These are marked as 'NA' ('Frozen' and 'Other: Smoked whether in shell or not…').

Finally for all others, a decrease in imports was observed ('Live, fresh or chilled: Flat oysters…' (-78%); 'Frozen, dried, salted or in brine' (-100%); 'Prepared or preserved' (-69%)). Overall, a decrease of 5% in all oyster imports to the UK was observed between 2016 and 2022.

Table 18: Percentage growth in oyster imports to the UK between 2016 and 2022 (414)

| **Oyster category (commodity code)** | **Percentage [a, b, c] growth in imports between 2016 and 2022** |
|---|---|
| Live flat oysters/ *Ostrea* spp. (03071010) | 0% |
| Live, fresh, chilled, frozen, dried, salted or in brine (03071090) | 0% |
| Live, fresh or chilled: Flat oysters (of the genus *Ostrea*), live and weighing (shell included) not more than 40g each (03071110) | -78% |
| Live, fresh or chilled: Other (03071190) | 229% |
| Frozen (03071200) | NA |
| Other: Smoked, whether in shell or not, whether or not cooked before or during the smoking process, not otherwise prepared and other (03071900) | NA |
| Smoked, even in shell, even cooked but not otherwise prepared (03071910) | 0% |
| Frozen, dried, salted or in brine (03071990) | -100% |
| Prepared or preserved (16055100) | -69% |
| **Total** | -5% |

a) Rounded to whole numbers.
b) Negative percentages indicate where there was a decrease in imports as opposed to growth.
c) NA indicates where percentage growth could not be calculated because 0 imports were observed in 2016.

The top five countries from which the UK imported oysters between 2016 and 2022 is presented in Table 19 with weight of imports (kg) and percentage of total oyster imports also provided. These were France, Ireland, The Netherlands, Republic of Korea and New Zealand. Amongst these countries, Republic of Korea (1,138,217 kg (47%)) exported the most oysters, followed by France (861,730 kg (35%)). New Zealand (23,313 kg (0.95%)) exported the least oysters to the UK.

Table 19: Oyster imports from the top five countries exporting to the UK, in weight (kg) (414).

| **Country** | **2016 (kg) (%)** | **2017 (kg) (%)** | **2018 (kg) (%)** | **2019 (kg) (%)** | **2020 (kg) (%)** | **2021 (kg) (%)** | **2022 (kg) (%)** | **Total (kg) (%)** |
|---|---|---|---|---|---|---|---|---|
| France | 155,011 (41.0) | 184,838 (48.0) | 304,746 (69.0) | 61,452 (27.0) | 33,186 (24.0) | 21,614 (4.2) | 100,883 (28.0) | 861,730 (35.0) |
| Ireland | 79,280 (21.0) | 31,723 (8.2) | 17,448 (4.0) | 29,127 (13.0) | 1,207 (0.86) | 1,736 (0.34) | 114,025 (32.0) | 274,546 (11.0) |
| Netherlands | 14,877 (3.9) | 54,827 (14.0) | 11,313 (2.6) | 1,354 (0.59) | 193 (0.14) | 26,148 (5.1) | 3,256 (0.91) | 111,968 (4.6) |
| Republic of Korea | 126,672 (33.0) | 98,220 (26.0) | 104,606 (24.0) | 131,541 (58.0) | 91,158 (65.0) | 456,721 (90.0) | 129,299 (36.0) | 1,138,217 (47.0) |
| New Zealand | 3,300 (0.87) | 3,203 (0.83) | 2,005 (0.46) | 3,550 (1.6) | 6,625 (4.7) | 2,330 (0.46) | 2,300 (0.64) | 23,313 (0.95) |
| **Total (kg)** | 379,140 | 372,811 | 440,118 | 227,024 | 132,369 | 508,549 | 349,763 | 2,409,774 |

Table 20 shows the different categories of oysters imported to the UK from these top five exporting countries between 2016 and 2022. The most imported oyster category between 2016 and 2022 from these countries was ‘Prepared or preserved” (697,089kg), with the Republic of Korea exporting this category to the UK the most (506,682kg). This was followed by the ‘Other: Smoked, whether in shell or not…’ category (621,064kg), with France exporting the most of this category to the UK (513,469kg). Apart from where there were no imports, the least imported category was ‘Live, fresh or chilled: Flat oysters…’ (03071110) (85,965kg), with France exporting most of this to the UK (58,232kg). There were no imports of ‘Live flat oysters/ *Ostrea* spp.’ (03071010), ‘Live,

fresh, chilled, frozen, dried, salted or in brine' (03071090) or 'Smoked, even in shell, even cooked but not otherwise prepared' (03071910) from any of the top five countries exporting to the UK.

Table 20: Oyster categories from the top five countries exporting to the UK, in weight (kg), between 2016 and 2022 (414).

| **Oyster category (commodity code)** | **France (kg)** | **Ireland (kg)** | **Netherlands (kg)** | **Republic of Korea (kg)** | **New Zealand (kg)** | **Total (kg)** |
|---|---|---|---|---|---|---|
| Live flat oysters/ *Ostrea* spp. (03071010) | 0 | 0 | 0 | 0 | 0 | 0 |
| Live, fresh, chilled, frozen, dried, salted or in brine (03071090) | 0 | 0 | 0 | 0 | 0 | 0 |
| Live, fresh or chilled: Flat oysters (of the genus *Ostrea*), live and weighing (shell included) not more than 40g each (03071110) | 58,232 | 5,830 | 21,903 | 0 | 0 | 85,965 |
| Live, fresh or chilled: Other (03071190) | 137,155 | 181,628 | 80,095 | 0 | 205 | 399,083 |
| Frozen (03071200) | 1,795 | 1,219 | 9,231 | 464,506 | 1,130 | 477,881 |
| Other: Smoked, whether in shell or not, whether or not cooked before or during the smoking process, not otherwise prepared and other (03071900) | 513,469 | 47,280 | 0 | 41,637 | 18,678 | 621,064 |
| Smoked, even in shell, even cooked but not otherwise prepared (03071910) | 0 | 0 | 0 | 0 | 0 | 0 |
| Frozen, dried, salted or in brine (03071990) | 0 | 0 | 0 | 125,392 | 0 | 125,392 |
| Prepared or preserved (16055100) | 151,079 | 38,589 | 739 | 506,682 | 0 | 697,089 |
| **Total (kg)** | 861,730 | 274,546 | 111,968 | 1,138,217 | 23,313 | 2,406,474 |

### 10.1.2 UK oyster production

According to Seafish (a public body supporting the UK seafood industry), one of the key species of oysters farmed in the UK is the Pacific cupped oyster (*Crassostrea gigas*[14]*)*. Around 1,200 tonnes (1.2 million kg) of Pacific oysters are produced each year in the UK (416) (417).

In 2021, UK vessels landed a total of approximately 652,000 tonnes (652 million kg) of sea fish into the UK and abroad with a value of £921 million. Compared to 2020, this is a 5% increase in the quantity of sea fish landed and an 11% increase in value landed. The total quantity of shellfish landed in the UK in 2021 was 132,000 tonnes (132 million kg), about 20% of all seafood species landed in that year (418). UK vessels landed 258,000 tonnes (258 million kg) of fish abroad, which is approximately 36% of the total quantity (in weight) and 25% of the value of all fish landed by UK vessels. Additionally, 20,000 tonnes (20 million kg) of fish were landed into the UK by foreign vessels in 2021. There was a 48% decrease between 2020 and 2021 due to reduced access for foreign vessels into the UK waters, likely due to the Coronavirus pandemic. Of the total fish landed, 1,000 tonnes (1 million kg) were made up of shellfish (418).

Table 21 shows the weight of exports of oysters from the UK per year between 2016 and 2022. The top ten countries that the UK exports to are included in the table and the percentage weight per country compared to the total for the top ten countries is provided. The average across the period of 2016-2022 exported by the UK to all countries is approximately 1 million kg per year. Data was obtained from the Seafish Trade & Tariff Tool (419).

According to Table 21, between 2016 and 2022, the UK exported the most oysters to France (8,498,500 kg), followed by Ireland (2.2 million kg). In 2021, the UK exported the largest volume of oysters in total to all countries (2.3 million kg) in comparison to the other years.

[14] Also known more recently as *Magallana gigas*

Table 21: UK oyster exports between 2016 and 2022 (includes the ten countries the UK exports to the most) expressed as weight of oysters' exports (kg) and percentage weight (%) per country compared to the total for the top ten countries in brackets.

| **Country** | **2016 kg (%)** | **2017 (kg) (%)** | **2018 (kg) (%)** | **2019 (kg) (%)** | **2020 (kg) (%)** | **2021 (kg) (%)** | **2022 (kg) (%)** | **Total (kg) (%)** |
|---|---|---|---|---|---|---|---|---|
| France | 1,109,000 (63.7) | 1,027,000 (61.4) | 793,900 (55.8) | 676,600 (60.5) | 1,513,000 (90.8) | 2,054,000 (87.6) | 1,325,000 (91.4) | 8,498,500 (74.6) |
| Ireland | 490,000 (28.2) | 515,000 (30.8) | 440,900 (31.0) | 394,800 (35.3) | 121,000 (7.3) | 196,000 (8.4) | 68,000 (4.7) | 2,225,700 (19.5) |
| Spain | 97,000 (5.6) | 102,000 (6.1) | 74,700 (5.2) | 0 | 0 | 1,000 (0.0) | 4,000 (0.2) | 278,700 (2.4) |
| Hong Kong | 15,000 (0.8) | 439 (0.0) | 0 | 0 | 18,000 (1.1) | 17,000 (0.7) | 0 | 50,439 (0.4) |
| United Arab Emirates | 12,000 (0.7) | 14,000 (0.9) | 6,600 (0.5) | 9,000 (0.8) | 1,000 (0.1) | 409 (0.0) | 0 | 43,009 (0.4) |
| Germany | 7,000 (0.4) | 7,000 (0.4) | 8,200 (0.6) | 6,000 (0.5) | 1,000 (0.1) | 72,000 (3.1) | 463 (0.0) | 101,663 (0.9) |
| Malaysia | 4,000 (0.2) | 3,000 (0.2) | 2,800 (0.2) | 6,200 (0.6) | 0 | 0 | 0 | 16,000 (0.1) |
| Canada | 2,000 (0.1) | 0 | 0 | 0 | 0 | 0 | 295 (0.0) | 2,295 (0.0) |
| Portugal | 2,000 (0.1) | 1,000 (0.1) | 0 | 0 | 0 | 0 | 0 | 3,000 (0.0) |
| Malta | 1,000 (0.1) | 0 | 0 | 0 | 0 | 0 | 0 | 1,000 (0.0) |
| Singapore | 0 | 1,000 (0.0) | 2,700 (0.2) | 0 | 0 | 0 | 0 | 3,700 (0.0) |
| Barbados | 0 | 316 (0.0) | 0 | 0 | 0 | 0 | 259 (0.0) | 575 (0.0) |

