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Integrating uncertainty into official control decisions: Bayesian risk-based decision support for the safe reopening of live bivalve mollusk harvesting areas

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Abstract

The safety of live bivalve mollusks (LBM) depends on complex interactions between pathogen ecology, environmental variability, and regulatory monitoring outcomes. Conventional compliance-based reopening decisions for classified harvesting areas often rely on limited sampling data and deterministic thresholds, without formally accounting for prior scientific evidence or uncertainty. This study proposes a Bayesian decision-support framework that integrates peer-reviewed evidence on pathogen occurrence, accumulation dynamics, and persistence in LBM into a probabilistic regulatory model for area classification and reopening decisions.

A structured literature review was conducted to identify quantitative evidence describing the prevalence and behavior of bacterial, viral, and protozoan hazards in bivalve mollusks, including *Escherichia coli*, *Salmonella* spp., norovirus, hepatitis A virus, and protozoan parasites. This evidence was translated into literature-informed prior distributions representing baseline contamination probability and environmental risk conditions. A conjugate Bayesian β-binomial model was applied to integrate official monitoring data with prior knowledge, generating posterior distributions of the probability that microbial contamination exceeds acceptable thresholds. Decision criteria were established according to precautionary regulatory tolerance levels, expressed as the posterior probability of unacceptable contamination.

Numerical case studies and Monte Carlo simulations demonstrated how the proposed framework supports transparent and risk-based regulatory decisions: scenarios included reopening under low residual risk, persistent closure under high posterior probability of exceedance and borderline situations requiring additional sampling. Integration of environmental evidence and pathogen-specific persistence (notably viral contamination with slow depuration dynamics) substantially influenced posterior risk estimates and decision outcomes. The results demonstrate that identical monitoring outcomes may lead to different regulatory decisions depending on prior ecological evidence and uncertainty quantification.

The proposed Bayesian decision framework integrating ecological evidence provides a scientifically robust and transparent tool for competent authorities managing LBM harvesting areas. By formally incorporating prior scientific knowledge, environmental indicators, and uncertainty, the framework operationalizes the precautionary principle while enabling adaptive, evidence-based reopening decisions consistent with European Union food safety legislation.

Introduction

Live bivalve mollusks (LBM) are a major component of aquaculture and fisheries production and represent a food commodity of considerable nutritional and economic value. Owing to their filter-feeding behavior and continuous interaction with surrounding waters, however, they can accumulate pathogenic microorganisms of veterinary and public health concern. The consumption of raw or lightly cooked shellfish is therefore recognized as a potential route of transmission for foodborne and zoonotic infections.

Within veterinary sciences, LBM occupy a unique regulatory position as both aquatic animals and foods of animal origin. This dual regulatory status places them at the interface between animal health, environmental surveillance, and public health protection and has led to the development of a specific regulatory framework aimed at preventing risks to consumers (EFSA BIOHAZ Panel, 2011). European Union (EU) legislation recognizes the intrinsic vulnerability of LBM to environmental contamination and establishes dedicated hygiene and official control provisions for products intended for human consumption (European Parliament and Council of the European Union, 2004).

Because LBM efficiently concentrate microbial contaminants present in their growing waters, EU legislation relies on a classification system for harvesting areas based primarily on *Escherichia coli* as an indicator of fecal contamination. Areas classified as Class A may allow direct harvesting for human consumption, provided that microbiological criteria are consistently met. This indicator-based approach reflects the strong epidemiological association between fecal contamination and the presence of enteric bacterial, viral and protozoan pathogens in shellfish (European Commission, 2021).

The regulatory framework governing LBM in the EU is based on three core principles: (i) primary responsibility of the food business operator; (ii) risk-based official controls performed by competent authorities; and (iii) preventive controls at the level of primary production. Preventive control at harvesting area level constitutes the cornerstone of food safety management for LBM, as end-product testing and post-harvest treatments cannot reliably eliminate all microbiological hazards. Consequently, EU legislation adopts an area-based risk management approach founded on environmental monitoring and classification of harvesting areas.