| Country | 2016 kg (%) | 2017 (kg) (%) | 2018 (kg) (%) | 2019 (kg) (%) | 2020 (kg) (%) | 2021 (kg) (%) | 2022 (kg) (%) | Total (kg) (%) |
|---|---|---|---|---|---|---|---|---|
| Italy | 0 | 0 | 48,700 (3.4) | 2,100 (0.2) | 1,000 (0.0) | 0 | 0 | 51,800 (0.5) |
| Netherlands | 0 | 0 | 28,200 (2.0) | 4,100 (0.4) | 2,000 (0.1) | 0 | 5,000 (0.3) | 39,300 (0.3) |
| Taiwan | 0 | 0 | 10,200 (0.7) | 14,100 (1.3) | 6,000 (0.4) | 1,000 (0.1) | 2,000 (0.2) | 33,300 (0.3) |
| China | 0 | 0 | 0 | 1,900 (0.2) | 0 | 448 (0.0) | 0 | 2348 (0.0) |
| Gibraltar | 0 | 0 | 0 | 1,100 (0.1) | 0 | 0 | 0 | 1,100 (0.0) |
| Kuwait | 0 | 0 | 0 | 0 | 1,000 (0.0) | 0 | 0 | 1,000 (0.0) |
| South Korea | 0 | 0 | 0 | 0 | 276 (0.0) | 0 | 43,000 (3.0) | 43,276 (0.4) |
| Finland | 0 | 0 | 0 | 0 | 0 | 1,000 (0.0) | 0 | 1,000 (0.0) |
| Czech Republic | 0 | 0 | 0 | 0 | 0 | 464 (0.0) | 0 | 464 (0.0) |
| Qatar | 0 | 0 | 0 | 0 | 0 | 0 | 241 (0.0) | 241 (0.0) |
| **Total (kg) (%)** | 1,739,000 | 1,670,755 | 1,416,900 | 1,115,900 | 1,664,276 | 2,343,321 | 1,448,258 | 11,398,410 |

The FAOSTAT website was reviewed for data on UK oyster production. Data was present but could not be analysed to establish UK oyster production (413).

## 10.2 Global

### 10.2.1 Global oyster production

Table 22 presents the most popular oysters species produced globally.

Table 22: Global oyster production: popular oyster species (adapted from FAOSTAT - Fisheries and Aquaculture)(24)

| English name | Scientific name |
|---|---|
| Black lip pearl oyster | *Pinctada margaritifera* |
| Japanese pearl oyster | *Pinctada fucata* |
| Flat oysters | *Ostrea* spp. |
| Yaquina oyster | *Ostrea lurida* |
| Olympia oyster | *Ostrea conchaphila* |
| American cupped oyster | *Crassostrea virginica* |
| Hooded oyster | *Saccostrea cucullata* |
| Indian backwater oyster | *Crassostrea madrasensis* |
| Sydney cupped oyster | *Saccostrea glomerata* |
| Slipper cupped oyster | *Crassostrea iredalei* |
| Lugubrious cupped oyster | *Crassostrea belcheri* |
| Cortez oyster | *Crassostrea corteziensis* |
| Suminoe oyster | *Crassostrea rivularis* |
| Spiny rock oyster | *Saccostrea echinata* |

According to Botta *et al*. in a review article on global oyster aquaculture production and consumption, aquaculture production has grown over the past 50 years and is predicted to continue to flourish in order to meet the growing demand for seafood. Currently, aquaculture farming accounts for more than 50% of the world's fish food supply. According to FAOSTAT, molluscs, including oysters, are the second largest category of farmed seafood within aquaculture and accounted for 21% of all global aquaculture production in 2016 and within this category, oysters are the most produced species (12).

Oysters are one of the most popular species in aquaculture farming, due to their adaptability. They require no supplementary feed, medicines or chemicals during the grow-out phase (416). The majority of oyster species are located in marine and brackish areas, where water is shallow, thereby making it easy for them to be

farmed. According to Seafish (416), global oyster production in 2018 was around six billion kg and China produced 85% of this global figure. There are two distinct types of oysters used in aquaculture; the 'cupped' oyster (*Crassostrea/ Saccostrea* spp.) and the 'flat' oyster (*Ostreacea*): Cupped oyster species are genetically quite similar to each other and many geographically named oysters are the same species, for example, the Sydney rock oyster and the New Zealand rock oyster are *S. glomerata*; the Japanese/ Portuguese/Pacific oyster are *C. gigas*. Cupped oysters form the bulk of global oyster production and Pacific oysters include the main farmed species. Flat oysters have a much lower global production. Some species can be slower growing and less robust than the cupped oyster species, however they are often more highly prized gastronomically (416).

Table 23 presents the common oyster species produced globally, while Table 24 presents the top 15 oyster producing countries globally with the volume in weight (kg).

Table 23: Oyster species farmed globally (adapted from seafish.org) (416)

| **Species** | **Scientific name** | **Producer** |
|---|---|---|
| Pacific cupped oyster | *C. gigas* | China, Japan, Korea, Taiwan, Thailand, Australia, New Zealand, Malaysia, Canada, US, Mexico, France, Ireland, Netherlands, Channel Islands, UK, Spain, Portugal |
| European flat oyster | *Ostrea edulis* | France, Ireland, Netherlands, Channel Islands, UK, Spain, Portugal |
| Hooded oyster | *S. cuccullata* | Mauritius |
| Gasar cupped oyster | *Crassostrea gasar* | Senegal, Gambia |
| Cortez oyster | *C. corteziensis* | Mexico, Chile |
| American cupped oyster | *C. virginica* | US, Canada, Dominican Republic |
| Chilean flat oyster | *Ostrea chilensis* | Chile |
| Mangrove cupped oyster | *Crassostrea rhizophorae* | Cuba, Puerto Rico, Jamaica |
| Olympia oyster | *Ostreola conchaphila* | US |
| Indian backwater oyster | *C. madrasensis* | India, Sri Lanka |
| Slipper cupped oyster | *C. iredalei* | Philippines |
| Sydney rock oyster | *S. glomerata* | Australia |

Table 24: Global oyster production: key producers (countries) and volume in weight (kg) (2018) (adapted from seafish.org) (412)

| 15 largest oyster producers (2018) | Volume (kg) |
|---|---|
| China | 5,139,760,000 |
| Korea (Rep) | 303,200,000 |
| Japan | 176,000,000 |
| USA | 153,909,000 |
| France | 84,910,000 |
| Philippines | 28,708,000 |
| Indonesia | 24,863,000 |
| Taiwan | 22,035,000 |
| Thailand | 21,048,000 |
| Canada | 14,614,000 |
| Ireland | 10,369,000 |
| Australia | 6,558,000 |
| Mexico | 6,305,000 |
| India | 4,000,000 |
| UK | 2,325,000 |

### 10.2.2 Global oyster exports

Global export data was extracted from the UN Comtrade database (420). Commodity codes (and their definitions) used to extract global export data from the UN Comtrade database are listed Table 33 in appendix 14.6. To note, the commodity codes for extracting UN Comtrade data differ to those in the UK HMRC database because the Comtrade database only allows the use of six-digit codes. However, the same commodity groups are included. UN Comtrade data was extracted for 2016-2022 as this was the most complete dataset. This was for all countries included in Comtrade and has been analysed to determine the highest global exports of oysters. The top five global exporters of oysters are presented in Table 25 with weight of exports (kg) for each year between 2016 and 2022.

The top five countries exporting globally between 2016 and 2022 in the order of the highest trade volume were France (107 million kg), China (76 million kg), Republic of Korea (70 million kg)., Ireland (49 million kg) and Canada (29 million kg). They were also the countries among the 15 largest oyster producers in 2018 in section 10.2.1 (Table 24). In comparison with global oyster production, although France was the country with the fifth highest oyster production (85 million kg) in 2018, it exported the most oysters globally at 14 million kg for the same year. China and the Republic of Korea ranked first and second in terms of oyster production in 2018 respectively.

China exported 10 million kg and the Republic of Korea exported 11 million kg as the second and third countries, with the highest export volume behind France in 2018.

Some export figures may differ to production figures in terms of weight (in kg) due to self-reporting by countries within Comtrade and/ or due to import and re-export.

In comparison with UK oyster imports presented in section 10.1.1, France and Ireland were the two largest oyster exporters to the UK during 2016 – 2022, with trade volumes of 8.5 million kg (France) and 2.2 million kg (Ireland) respectively. The Republic of Korea, China and Canada also exported oysters to the UK, but at smaller volumes compared to France and Ireland. The Republic of Korea exported 43,276 kg, China exported 2,348 kg, and Canada exported 2,295 kg during this period.

Table 25: Oyster exports from the top five countries exporting globally, in weight (kg)

| **Top five countries** | **2016 (kg)*** | **2017 (kg)*** | **2018 (kg)*** | **2019 (kg)*** | **2020 (kg)*** | **2021 (kg)*** | **2022 (kg)*** | **Total (kg)*** |
|---|---|---|---|---|---|---|---|---|
| France | 15,109,747 | 14,227,844 | 13,798,248 | 14,290,191 | 11,896,897 | 17,312,826 | 20,389,567 | 107,025,320 |
| China | 16,713,202 | 13,862,802 | 10,602,275 | 7,513,960 | 95,28,396 | 9,228,114 | 8,530,032 | 75,978,780 |
| Republic of Korea | 8,291,165 | 9,157,930 | 11,067,022 | 11,143,777 | 9,635,824 | 10,849,347 | 9,378,418 | 69,523,481 |
| Ireland | 7,219,518 | 7,648,425 | 5,787,572 | 6,864,576 | 5,483,670 | 8,138,437 | 7,891,720 | 49,033,917 |
| Canada | 3,796,079 | 3,951,169 | 3,923,739 | 4,090,966 | 2,503,318 | 4,769,753 | 6,398,910 | 29,433,933 |

*Rounded to nearest whole number.

# 11 Uncertainty and knowledge gaps

The level of uncertainty was estimated according to the categorisation defined in the ACMSF report on risk representation (Table 26) (3). Justifications for the uncertainty assigned to each area of the risk profile are provided in Table 27.

Table 26: Categories of uncertainty defined in the ACMSF report on risk representation (3).

| Category | Definition |
|---|---|
| Low | There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions. |
| Medium | There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another. |
| High | There are scarce or no data; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them. |

Multiple knowledge gaps were identified during the review of information for this risk profile. All gaps were in areas regarding hazard characterisation. Control areas were very well defined, even where hazards are not well described, this is believed to be because the bioaccumulation via filter feeding is well understood. So, while the effects and other characteristics may not be well understood, prevention measures are likely to be applicable to multiple hazards. As well as the uncertainty and justification, Table 27 includes notes on identified knowledge gaps and discussion on potential impacts of this. Where appropriate, the impact of a knowledge gap is discussed as low, medium or high with some justification. This is based on expert judgment, taking into account the scope of this risk profile and the levels of uncertainty.

Table 27: Assessed level of uncertainty and justification for oyster risk profile, including impacts of knowledge gaps.

| Risk profile section/ information source | Notes on uncertainty (including impacts of knowledge gaps) | Uncertainty score |
|---|---|---|
| **Hazard identification** | Data in this category is predominantly from the seafood risk tool (SRT) for assessing and mitigating chemical and pathogen hazards in the aquaculture supply chain published in February 2022 by Stentiford *et al*. A review of other data sources did not identify any more recent data sources with a similar scope to the SRT but did identify nine hazard categories not noted within the SRT (*Y. enterocolitica; S. aureus; T. gondii; Microsporidia;* microplastics and nanoplastics; yessotoxin; pectenotoxin; cyclic imines; and HPV chemicals).<br>Manual literature review – subject to human error leading to missed information. Considered unlikely given the production and review of the SRT by multiple experts, the review of additional data sources by two analysts and the review of this risk profile by multiple experts. All known emerging hazards have been included, however, unknown emerging hazards cannot be ruled out.<br>The hazard list was refined before being carried forward to the section on hazard characterisation to remove any hazards of risk solely to animals and deemed to not be associated with oysters specifically or to pose a public health risk. Hazards also considered not to be specific to import (physical and allergen hazards) were also identified but not carried forward to hazard characterisation. This is not considered to add significant uncertainty because hazards not carried forwards are well-defined in literature and within international guidance and standards. The risk profile aims to characterise the risk of oysters in relation to public health, not animal health. Hazards associated with animal health alone are not within the remit of the FSA. Furthermore, as per the section on risk mitigation and management options, it is considered that many controls recommended are applicable to multiple hazards as they take into account the physiology of oysters and the production process. | Low |
| **Hazard characterisation** | See comments for hazard identification regarding the refinement of the hazard list.<br>The SRT was also used in this section to provide some scoring information around the control of hazards listed. However, this was not the main source of information. Literature for the UK or similar (EU, USA) and published more recently was prioritised for hazard characterisation where possible. In some cases, it was not possible to determine prevalence or severity. | Low |

| Risk profile section/ information source | Notes on uncertainty (including impacts of knowledge gaps) | Uncertainty score |
|---|---|---|
| | Some hazards were less well-defined. Information on POCs, veterinary pharmaceuticals, personal care products. microplastics and HPV chemicals were the least well defined as these areas are dependent on multiple variables such as the growing area, laws within the country of production for chemical usage, limited knowledge around health effects and outcomes and potentially infinite lists of chemical compounds which could be part of the hazard grouping. For instance, within POCs, microplastics and HPV chemicals, it was impossible to characterise all potential chemical compounds. Those which were identified in literature as either most commonly found or associated with oysters were included. These are often considered emerging hazards as they cover groups of chemicals which have not yet been fully defined and characterised. It should be borne in mind that these groups may continue to expand and that information around the toxicity and prevalence of the chemicals within them is likely to be dynamic and could become quickly out of date. The impact of the noted knowledge gaps regarding emerging hazards is considered low – medium. This risk profile includes comprehensive information on mitigation measures, many of which can be effective without full knowledge of emerging hazards. However, it is noted that additional research and continued monitoring will be required.<br>Most other hazards (microbiological hazards, biotoxin hazards) were well-defined. Limited information for these was usually within the context of prevalence. This was often due to geographical and seasonal changes (for example, HABs leading to presence of biotoxins) or lack of recorded data. Where possible information has been included, and where it was not found or was limited, this has also been recorded. Also, where possible, WHO estimates of DALYs have been included to indicate the prevalence of disease caused by the hazard. Where the WHO have not provided estimates for a hazard, it has been noted.<br>It was not possible to estimate the severity of disease for all hazards in the same way. It was possible to estimate severity for microbiological hazards. However, estimating severity for chemical hazards was not performed because it is more complex due to the dose-response relationship. In all cases, severity was provided in the context of the general population, although vulnerable groups have been noted. Where severity had not been provided by the ICMSF, it was estimated using literature or the expertise of the analyst. The impact of the noted knowledge gaps is considered low because it is still possible to define a hazard without severity, particularly in the | |

| Risk profile section/ information source | Notes on uncertainty (including impacts of knowledge gaps) | Uncertainty score |
|---|---|---|
| | case of chemicals. The scope of this risk profile is for risks associated with oysters and means to mitigate them where possible. It is not a full risk assessment.<br>Manual literature review – subject to human error leading to missed information. Considered unlikely given the production and review of the publications used and the review of this risk profile by multiple experts. | |
| **Risk mitigation and management options** | Information sources for this section include international guidance and standards which are widely supported and distributed. Mitigation measures and management options identified are considered to be effective and applicable in the context of a range of hazards.<br>It was difficult to determine exactly how well implemented these measures are in different regions by different states. Knowledge gaps and uncertainties regarding legislation and control are discussed below.<br>Poorly defined hazards are discussed under hazard characterisation above.<br>The impact of the noted knowledge gaps associated with risk mitigation measures is considered unknown but likely to be low. It is unclear what the impact of uncertainty and gaps in knowledge around emerging hazards may be on the effectiveness of risk mitigation and management options. However, it was noted that these options are largely based on a range of hazards and the physiology of LBMs, as well as being aimed at different areas of the supply chain. Hence, targeting the filter feeding nature of LBMs at different points in production, where most hazards exploit this physiology.<br>Manual literature review – subject to human error leading to missed information. Considered unlikely as international organisations are comprehensive and well-known. | Low |
| **Legislation and control** | Information on UK import, and domestic legislation was clear and available.<br>Similarly, to risk mitigation and management options, it was unclear to what extent states follow the international guidance via their legislation. Information on international legislation is largely self-reported by other countries and there are some gaps on what some countries report to be in place. It was also not possible to summarise the legislation of all countries globally.<br>The impact of the noted knowledge gaps is considered to be low given the scope of this risk profile is identify potential risk associated with oysters and mitigation measures available to mitigate them where possible. It was considered that while it may be unclear to what extent | Low |

| Risk profile section/ information source | Notes on uncertainty (including impacts of knowledge gaps) | Uncertainty score |
|---|---|---|
| | international legislation may be in line with guidance, that measures are in place within the UK import system to assess these countries and control products entering the UK.<br>Manual search – subject to human error leading to missed information. This is of more note for international legislation. | |
| **UK consumption patterns** | Chronic consumption estimates for oysters have been estimated using the DNSIYC and the NDNS for all age groups between four months and 95 years.<br>Consumption estimates made with a small number of consumers may not be accurate. If the number of consumers is less than 60, this should be treated with caution and may not be representative for a large number of consumers. In this case, all estimates were below 60.<br>There was some data on seafood consumption at home, but this was not specific to oysters.<br>The impact of the noted knowledge gaps is considered low-medium due to the gap in data around the behaviour for common consumers of oysters. The assumption is that they are likely to be consumed raw and there is some information on portion sizes. This is not a full risk assessment and so does not impact the scope of the risk profile in the same way as for a risk assessment where it would be important to estimate exposure. | Medium |
| **International trade and production** | UK HMRC data was pulled from the FSA Trade Visualisation Tool, it is considered a reliable and timely data source. This is updated on 16th of each month. There is a two-month time lag for example, January data would be updated on 16th March. Sometimes there may be a delay due to HRMC data availability. This is only relevant for the time period for which the data was pulled. Imports could be subject to significant change in a short space of time.<br>UN Comtrade data is for country of dispatch, not country of origin. In the analysis, it is assumed that all exports of a commodity from a country originated from that country, i.e., no re-exporting. Although data for both imports and exports are given, they are not symmetrical – i.e., the volume of a commodity that country A exports to country B often doesn't match the volume that country B imports from country A. In general, import data is more reliable and so has been used throughout the analysis. UN Comtrade is not fully up to date for all countries (not even up to 2020 for some). Although information up until 2022 has been provided. It is also self-reported and may be subject error. | Medium |

| Risk profile section/ information source | Notes on uncertainty (including impacts of knowledge gaps) | Uncertainty score |
|---|---|---|
| | The codes used in the analysis of HMRC data may be slightly different to the codes used in the analysis of UN Comtrade data for some commodities – so they are not directly comparable. (UN Comtrade commodity codes only went up to six digits, whereas HMRC data go up to eight digits). The same commodity groups were considered, however.<br>Data for UK production and exports are limited.<br>Data for the types of oysters produced in regard to exports by different countries is limited.<br>The impact of the noted knowledge gaps is considered low because the missing data is not considered to affect the scope of the risk profile significantly. It was possible to identify the risks and mitigation measures associated with oysters. It would be useful to understand the types of oysters and exports associated with different countries. However, it is considered that this information would be included in any market access request for export the UK and does not significantly impact the types of hazards requiring control. Risk mitigation and management options are aimed at a range of hazards and different areas of the supply chain and not specific types of oysters. Types of hazards may be relevant to geographical location, but this is considered in the hazard categorisation and the growing area controls included in the risk mitigation section. | |
| **Future considerations** | This is a short section to summarise what should be considered in the future in terms of continued monitoring of the risks associated with oysters. It is not intended to provide a comprehensive list but to summarise potential factors which may affect the hazards identified within the risk profile, and also emerging hazards. It is also not intended to predict the effects of these factors but to illustrate the necessity for continued review. It was difficult to predict future events and also to incorporate a large amount of related literature. There are likely to be knowledge gaps in these areas given they are emerging issues. However, much of the standards and guidance discussed in this risk profile are aimed at identifying changes in currently identified hazards and are also owned by international organisations which monitor emerging risks and update the guidance. | Medium |

# 12 Future considerations

This section discusses future considerations in the context of how the hazards associated with oysters may change in the future. It is not intended to provide a comprehensive list of emerging issues but to summarise the potential factors which may affect the hazards identified within this risk profile. It is also not intended to predict the effects of these factors or of the changes in risk, but to illustrate that the information and conclusions presented in this risk profile may need to be considered within the context of the timeframe it was produced. I.e., the necessity for continued review. A large literature review has not been performed for this section, but rather a short review to identify the main factors. The standards and guidance discussed within this risk profile (see section 7) should be consulted for additional recommendations on controls. These are aimed at identifying changes in currently identified hazards and monitoring them and are owned by international organisations which monitor emerging risks and update these standards and guidance.