Commission Implementing Regulation (EU) 2019/627 (European Commission, 2019) establishes detailed rules for official controls on LBM, including provisions on the classification, closure and re-opening of harvesting areas (Articles 62-65). In particular, Article 63 specifies that an area may be re-opened only when the health standards set out in Regulation (EC) No 853/2004 (European Commission Parliament and Council, 2004) are again fulfilled and when the molluscs do not present any other risk to human health. Following a non-compliant result, harvesting must be suspended and should resume only once the competent authority has verified that the situation no longer poses a risk to consumers. This requirement extends beyond the parameter that triggered closure and necessitates a comprehensive evaluation of potential hazards.

Because absolute safety can never be demonstrated in food systems, the requirement that mollusks must not present any additional risk introduces an explicitly precautionary and risk-based dimension that goes beyond simple compliance with microbiological criteria. In practice, this condition cannot be demonstrated through a single analytical result but requires integration of multiple sources of information, including microbiological monitoring data, environmental investigations, epidemiological evidence and knowledge of pathogen ecology.

EU guidance documents for official controls on LBM (European Commission, 2021) provide general principles but do not specify a harmonized methodological framework for conducting this integrated risk assessment during the re-opening phase. As a result, competent authorities may apply different approaches, potentially leading to variability in re-opening decisions. A structured and transparent methodology capable of integrating heterogeneous evidence is therefore needed to support consistent and defensible decision-making.

Risk assessment during the re-opening phase must consider the results of the Sanitary Survey carried out following Article 56 of Regulation (EU) 2019/627, historical monitoring and epidemiological data and the biological characteristics of pathogens potentially transmitted through shellfish consumption (FAO and WHO, 2021). Particular attention is required for fecal-associated hazards—such as enteric viruses and protozoan parasites—which are not routinely monitored but are linked to contamination events, as well as for naturally occurring environmental pathogens such as *Vibrio* spp., whose occurrence is influenced by temperature, salinity and seasonal conditions (Codex Alimentarius, 2013).

Bayesian inference offers a coherent framework for integrating diverse evidence sources and explicitly representing uncertainty in regulatory decision-making (Bernardo and Smith, 1994). Sequential microbiological results, environmental observations and epidemiological information can be combined to estimate the probability that a harvesting area still poses a residual risk to consumers. Importantly, Article 63 does not require demonstration of zero risk, but rather evidence that any remaining risk is sufficiently low to be considered acceptable within the principles of food safety risk management.

In this context, the aim of the present article is to develop a structured probabilistic framework for consumer risk assessment during the re-opening of LBM harvesting areas following temporary closure and to clarify how heterogeneous sources of evidence can be integrated within a Bayesian decision-making approach consistent with Article 63 of Regulation (EU) 2019/627.

Materials and Methods

A preliminary regulatory analysis was conducted to define the decision context and the constraints imposed by EU legislation. Regulation (EC) No 853/2004 provides prescriptive microbiological criteria for area classification, whereas Regulation (EU) 2019/627 introduces a non-prescriptive, precautionary requirement regarding residual consumer risk. Within this context, the re-opening decision was modelled as a probabilistic inference problem, in which the Bayesian framework incorporates multiple sources of evidence commonly generated within official control systems, including:

- microbiological monitoring data (*e.g.*, *Escherichia coli* results) collected for harvesting area classification;
- sanitary survey data describing environmental contamination sources, hydrological characteristics and potential pollution events;
- historical surveillance and epidemiological data, including previous closures and foodborne outbreak notifications;
- peer-reviewed scientific literature describing pathogen occurrence, accumulation dynamics and persistence in LBM as summarized in Table 1 (Lees, 2000; Schets *et al.*, 2007; Martinez-Urtaza *et al.*, 2008; Maalouf *et al.*, 2011; EFSA BIOHAZ, 2011; EFSA BIOHAZ, 2012; Le Guyader *et al.*, 2012; Campos *et al.*, 2014; EFSA BIOHAZ, 2015; Baker-Austin *et al.*, 2018; FAO, 2021; Savini *et al.*, 2021; Desdouits *et al.*, 2023; Nemes *et al.*, 2023; EFSA BIOHAZ, 2024; Ekundayo & Ijabadeniyi, 2024; Feherenbach *et al.*, 2024; Kim *et al.*, 2024; Malham *et al.*, 2025; Pavlova *et al.*, 2025; Tene *et al.*, 2025; Okamoto, 2026).