## 12.1 Vulnerable population changes

There are certain groups of consumers that are considered to be more susceptible or 'vulnerable' to foodborne risks due to the status of their immune system, such as older people, young children, cancer patients, patients undergoing immunosuppressive or cytotoxic treatment, unborn and newly-delivered infants, pregnant women, diabetics, those with alcoholism and/ or alcoholic liver disease, those with a range of other conditions and people with allergies (421). Susceptible populations are increasing. For example, there is generally an increasing population in the UK with increasing numbers of children and pregnant women. Furthermore, there is an aging population due to increased life expectancy, the Office for National Statistics (ONS) predicts that in the UK in 50 years' time, that it is likely for there to be an additional 8.6 million people aged 65 years and over (422). Another example is that the estimated prevalence of individuals with diabetes is also expected to rise in the UK from 3.8 million (in 2019) to 5.5 million by 2030 and from 463 million to 578 million worldwide (423).

Section 9 of the risk profile reviews consumption data, evidence and data suggest that the consumption of oysters is predominantly from those aged between 16 and 64 in the higher income bracket. Evidence is somewhat inconclusive; therefore, any potential future risk analysis should consider the demographic of the population most likely to consume oysters, including changes to this demographic. Consideration of the vulnerable population may require additional detail given the potential expansion of this population who may be more susceptible to hazards associated with oyster consumption. Hazards within the scope of this risk profile are characterised fully in section 6, however severity is mostly in the context of the general population, although where important, vulnerable groups are noted. This may need further investigation in the future in terms of the demographic noted above, but also the types of hazards posing a risk. This area will remain dynamic. Additionally, controls may need to be altered.

### 12.2 Emerging hazards

Section 5 and 6 of the risk profile set out the hazard identification and characterisation. Hazards which may pose a risk to human health through consumption of oysters may change over time, as research and evidence emerges. For example, the evidence of the health effects of microplastics in isolation and the effects of microplastics as a vehicle for other contaminants is an emerging food safety consideration (29). The ‘vector effect’ of microplastics as a carrier of chemical and biological agents will need consideration in risk assessments as emerging evidence unfolds (424).

Microbiological risks require monitoring, including the emergence of new strains or altered pathogenicity of existing strains and changes to antimicrobial resistance. For example, *Vibrio* spp. pose an increased risk of infection for vulnerable groups and the pathogenesis of *Vibrio* spp. is an emerging topic of interest with recent evidence citing the ability of *Vibrio* spp. to acquire atypical virulence genes (425). Furthermore, viruses can adapt and change, for example in a 2016 paper titled ‘Human norovirus transmission and evolution in a changing world’, Graff *et al* cite the rapid rate of the genetic and antigenic evolution of circulating noroviruses which may affect pathogenesis (426). Less predictable factors are the emergence of new diseases

and viruses which may be driven by viral factors, animal host factors, environmental factors, and/or anthropogenic factors (427). This is a dynamic area and should remain under review. The list of hazards associated with oysters may change, requiring additional hazard identification, or additional information of noted hazards may be available, requiring additional hazard characterisation. Controls may need to be altered.

### 12.3 Climate change

The factors that contribute to changing risks are multifactorial, for example climate change, including increasing temperature, may have multiple effects on aquaculture but these are difficult to predict with certainty (428). It is well cited that increased sea temperatures act as a driver of oyster population changes. There is evidence that increased sea temperature leads to increased mortality of native oyster species which are more susceptible to changes in temperature allowing better survival of the invasive Pacific oyster species. This has been documented in Northern European waters (429).

Various elements of climate change can affect aquaculture and the oyster population; including rising temperatures, sea-level rises, ocean acidification, changes in rainfall patterns, changes in sea surface salinity and severe climatic events (430). Sea-level rises can result in coastal erosion, affecting coastal geomorphology and hydrodynamics. Increased precipitation and storm events may result in higher sediment loading in coastal areas, which may cause stress or physical damage to fish and shellfish. Stress can lower shellfish immunity making them more prone to disease (428). These factors mostly relate to issues around loss of production. An example of a public health risk is that flooding could increase sewage discharge into growing areas, or increased precipitation can increase POC concentrations and agricultural run-off (431). This could potentially lead to an increase in the prevalence of multiple hazard types including microbiological and chemical hazards present in sewage and agricultural run-off (for example, STEC; personal care products, veterinary pharmaceuticals), as well as naturally present chemical hazards such as heavy metals.

In terms of sea temperature, as many host-pathogen interactions are dependent on changes in the environment, a change in temperature can alter the likelihood of disease outbreaks, it is not fully understood how this will affect marine host-pathogen interactions (427). Increases in ocean temperature have been evidenced as increasing the abundance and distribution of HABs, and the uptake of toxins of molluscs, including oysters. HABs have become more common and there is a growing recognition of the role of climate change in the build-up of several HABs. Many HAB species are capable of producing biotoxins that concentrate in the tissues of bivalve shellfish and, when consumed by humans, can result in shellfish poisoning syndromes(432). The most common intoxications associated with toxin-contaminated bivalves include ASP, DSP and PSP, respectively. Bacterial pathogens present in waters may also change and increase with changing temperature, for example, V*ibrio* spp. have recently been identified for the first time in the UK at three sites with sea-surface temperatures above 18°C. These species were *V. rotiferianus* and *V. jasicida* and are considered animal pathogens, however an increase in the range of *Vibrio* spp. is a concern for potential presence of species pathogenic to humans and implications for the ecosystem, including issues around shellfish production (433). Environmental changes, including temperature increases, have been linked to enhanced disease expression, climate shifts can impair the immune response of a host and increase the frequency of disease. This is especially true for ectothermic organisms, such as shellfish (427).

Ocean acidification is a reduction in the pH of the ocean over an extended period of time caused primarily by uptake of carbon dioxide from the atmosphere (434). Ocean acidification poses a greater risk to bivalve shellfish compared to fish, as shell formation is inhibited by reduced carbonate availability in acidic waters. Bivalves are also poor acid-base regulators (428). This acidification affects the growth cycle of oysters, shell thickness and also reduces their immunity making them more prone to infections by *Vibrio* spp. (435).

Therefore, climate change may have a significant impact on the prevalence and types of hazards observed in oysters in different geographical locations. These areas should remain under review to determine if further hazard identification and characterisation are required. Additionally, if controls need to be altered.

## 12.4 Globalisation and changing human behaviour

The global population is predicted to increase from 7.3 billion to 8.5 billion by 2030, 9.7 billion by 2050 and exceed 11 billion by 2100 (436). Food production is expected to rise faster than the population due to the emergence of a larger proportion of people who have greater spending power and typically consume more animal protein than people with lower incomes (437). The rapid growth in seafood consumption has led to wild capture fisheries and aquaculture accounting for 50% of the worlds overall global animal production (1). Aquatic food plays an important role in both providing essential daily nutrition as well as generating substantial income for multinational companies trading in export markets (437).

While, seafood trade globally is generally increasing (438), less than 5% of total world bivalve mollusc production enters international markets; one of the lowest proportions in seafood trade. This is due to the nature of bivalve molluscs, which are highly perishable and considered a high-risk food. Section 10.2.2 illustrates that the top five countries exporting oysters globally between 2016 and 2022 in the order of the highest trade volume were France, China, Republic of Korea, Ireland and Canada. They are also among the 15 largest oyster producers in 2018, provided in section 10.2.1. It also illustrates an increasing trend in yearly exports for the top exporter, France, between 2016 and 2022, exporting approximately 15 million kg in 2016 and 20 million kg in 2022. Similarly, the Observatory of Economic Complexity (OEC) states that between 2020 and 2021 global exports of oysters grew by approximately 53% (439).

The SRT article also references an “increased reliance on protein arising from aquaculture in global diets”, from an article on ‘Aquatics foods to nourish nations’ by Golden *et al*, and ‘blue foods’[15] being cited as more sustainable. The SRT states that this should be placed into context with “the impact of mass global human migrations to coast zones” cited from an article on ‘Sea-level rise and human migration’ by Hauer *et al*. As well as the global pressures on water supply, quality of available

[15] Blue foods – aquatic foods.

water systems, and waste disposal cited from the UN World Water Development Report, 2017 (1) (440) (441) (442) (443).

Therefore, globalisation will be an important consideration when assessing the risk of hazards identified in the future. Also bearing in mind changes in human activities such as increased reliance on aquaculture which may lead to changes in production methods, movement to coastal areas which may lead to introduction of more or different hazards to the system and altered usage of water systems.

# 13 Conclusions

Generally, there are two main types of oysters used in aquaculture – the Pacific cupped oyster (*C. gigas* – now also referred to as *M. gigas*) and the European flat oyster (*O. edulis*). However, the key farmed oyster species are identified more specifically and discussed in section 10. The UK generally produces the Pacific cupped oyster, at approximately 1.2 million kg per year and exports approximately 1.6 million kg per year. A percentage of UK exports include oysters landed abroad, hence the difference in production vs. export. The UK imports approximately 350,000 kg of oyster per year, and where they are imported, they are more commonly processed (prepared or preserved; smoked; frozen), however there were significant imports of fresh oysters. The main exporters of oysters to the UK were (in the order of weight of import) the Republic of Korea, France and New Zealand between 2016 and 2022. Globally, France, China, Republic of Korea, Ireland and Canada were the highest exporters of oysters between 2016 and 2022 (in order of weight of export).

In terms of UK consumption, data was difficult to interpret. UK consumption surveys indicate that oysters are rarely eaten by the general population, which was supported by the FSA Food and You survey. Therefore, it was difficult to determine the demographic of those who may be higher consumers, how often they may eat them and what their portion sizes may be. However, it was possible to determine that that oysters are most commonly eaten raw and by groups in higher socio-economic classes from the results of the Food and You survey.

Many potential hazards have been identified in oysters, most of which are well-characterised and well known. Bivalve molluscs obtain food by filter feeding and so are bioaccumulators of diverse hazards from aquatic environments, hence these hazards have been identified across hazard groups including microbiological hazards and chemical hazards. The mostly likely illness occurring from the consumption of raw oysters would often be considered to be a microbiological hazard, for example norovirus and *Vibrio* spp., given the likelihood of raw consumption. However, other hazards include marine biotoxins resulting from HABs, for example, which are thermostable and so are unaffected by whether the

commodity is consumed raw or not. It is also clear that the potential for chemical hazard accumulation may be high, depending on the growing environment, and that the types of chemical hazard may be numerous.

Generally, severity of the microbiological hazards associated with oysters was considered low for the general population, although it is clear that severity could be higher for some of the characterised hazards and that susceptible individuals are likely to suffer from more severe illness for a number of the potential hazards. SRT impact scores generally provide an indication of where controls may reduce the impact of hazards and where this may be accrued along supply chain. It is recommended that the impacts set out for hazards within this risk profile are utilised to consider which controls should be further investigated to determine which may ensure safety of imports from specific countries of origin where some hazards may be of more concern. Where there is limited information on the impact of controls upon the hazard, it is recommended that these hazards are borne in mind when considering the country of origin, especially controls within a country where the hazard may be more prevalent.

International guidance on risk management mitigation measures is widely available and accepted. The UK itself has contributed to this guidance and works in line with it, as do other countries (see section 7). This guidance is based on mitigating risks associated with oysters via monitoring and includes steps at the growing phase (where oysters are farmed), harvesting, processing, transport and retail. Guidance for each of these areas is comprehensively provided mostly via the FAO Technical Guidance for the Development of the Growing Area Aspects of Bivalve Mollusc Sanitation Programmes. Additional guidance and standards set out for the latter parts of the supply chain were predominantly via CODEX standards, most of which are referred to within the SRT. EU legislation is also quoted and considered in line with this guidance. The FAO and CODEX guidance, and EU legislation were set out within the SRT within an RMM applied to the LBM scenario. It is clear that these internationally accepted measures reduce the risk in multiple areas of the supply chain. The conclusions drawn from interpretation of the SRT analysis suggest that measures applied early on the in the supply chain, i.e., at the point of growing area selection and management, will reduce the impact of the hazard in the latter phases.

And therefore, in many cases, reduce the requirement for additional control measures outside of the general hygiene measures set out in CODEX guidance. There are, however, options for when the growing area is under a classification that is not ideal for risk mitigation, such as depuration and short-term relay of oysters from Class B waters.

The guidance set out here has been used to create a proposed checklist for auditors. This is not an exhaustive list of all points to be considered by UK auditors and is not intended to replace any current checklists or programs used by UK auditors. It is intended as an additional information point to aid the efficiency of auditing when considering oysters specifically.

GB import legislation is currently in line with that of the EU due to REUL, this may be subject to change after the time of writing. GB domestic legislation on oyster production demonstrates the compliance of GB with international guidance and standards set out under risk mitigation and management options. It was not possible to summarise the legislation for all countries globally, however, for the countries selected, legislation was comparable in all circumstances, although information for China was more limited. It was self-reported and therefore difficult to determine exactly to what extent countries follow international guidance and standards. It is recommended that the legislation for countries seeking to import into the UK is reviewed to ascertain if it is comparable to the best practice established within FAO and CODEX guidance and standards.

Overall, it is clear that oysters are a high-risk product for import, particularly for certain population groups, given their physiology and likelihood for raw consumption, but that measures are available to mitigate the risk in many cases. However, risk mitigation is variable, depending on the hazard of concern. Notably, there are a number of emerging chemical hazards which are less well-defined and/ or may comprise a vast hazard group which is not fully characterised and continues to expand (microplastics, POCs, veterinary pharmaceuticals and personal care products, HPV chemicals). Furthermore, marine biotoxin hazards cannot be controlled after accumulation within the commodity except for the removal of the commodity from the supply chain because purification techniques will not remove

them. Mitigation measures for biotoxins must be in place very early on during the supply chain, i.e., at the stage of selecting and monitoring growing areas. Relaying methods may be used but must be implemented before harvest and will require a long period of time to sufficiently show a decrease in biotoxin levels in the commodity, allowing safe harvest.

Information on future considerations regarding hazards associated with oysters, including vulnerable population changes, emerging hazards, climate change, globalisation of the seafood trade and changes in human behaviour was reviewed. These could have a significant effect on the types and prevalence of hazards observed in oysters, but also their potential effects on the population. This review is not intended to provide a comprehensive list but to summarise potential factors which may affect the hazards identified within the risk profile, and also emerging hazards. It is also not intended to predict the effects of these factors but to illustrate the necessity for continued review. It is difficult to predict future events and also to incorporate a large amount of related literature. There are likely to be knowledge gaps in these areas given they are emerging issues. However, many of the standards and guidance discussed in this risk profile are aimed at identifying changes in currently identified hazards and monitoring them, they are also owned by international organisations which monitor emerging risks and update the documents. It is recommended that these areas are monitored by risk assessors and risk managers for emerging risks, including emerging hazards, an increase in the vulnerable population and effects of climate change and globalisation on the spread of hazards. Also, that the guidance and standards provided are reviewed to ensure that updates are considered.

In the context of importing into the UK, measures in place in the country of origin should be investigated, with reference to the international guidance and standards and UK import legislation set out in this risk profile, to estimate the relative safety of the product from that specific country. If these initial investigations do not provide clarity, or indicate a concern, a full country audit and/ or full import risk assessment should be instigated to gather further information and/or to estimate the risk associated specifically with oysters from a country of origin in order to ensure safety of imports into the UK.

# 14 Appendix

## 14.1 Glossary

Table 28: Glossary of terms and acronyms

| Acronym/ abbreviation | Definition |
|---|---|
| **ACMSF** | Advisory Committee on the Microbiological Safety of Food |
| **AH** | Animal health hazard |
| **AIDS** | Acquired Immunodeficiency Syndrome |
| **Allergen** | An otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, a protein found in food capable of triggering a response in individuals sensitised to it (444). |
| **AMPA** | α-amino-3-hydroxy-5-methyl-4-isoxazolepropionate |
| **ANSES** | French Agency for Food Environmental and Occupational Health and Safety |
| **APQSL** | Agricultural Product Quality Safety Law (China) |
| **AQSIQ** | General Administration of Quality Supervision Inspection and Quarantine (China) |
| **ARfD** | Acute Reference Dose |
| **ASP** | Amnesic Shellfish Poisoning |
| **AZA** | Azaspiracid |
| **AZP** | Azaspiracid shellfish poisoning |
| **Bacteria** | Small single-celled organisms. Found almost everywhere on Earth and vital to the planet's ecosystems. Some species can live under extreme conditions of temperature and pressure. |
| **BAP** | Best Agricultural Practice |
| **BBP** | Benzyl butyl phthalate |
| **Blue foods** | Aquatic foods |
| **$BMDL_{01}$** | Benchmark Dose Level associated with 1% extra risk of adverse effect. The BMDL is the lower confidence limit and is regarded as a dose where the observable physical effect is less than the predetermined benchmark response. |
| **BT** | Benzothiazole |
| **BTR** | Benzotriazole |
| **BTX** | Brevetoxin |
| **BUVS** | UV light stabiliser |
| **bw** | Body weight |

| Acronym/ abbreviation | Definition |
|---|---|
| **CAC** | The CODEX Alimentarius Commission is the central part of the join FAO/ WHO Food Standards programme and was established by the FAO and WHO (445). |
| **cAMP** | Cyclic adenosine monophosphate |
| **CCFICS** | CODEX Committee on Food Import and Export Inspection and Certification Systems |
| **CCP** | Critical Control Point |
| **CDC** | Centre for Disease Control and Prevention (US) |
| **CDS** | Catch documentation scheme |
| **Cefas** | Centre for Environment Fisheries and Aquaculture Science (UK) |
| **CFDA** | China Food and Drug Administration |
| **CFIA** | Canadian Food Inspection Agency |
| **CFUs** | Colony Forming Units |
| **cGMP** | Cyclic guanosine monophosphate |
| **CH (Chemical hazard)** | Substances with the potential to cause adverse health effects that either occur naturally or are added during food production or handling (446). |
| **Cl-OPE** | Chlorinated-OPEs |
| **CIs** | Cyclic Imines |
| **CODEX** | The CODEX Alimentarius is an international set of food standards, guidelines and codes of practice, adopted by the CAC, which aim to contribute to the safety, quality and fairness of the international food trade. |
| **CONTAM Panel** | The Panel on Contaminants in the Food Chain (EFSA) |
| **CRA** | Chemical Risk Assessment team (FSA) |
| **CSSP** | Canadian Shellfish Sanitation Program |
| **DA** | Domoic acid |
| **DAEC** | Diffusely adherent *E. coli* |
| **DAFF** | Department of Fisheries Agriculture, Fisheries and Forestry (Australia) |
| **DALY** | Disability Adjusted Life Years – a measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. |
| **DBP** | Dibutyl phthalate |
| **Defra family food datasets** | Detailed annual statistics on family food and drink purchases in the UK |
| **DEHP** | Di(2-ethylhexyl) phthalate |
| **DEP** | Diethyl phthalate |
| **Depuration** | A process whereby shellfish are treated to purge bioaccumulated contaminants (305). |
| **DFO** | Fisheries and Oceans Canada |

| Acronym/ abbreviation | Definition |
|---|---|
| **DG SANTE** | Directorate General for Health and Food Safety (EC) |
| **Diastereoisomer** | Also spelled diasteromer, either member of a pair of substances that differ with respect to the configurations of their molecules (i.e., stereoisomers) and that lack a mirror-image relationship (i.e., are not enantiomers). |
| **DMP** | Dimethyl phthalate |
| **DNA** | Deoxyribonucleic Acid |
| **DnBP** | Di-n-butyl phthalate |
| **DNOP** | Di-n-octyl phthalate |
| **DNSIYC** | Diet and Nutrition Survey of Infants and Young Children (UK) |
| **DSP** | Diarrhoeic Shellfish Poisoning |
| **dw** | Dry weight |
| **EAEC** | Enteroaggregative *E. coli* |
| **EAT** | Exposure Assessment Team (FSA) |
| **EC** | European Commission |
| **EDA** | Economic Development Agency (South Australia) |
| **EDCs** | Endocrine Disrupting Compounds |
| **EEC** | European Economic Community |
| **EFSA** | European Food Safety Authority |
| **EHC** | Export Health Certificate |
| **EHEC** | Enterohemorrhagic *E. coli* |
| **EIEC** | Enteroinvasive *E. coli* |
| **ECCC** | Environment and Climate Change Canada |
| **EPEC** | Enteropathogenic *E. coli* |
| **Epi-DA** | Diastereoisomer of DA |
| **ER** | Oestrogen receptor |
| **ETEC** | Enterotoxigenic *E. coli* |
| **EU** | European Union |
| **FAO** | Food and Agricultural Organisation of the United Nations |
| **FAOSTAT** | FAOSTAT provides free access to food and agriculture data for over 245 countries and territories and covers all FAO regional groupings. from 1961 to the most recent year available. |
| **FBO** | Food Business Operator |
| **FDA** | Food and Drugs Administration (US) |
| **Food and You Survey** | A biennial survey performed by the FSA to explore the UK public's attitudes, reported knowledge and behaviour relating to food safety and production |
| **Foodborne disease** | Foodborne diseases are caused by contamination of food and occur at any stage of the food production, delivery and consumption |

| Acronym/ abbreviation | Definition |
|---|---|
| | chain. They can result from several forms of environmental contamination including pollution in water, soil or air, as well as unsafe food storage and processing (447). |
| **FSA** | Food Standard Agency (UK) |
| **FSA (Japan)** | Food Sanitation Act (Japan) |
| **FSANZ** | Food Standards Australia and New Zealand |
| **FSMS** | Food Safety Management System |
| **FSS** | Food Standards Scotland |
| **GAA** | Global Aquaculture Alliance |
| **GAC** | General Administration of Customs (China) |
| **GB** | Great Britain – England, Scotland, Wales |
| **GBS** | Guillain-Barré syndrome |
| **GBq** | Giga-Becquerel (unit of radioactivity) |
| **GHP** | Good Hygiene Practices |
| **GI** | Gastrointestinal |
| **GP** | General Practitioner/ General Practice |
| **GS1** | International organisation developing and maintaining barcodes and the corresponding issue company prefixes– China branch |
| **GYM** | Gymnodimine |
| **HABs** | Harmful Algal Blooms |
| **HACCP** | Hazard Analysis Critical Control Point |
| **HAV** | Hepatitis A Virus |
| **Hazard** | A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (448). |
| **Hazard characterisation** | The qualitative and/ or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food (449). |
| **Hazard identification** | The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or groups of foods (449). |
| **HBGV** | Health Based Guidance Value |
| **HC** | Health Canada |
| **Heavy metal** | Heavy metals are defined as metallic elements that have a relatively high density compared to water (450). |
| **HEV** | Hepatitis E Virus |
| **HH** | Human health hazard |
| **HIV** | Human Immunodeficiency Virus |
| **HMRC** | His Majesty's Revenue and Customs (UK) |
| **HPV chemical** | Defined by the OECD as chemicals with a production of over 1000 tonnes/ year and by the |

| Acronym/ abbreviation | Definition |
|---|---|
| | US EPA as compounds produced at a minimum of 500 tonnes/ year (262). |
| **HRT** | Hormone Replacement Therapy |
| **HUS** | Haemolytic-uraemic syndrome |
| **IARC** | International Agency for Research on Cancer |
| **ICMSF** | International Commission on Microbiological Specifications for Foods |
| **IID/ IID2** | Infectious intestinal disease (IID2 = Longitudinal study of infectious intestinal disease in the UK (IID2 study)) |
| **IOC** | Intergovernmental Oceanographic Commission |
| **IRL** | Interim Reference Level |
| **ISO** | International Organisation for Standardisation |
| **ISSC** | Interstate Shellfish Sanitation Conference (US) |
| **LBM** | Live Bivalve Molluscs |
| **LHA** | Local Health Authorities (UK) |
| **LOAEL** | Lowest observed adverse effect level |
| **LOD** | Limit of Detection |
| **LOQ** | Limit of Quantification |
| **MAFF** | Ministry of Agriculture Forestry and Fisheries (Japan) |
| **MGA** | Melengestrol acetate |
| **Microbiological hazard** | Occur when food is contaminated with microorganisms. This hazard group includes bacteria, viruses, parasites and prions (451). |
| **Microplastics** | Small pieces of plastic, less than 5 mm (0.2 inch) in length, that occur in the environment as a consequence of plastic pollution. |
| **ML** | Maximum Level |
| **MOFCOM** | Ministry of Commerce (China) |
| **MOU** | Memoranda of Understanding |
| **MPI** | Ministry for Primary Industries (New Zealand) |
| **MPL** | Maximum Permissible Level |
| **MPN** | Most Probable Number |
| **MRA** | Microbiological Risk Assessment team (FSA) |
| **MRL** | Maximum Residue Level |
| **MRSA** | Methicillin-resistant *S. aureus* |
| **MSC** | Male Specific Coliphage |
| **MSSA** | Methicillin-susceptible *S. aureus* |
| **Natural biotoxin hazards** | Toxic compounds naturally produced by living organisms. Not harmful to the organism itself but may be toxic to others. Diverse structures, biological functions and toxicity. Include aquatic biotoxins, phytotoxins (produced by plants), mycotoxins, bacterial toxins (452). |
| **NBP** | National Biosecurity Plan |
| **NDNS** | National Diet and Nutrition Survey (UK) |

| Acronym/ abbreviation | Definition |
|---|---|
| **NI** | Northern Ireland |
| **NOAA** | National Oceanic and Atmospheric Administration (US) |
| **NOAEL** | No observed adverse effect level |
| **non-NMDA** | Non-N-methyl-D-aspartate |
| **NoV** | Norovirus |
| **NP** | Nanoplastics - most recently defined as particles of a size between 1 and 1000nm which result mainly from degradation of larger plastic particles. |
| **NPC** | National People's Congress (China) |
| **NRL** | National Reference Laboratory |
| **NSAID** | Nonsteroidal anti-inflammatory drug |
| **NSP** | Neurological Shellfish Poisoning |
| **NSSP** | National Shellfish Sanitation Program |
| **NTS** | Non-typhoidal Salmonella |
| **OA** | Okadaic acid |
| **OCD** | Obsessive Compulsive Disorder |
| **OEC** | Observatory of Economic Complexity |
| **OECD** | Organisation for Economic Cooperation and Development |
| **OPE** | Organophosphate ester |
| **PAE** | Phthalate ester |
| **Parasite** | An animal or plant that lives in or on another animal or plant and gets food or protection from it (453). |
| **Personal care products** | Cosmetic, medicinal or recreational products and drugs used by humans (1). |
| **PFAS** | Perfluoroalkyl and Polyfluoroalkyl Substances |
| **PIRSA** | Department of Primary Industries and Regions South Australia |
| **PITX** | Palytoxin |
| **PMP-AB** | Progressive Management Pathway for Aquaculture Biosecurity |
| **POAO** | Products of Animal Origin |
| **POC/ POP** | Persistent Organic Chemicals / Persistent Organic Pollutants |
| **ppt** | Parts per thousand |
| **PRC** | Peoples Republic of China |
| **PTMI** | Provisional Tolerable Monthly Intake |
| **PTSD** | Post-traumatic stress disorder |
| **PTX** | Pectenotoxin |
| **Radioactive isotopes** | Isotopes of a particular atom retain the same chemical properties but have different masses (454). |
| **Radiological contaminant** | Undesirable radioactive material (with a potentially harmful effect) that is either airborne |

| Acronym/ abbreviation | Definition |
|---|---|
| | or deposited in (or on the surface of) structures, objects, soil, water, or living organisms (people, animals, or plants) in a concentration that may harm people, equipment, or the environment (455). |
| **REUL** | Retained EU Law |
| **Risk** | A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (449) . |
| **RMM** | Risk Mitigation Matrix |
| **RNA** | Ribonucleic Acid |
| **RTE** | Ready to eat (foods) |
| **SA Health** | South Australia Food and Controlled Drugs Branch |
| **SASQAP** | South Australian Shellfish Quality Assurance Program |
| **Seafish** | A public body supporting the UK seafood sector |
| **Severity of detriments** | A qualitative scale for the severity of detriments of foodborne risks derived by the ICMSF to define the severity impact of foodborne illness. |
| **SFCR** | Safe Food for Canadians Regulations |
| **SM** | Shellfish meat (used in EFSA opinion) |
| **SPA** | Synthetic phenolic antioxidant |
| **Spp.** | Plural of species, indicates several species. |
| **SPS** | Sanitary and Phytosanitary |
| **SPX** | Spirolides |
| **SRT** | Seafood Risk Tool |
| **SSRI** | Selective serotonin reuptake inhibitor |
| **STEC** | Shiga-toxigenic *E. coli* |
| **STX** | Saxitoxin |
| **TBRA** | Trenbolone acetate |
| **TCDD** | 2,3,7,8- tetrachlorodibenzo para dioxin |
| **TCEP** | Tris(2-carboxyethyl) phosphine hydrochloride |
| **TCiPP** | Tris-(chloroisopropyl) phosphate |
| **TCPP** | Tris (chloroisopropyl) phosphate |
| **TDCiPP** | Tris-1,3-dichloro-isopropyl |
| **TDH** | Thermostable Direct Haemolysin |
| **TDI** | Tolerable Daily Intake |
| **Teagasc** | Irish Agriculture and Food Development Authority |
| **TEF** | Toxic Equivalency Factor |
| **TnBP** | Tri-n-butyl phosphate |
| **TPhP** | Tri-phenyl phosphate |
| **TRH** | TDH – related haemolysin |
| **TTR** | Methylated tolyltriazoles |
| **TTX** | Tetrodotoxin |
| **UK** | United Kingdom – GB and NI. |

| Acronym/ abbreviation | Definition |
|---|---|
| **UKOSPSTA** | UK Office for Sanitary and Phytosanitary Trade Assurance |
| **UN** | United Nations |
| **UN Comtrade** | Aggregates detailed global annual and monthly trade statistics by product and trading partner for use by governments, academia, research institutes, and enterprises. Data compiled by the UN Statistics Division covers approximately 200 countries and represents more than 99% of the world's merchandise trade. |
| **US EPA** | United States Environmental Protection Agency |
| **USA** | United States of America |
| **USCO** | US Codex Office |
| **USDA** | US Department of Agriculture |
| **USNSSP** | United States National Shellfish Sanitation Program |
| **UV** | Ultraviolet |
| **Veterinary pharmaceutical** | Veterinary medicines and other chemicals widely used in aquaculture to treat disease as anaesthetics, and to manipulate physiology and immunity of stock (1). Any substance or combination of substances presented as having properties for treating or preventing disease in animals. Or any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis (456). |
| **Virus** | An infectious microbe consisting of a segment of nucleic acid (either DNA or RNA) surrounded by a protein coat. Cannot replicate alone; it must infect cells and use components of the host cell to make copies of itself (457). |
| **VISA** | Vancomycin-intermediate *S. aureus* |
| **VRSA** | Vancomycin-resistant *S. aureus* |
| **WHO** | World Health Organisation |
| **WOAH** | World Organisation for Animal Health |
| **WTO** | World Trade Organisation |
| **XTR** | Xylyl triazole |
| **YTX** | Yessotoxin |
| **ZEA** | Zearalenone |

## 14.2 Full hazard list from the SRT

The SRT is generalised for aquatic animals, so in some cases the hazards listed (and information provided for them) is applicable to aquatic species which are not oysters, or even LBMs (1). In most cases, the hazards and information provided are applicable to oysters, and where possible additional data sources have been used to show this. Table 29 also includes AH deemed to affect the supply chain but not human health, which are not with the scope of this risk profile because it considers hazards which may pose a public health risk.

Table 29: Adapted from "A seafood risk tool for assessing and mitigating chemical and pathogen hazards in the aquaculture supply chain": Hazard categories, types and examples of hazards with the potential to interact with, and impact, oysters in the supply chain (1)

| Hazard category | Hazard type | Example hazard | Source, interaction with oysters and potential for impact [a] |
|---|---|---|---|
| **Chemical (CH)** | CH1: Heavy metals | Cadmium, mercury, lead, zinc and copper. | A range of natural or anthropogenic sources with potential to bioaccumulate and biomagnifying. There is direct impact of heavy metals on survival, growth and development of early life stages of a wide range of aquatic animals (458) (459), including oysters. There is potential to impact human health via consumption (460) (461). |
| | CH2: persistent organic chemicals (POCs) | Dioxins, furans, polychlorinated Biphenyls (PCBs), perfluorinated Compounds (PFCs), polybrominated diphenyl ethers (PBDEs), polycyclic aromatic hydrocarbons (PAHs) and a range of emerging contaminants. | Contaminants of aquatic environments and animals which are persistent. Can bioaccumulate and biomagnify in seafood. Dioxins, furans and PCBs are readily absorbed via the human intestine and pass to infants via breastmilk (462). Natural and anthropogenic PAHs are genotoxic, immunotoxic and carcinogenic (463). Contaminants of aquatic environments and animals which are persistent. Can bioaccumulate and biomagnify in seafood. Dioxins, furans and PCBs are readily absorbed via the human intestine and pass to infants via breastmilk (462). Natural and anthropogenic |

| Hazard category | Hazard type | Example hazard | Source, interaction with oysters and potential for impact [a] |
|---|---|---|---|
| | | | PAHs are genotoxic, immunotoxic and carcinogenic (463). Polybrominated compounds, like PBDEs, are neurotoxic and cause endocrine disruption (464). PFCs invoke developmental toxicity (465). Potential for additive 'mixture' effects of multiple persistent organic chemicals (464). Seafood source location important when assessing risk of human exposure (466). Indirect effects on growth, development and survival of aquatic animals, including oysters, is likely (467) |
| | CH3: radiological contaminants | Radioactive isotopes, in particular strontium-90, caesium-137, plutonium isotopes and naturally occurring radioactive elements, such as radium-226 and polonium-210. | Levels of radioactivity from anthropogenic and natural sources present in seafood are generally extremely low with no direct legislation prescribing safety limits. Instead, specific legislation is based on radiological risk assessments, particularly where nuclear accidents or emergencies occur, and then regional regulations may be enforced (for example, Council Regulation (Euratom) 2016/52) (468). There is legislation detailing maximum permitted levels of radionuclides in seafood activated, potentially accumulating in seafood and impacting trade, an example is from the Fukushima incident (469). Chronic radiation exposure (well above normal background levels) can impact reproduction and early life stages of aquatic animals (470) (471), including oysters. |
| | CH4: natural biotoxins | Paralytic shellfish poisoning (PSP), amnesic shellfish poisoning (ASP), diarrhetic shellfish poisoning (DSP), ciguatera, palytoxin and tetrodotoxin. | Produced by certain microalgae and bacteria in freshwaters and open oceans. Phycotoxins, for example, PSP, bioaccumulate in filter-feeding hosts and biomagnify. Acute risk to human consumers predominantly via consumption of contaminated molluscs—most phycotoxins are thermostable, resisting cooking (472). Poisoning by other toxins, for example, ciguatoxin, are linked to consumption of high-trophic-level carnivorous fish (473). Emerging toxins, for example, tetrodotoxin, occurring in specific fish hosts.(472). Some indirect effects of biotoxins on health of farmed fish stocks occur. |

| Hazard category | Hazard type | Example hazard | Source, interaction with oysters and potential for impact [a] |
|---|---|---|---|
| | CH5: veterinary pharmaceutical and personal care chemicals | Antibiotics, ibuprofen, recreational drugs, sertraline, tamoxifen, salicylic acid and a range of emerging contaminants. | Veterinary medicines and other chemicals are often used (including illegally) in aquaculture to treat disease, as anaesthetics, and to manipulate physiology and immunity of stock. Residues can reside in edible components of seafood, with potential to impact human health. Antibiotics use and misuse can drive emergence of antimicrobial resistant (AMR) microbes, some of which may impact health of seafood consumers (474). Pharmaceutical and personal care products (PPCPs) enter waterways and accumulate in edible components of seafood (475), including oysters. Impacts are probably greatest where seafood arises from production in high-population-density urbanised waterways, including effects of human medicines and personal care chemicals on health of aquatic animals (476) (477). Complex mixture effects are likely, though there is limited information available on this. |
| | CH6: allergens | Tropomyosin, troponin C, arginine kinase, β-parvalbumin, histamine and other natural allergens. | Seafood allergy is a hypersensitivity disorder caused by numerous natural and spoilage-related elements present in fish and shellfish. Prevalence is increasing due to increasing seafood consumption, though misdiagnosis is frequent (478). Common allergens are parvalbumin, tropomyosin and other proteins/peptides in fish and shellfish muscles. Histamine fish poisoning is a common seafood-borne disease associated with consumption of spoiled oily fish (for example, tuna) where muscle histidine is converted to histamine by bacterial histidine decarboxylase. Cooking destroys the bacteria but not the histamine (479).<br>Allergens are natural components of fish and shellfish tissues; thus, impacts are not associated with production phases of seafood. |
| **Animal pathogens (AH)** | AH1: viral pathogens | Tilapia lake virus, white spot syndrome virus, oyster herpesvirus, infectious salmon anaemia virus, | Taxonomically diverse DNA and RNA viral pathogens impacting health and survival of many wild and farmed seafood species. Originating in wildlife, viruses transmit efficiently within and |

| Hazard category | Hazard type | Example hazard | Source, interaction with oysters and potential for impact [a] |
|---|---|---|---|
| | | infection pancreatic necrosis virus, pilchard orthomyxovirus and novel emergent pathogens. | between wild populations and captive stock, and emergence of novel pathogens is common. Viruses may be translocated between farms and regions as well as via global trade of live animals and fresh or frozen products, those with the greatest impact potentially becoming notifiable to the WOAH (480). Catastrophic production losses are reported in early-life and grow-out phases in aquaculture and in wild stocks. Viral pathogens reported in seafood species so far are not considered to be hazardous to human health. Novel technologies are revealing aquatic virus hyperdiversity, some of which may be linked to eventual emergence of pathogenic conditions in hosts. |
| | AH2: bacterial pathogens | *Vibrio*, *Aeromonas*, *Flavobacterium*, *Pseudomonas*, *Streptococcus*, *Lactococcus*, *Mycobacterium*, obligate intracellular agents and novel emergent pathogens. | Taxonomically diverse prokaryotic pathogens impacting health and survival of many wild and farmed seafood species. Include obligate pathogens and opportunistic agents causing disease in permissive scenarios. Translocation between farms, regions and nations reported. Potential for listing as notifiable diseases by WOAH (480). Single pathogen paradigms being augmented by studies on microbiomes/ pathobiomes, including AMR strains (481). Catastrophic production losses associated with early-life/grow-out phases and trade (in live animals/products where pathogen is listed). Some genera are considered zoonotic (482). If so, these will also be listed under HH. |
| | AH3: protistan pathogens | *Bonamia* spp., *Enterocytozoon* spp., *Paramoeba* spp., *Ichthyophthirius* spp., *Kudoa* spp., *Hematodinium* spp. and novel emergent pathogens. | Taxonomically diverse microbial eukaryotic organisms infecting tissue/organ/skin/blood systems of many wild and farmed seafood species. Epizootics reported in early-life and grow-out phases of production. Pathogens can drive mortality, cause product spoilage and affect trade. Lack of research on taxonomically obscure groups underlies frequent emergence of novel pathogens, even in |

| Hazard category | Hazard type | Example hazard | Source, interaction with oysters and potential for impact [a] |
|---|---|---|---|
| | | | commonly exploited hosts (483). Some have zoonotic potential for example, *Enterocytozoon* spp. – see hazard category HH2. |
| | AH4: metazoan pathogens | Platyhelminthes, cestodes, trematodes, nematodes, acanthocephalans and crustacean parasites. | Taxonomically diverse metazoan eukaryotic organisms infecting many wild and farmed seafood species. Crustacean parasites cause significant direct losses in grow-out and during grading/harvest phases for salmon (484). Platyhelminthes impact grow-out and trading of salmonids and are listed by WOAH owing to potential for impact on wild stocks (480).<br>Nematode, trematode and cestode infestations cause pathology in invertebrate and fish hosts. Pathology is usually limited but can cause marketing issues for products—some have zoonotic potential (covered under hazard category HH3). |
| | AH5: syndromes | Red mark syndrome, proliferative gill inflammation, white faeces syndrome, epizootic shell disease and various pathobiome disorders. | Syndromes are groupings of clinical signs associated with a particular health condition but for which specific aetiology has not been elucidated. Often associated with disorders in major organ systems, including skin, gills, carapace and gut. Emerging molecular diagnostic tools are augmenting pathology studies to identify cryptic pathogens or multi-agent dysbiosis (485). Development of syndromes may be driven by influence of wider stressors (including climate, feed quality, host genetics, exposure to chemicals and so on). Increased focus is required due to their impact on yield in numerous aquaculture sectors. |
| **Human pathogens (HH)** | HH1: environmental pathogens | Members of genus *Vibrio*, including *V. vulnificus*, *V. parahaemolyticus* and *V. cholerae*. | Autochthonous constituents of aquatic environments, often favouring warm/brackish conditions. Responsible for human illness associated with seafood contact and consumption, particularly of filter-feeding molluscs. Clinical manifestations range from mild-to-severe gastroenteritis to primary septicaemia and death (the latter from wounding following contact with contaminated shellfish) (83). *Vibrio* spp. are acknowledged as important sources of seafood- |

| Hazard category | Hazard type | Example hazard | Source, interaction with oysters and potential for impact [a] |
|---|---|---|---|
| | | | associated illness, but global surveillance is lacking. Climate change offers opportunities for further emergence and potential pandemic spread (83) (486). While main effects occur in the consumption phase, some taxa (for example, *V. parahaemolyticus*) are important aquatic animal pathogens affecting early-life and grow-out phases (see hazard category AH2). |
| | HH2: anthropogenically derived pathogens | Enteric viruses (norovirus, poliovirus and, hepatitis A and E), bacteria (for example, *Salmonella enterica*, *Escherichia coli* and *Campylobacter jejuni*) and parasites (for example, *Giardia*, *Cryptosporidium* and *Enterocytozoon* spp.). | Originating from human, animal or industrial sources that contaminate waterways via wastewater and run-off. Cause foodborne illness via consumption of seafood. Numerous viral, bacterial and parasite taxa detected in freshwater and marine seafood destined for human consumption (for example, *Salmonella*) (87). Contamination in harvest (including processing, handling and storage) via human-driven contamination. Foodborne pathogens impact trade and consumption phases, with bivalve molluscs being the most common source of consumer illness, particularly where products are eaten raw (487). Foodborne pathogens do not have a significant direct impact on the health of aquatic animals during production phases. |
| | HH3: zoonotic pathogens | *Anisakis* spp., *Paragonimus* spp., *Mycobacterium* spp., *Streptococcus agalactiae*, *Diphyllobothrium* spp. and AMR agents. | Aquatic animal pathogens able to be transmitted to cause infection in humans. Include direct infection by bacterial pathogens via contact/ consumption, parasites where humans act as reservoir, paratenic or definite hosts (for example, *Paragonimus*) (488) and AMR agents associated with seafood that may be transmitted to humans via contact/ consumption (for example, *Streptococcus*) (489). Zoonotic parasite transmission generally associated with consumption of raw/undercooked seafood, causing gastro-intestinal complications or more systemic infection. Aquatic zoonoses are probably under-reported, with the occurrence of |

| Hazard category | Hazard type | Example hazard | Source, interaction with oysters and potential for impact [a] |
|---|---|---|---|
| | | | emerging pathogens increasing as contact between aquatic animals and people increases. |

a) Information in this column is largely taken from the SRT article. Additional references have been included to ensure that the information relates to oysters as these are within the scope of this risk profile.

### 14.3 SRT schema and scoring method summary

The SRT uses a two-step semi-quantitative risk assessment schema to calculate impact. This is provided as a multiple of scores for severity of harm caused and likelihood of harm occurring. The application of the SRT requires the aquaculture scenario to be defined, including data on specific taxonomy, geography, seasonality, production method, product type, proposed market and intended end use of the products (1).

The SRT has been applied to a hypothetical aquaculture scenario intending to produce farmed bivalve molluscs in coastal waters of a non-EU marine state for live export and raw consumption within the EU. This was chosen by the authors of the SRT as it represents a scenario where multiple CH, AH and HH hazards are likely to interact with different supply chain phases, and where recognised control measures are available at different levels to mitigate hazard impact. Impact scores for hazard categories included within the SRT article, which interact with discrete phases of the seafood supply chain, were calculated as a multiple of “severity of harm” (part one) and “likelihood of occurrence” (part two) (1). Table 30 sets out the SRT schema.

Table 30: Adapted from: The Seafood Risk Tool (SRT) schema (1).

| **Score** | **Part one: Severity** | **Part two: Likelihood of occurrence** |
|---|---|---|
| 1 [Negligible] | Zero or negligible negative impact on the health or survival of animals in production, the ability to harvest, the effect on product or animals in processing, the trade of live animals or seafood products, or the health or survival of humans consuming products or animals | Negligible likelihood of occurrence of hazard resulting in harm*<br><br>*No empirical evidence |
| 2 [Very low] | Minimal and transitory negative impact on the health or survival of animals in production, the ability to harvest, the effect on product or animals in processing, the trade of live animals or seafood products, or the health or survival of humans consuming products or animals | Very low likelihood of occurrence of hazard resulting in harm*<br><br>*Isolated empirical cases |
| 3 [Low] | Low but noticeable, short-lived negative impact on the health or survival of animals in production, the ability to harvest, the effect on product or animals in processing, the trade of live animals or seafood products, or the health or survival of humans consuming products or animals | Low likelihood of occurrence of hazard resulting in harm*<br><br>*Low numbers of spatially and temporally discrete empirical cases |
| 4 [Medium] | Noticeable and moderately sustained negative impact on the health or survival of animals in production, the ability to harvest, the effect on product or animals in processing, the trade of live animals or seafood products, or the health or survival of humans consuming products or animals | Medium likelihood of occurrence of hazard resulting in harm*<br><br>*Numerous spatially and temporally separated empirical cases |
| 5 [High] | Very significant and long term or persistent negative impact on the health or survival of animals in production, the ability to harvest, the effect on product or animals in processing, the trade of live animals or seafood products, or the health or survival of humans consuming products or animals | High likelihood of occurrence of hazard resulting in harm*<br><br>*Many spatially and temporally |
| 6 [Very high] | Catastrophic impact on the health or survival of animals in production, the ability to harvest, the effect on product or animals in processing, the trade of live.<br>animals or seafood products, or the health or survival of humans consuming products or animals | Very high likelihood of occurrence of hazard resulting in harm*<br>*Extensive spatial and temporal empirical cases |

The method is fully described within the SRT article. However, in summary, the SRT scores were generated for each hazard category or subcategory, according to the framework. Impact and likelihood scores (with supporting evidence) for discrete hazard categories acting at specific phases in the supply chain for LBMs were provided by subgroup for each category to a coordinator. The coordinator (an expert in the scenario under consideration), working with representatives of each subgroup, then agreed a final score for each hazard (at each phase) on the basis of evidence presented, using a probabilistic approach. Subgroups were asked to assess three control states. The evidence used was a mixture of peer review, grey literature and expert opinion generated within subgroups (1).

Scores for part one (severity of harm) and part two (likelihood of occurrence) were calculated using the schema, and derived for six phases: early life, grow out, harvest, processing, trade and consumption. Part one and part two scores for each phase were provided for the three control states listed above: 1 (uncontrolled), 2 (controlled - hazards controlled at discrete stages but benefits not rolled into the next stage) and 3 (controlled - hazards controlled at discrete stages and benefits rolled on to the next stage). So, three part one and three part two scores were provided for each of the six phases (1).

The scores for part one and part two for each phase and control state were then combined via multiplication to give an overall impact score for each phase. Using the schema, the maximum score for part one or part two is six, therefore the maximum impact score for each phase and control state is 36, because of the multiplication step. The impact scores for each of the six phases under each control state were then summed to give an overall impact score for each control state. The maximum overall impact score for each control state for each phase is 216. I.e., there is a score for the uncontrolled state in which no controls are applied, control one where either standalone/non-accrued control measures are applied at discrete phases of supply and control two where the benefit of controls applied at one phase are accrued in subsequent phases of supply. Lower scores for score two than score one suggest that control is possible, lower scores for score three than score two suggest that benefits can be accrued and maintained throughout the supply chain (1).

## 14.4 NDNS and DNSIYC food codes used to estimate UK consumption

The following table includes the food codes from the NDNS (5) and DNSIYC (9) to estimate UK consumption data in section 9.1.1.

Table 31: NDNS and DNSIYC food codes used to estimate UK consumption in section 9.1.1 (5) (9)

| Food code | Food name |
|---|---|
| 8276 | OYSTERS SMOKED CANNED |
| 1571 | OYSTERS RAW |
| 1572 | OYSTERS RAW WEIGHED WITH SHELL |

## 14.5 Commodity codes used to extract UK HMRC import data

Table 32: Commodity codes (and their definitions) used to extract UK HMRC import data from the FSA Trade Visualisation Dashboard (414)

| Commodity code | Definition |
|---|---|
| 03071010 | Live flat oysters/ *Ostrea* spp. |
| 03071090 | Live, fresh, chilled, frozen, dried, salted or in brine |
| 03071110 | Live, fresh or chilled: Flat oysters (of the genus *Ostrea*), live and weighing (shell included) not more than 40g each |
| 03071190 | Live, fresh or chilled: Other |
| 03071200 | Frozen |
| 03071900 | Other: Smoked, whether in shell or not, whether or not cooked before or during the smoking process, not otherwise prepared and other |
| 03071910 | Smoked, even in shell, even cooked but not otherwise prepared |
| 03071990 | Frozen, dried, salted or in brine |
| 16055100 | Prepared or preserved |

## 14.6 Commodity codes used to extract global UN Comtrade data

To note, the commodity does for extracting UN Comtrade data differ to those in the UK HMRC database because the Comtrade database only allow the use of 6-digit codes. The same commodity groups are covered.

Table 33: Commodity codes (and their definitions) used to extract global import data from the UN Comtrade database (420)

| Commodity code | Definition |
|---|---|
| 030710 | Oysters, whether/ not in shell, live/ fresh/ chilled/ frozen/ dried/ salted/ in brine |
| 030711 | Molluscs; oysters, whether in shell or not, live, fresh or chilled |
| 030712 | Molluscs; oysters, whether in the shell or not, frozen |
| 030719 | Molluscs: oysters, whether in shell or not, dried, salted, or in brine, smoked, cooked or not before or during the smoking process |
| 160551 | Mollusc preparations: oysters, prepared or preserved. |

## 14.7 Proposed checklist for auditors

This section includes a checklist proposed for UK auditors using the information reviewed for this risk profile, particularly in section 7. This is not an exhaustive list of all points to be considered by UK auditors and is not intended to replace any current checklists or programs used by UK auditors. It is intended as an additional information point to aid the efficiency of auditing when considering oysters specifically. Auditors should also assess the difference between geographical locations for the risk of potential hazards associated with oysters.

Table 34 sets out the proposed checklist for use by UK auditors considering the risk mitigation and management options set out in section 7 which are considered to be essential and therefore it is proposed that auditors always check that these are in place, or that there is at least an alternative. This may be subject to expert opinion. These options include those set out in the FAO Technical Guidance for the Development of the Growing Areas Aspects of Bivalve Molluscs' Sanitation Programmes (490). This guidance is not specific to certain types of hazards, so some countries may have different considerations depending on the geographical location and hazards associated with this. Hence, there is a requirement for a growing area risk profile and growing area classification. It is, however, specific to LBMs, and in the case of this risk profile, oysters. Furthermore, options also include considerations of CODEX guidance set out in section 7 relating to hygiene, storage and processing.

Guidance used in section 7 is subject to change due to the potential for updates by FAO and CODEX. This should continue to be reviewed when considering international standards and recommendations for controls.

Table 34: Proposed checklist for auditors: risk mitigation and management options recommended as always in place in the country of interest.

| **Risk mitigation and management option** | **Details** |
|---|---|
| Growing area classification | Clear method of growing area classification as per international guidance (FAO). With clear definitions of growing area classes. |
| Growing area assessment | Related to classification. An initial assessment and risk profile should be carried out in order to classify and/ or implement control measures. A risk profile should include all potential risks associated with the growing area according to geographical location. This is of particular importance for certain growing areas within specific countries and the auditor should take note of these risks. Assessments should consider all types of hazards. |
| Growing area monitoring | Demonstration of monitoring of the growing area over a period of time with consideration of the risks identified in initial assessments. A monitoring plan should be in place. Monitoring should consider all relevant types of hazards. |
| Growing area management | Demonstration of the use of control measures to ensure the maintenance of the growing area with consideration of the risk identified in initial assessments and the classification assigned. There should be notification of any changes and further assessments performed if the area changes, particularly in a way which may constitute a change to its classification. |
| Growing area review | There should be an ongoing review plan in place to check the continued relevance of the initial growing area risk profile and assessments. |
| Control measures in place with relevance to growing area classification | This will depend on the growing area classification and associated assessments. There should be a control plan in place with relevance to the risks identified and proposed use of the product. For example, as set out in section 7.3.2, GB uses depuration for decontamination of oysters from Class B growing areas. Demonstration of similar control measures for specific growing area classifications and associated risks should be in place in countries of origin, or at least consideration of measures which may be required should the product be produced within certain conditions. |

# 15 References


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