The full conceptual figure linking available data to Bayesian decision model is shown in Figure 1.

Monitoring observations were assumed to be conditionally independent, unless explicit dependency structures were identified and incorporated into the model structure (Gelman *et al.*, 2014). Data were modelled using appropriate likelihood functions (*e.g.*, β-Binomial formulations), while prior distributions reflected historical data, scientific knowledge and precautionary assumptions consistent with regulatory practice (Spiegelhalter *et al.*, 2004).

Posterior distributions were obtained by updating prior beliefs with observed evidence, yielding probabilistic estimates of contamination and residual risk (Ranta *et al.*, 2015).

Decision metrics were formulated to support regulatory judgement, for example by evaluating whether the posterior probability of an unacceptable risk remained below a precautionary tolerance level defined by the competent authority.

Uncertainty arising from limited data, measurement error and model assumptions was explicitly represented within the Bayesian framework. Sensitivity analyses were conducted to assess the influence of prior distributions and key parameters on posterior risk estimates.

In line with the precautionary principle, conservative priors were applied where empirical data were scarce, ensuring that uncertainty was not interpreted as evidence of safety (Greenland, 2006).

Consumer risk during the re-opening phase was characterized through posterior probability distributions rather than deterministic point estimates. Key outputs of the model are:

- the posterior probability that contamination exceeds a defined threshold relevant to consumer protection;
- the probability of compliance with regulatory microbiological criteria conditional on re-opening;
- credible intervals (CIs) reflecting uncertainty and data limitations.

The Monte Carlo simulation, performed using R software version 4.4.0, was applied to confirm the posterior probability of exceedance under different scenarios (Johnson *et al.*, 2022) (Van der Voet *et al.*, 2007).

The analytical framework was designed to be transparent, reproducible and adaptable to different harvesting areas, pathogen profiles and data availability scenarios encountered in official control practice. The mathematical foundations and some examples are shown in *Supplementary Table 1.*

Results and Discussion

The preliminary regulatory analysis confirmed that re-opening of LBM harvesting areas under Article 63 of Regulation (EU) 2019/627 requires a documented demonstration that residual consumer risk is acceptably low, beyond simple compliance with microbiological classification criteria defined in Regulation (EC) No 853/2004.

Within this framework, the re-opening decision was successfully formalized as a probabilistic inference problem in which available evidence updates prior knowledge on the true probability of microbiological non-compliance or hazard presence (θ). The Bayesian framework, which integrated microbiological monitoring data, environmental Sanitary Survey information, historical surveillance data and scientific knowledge on pathogen ecology, produced posterior distributions that quantified residual uncertainty and consumer risk.

Application of the β-Binomial model allowed updating of prior information with observed monitoring data to obtain posterior distributions of θ. Overall, posterior estimates were strongly influenced by both observed non-compliant samples and the strength of prior information derived from historical and environmental data.

The Monte Carlo simulation, as shown in *Supplementary Table 2*, confirmed that posterior risk estimates were highly sensitive to both prior assumptions and observed exceedances.

In scenarios characterized by sustained compliance and favorable prior information, posterior means of θ decreased markedly compared with prior expectations. Conversely, when non-compliant results were observed or when prior evidence indicated persistent environmental contamination, posterior distributions remained centered at higher contamination probabilities, even when recent monitoring results were favorable.

Posterior uncertainty decreased progressively with increasing sample size, reflecting the accumulation of informative monitoring data. However, in situations with small sample sizes or conflicting evidence, posterior (CIs) remained wide, reflecting substantial residual uncertainty. This behavior ensured that uncertainty remained explicitly quantified rather than concealed by deterministic summaries.

The principal regulatory metric derived from the model was the posterior probability that contamination exceeded the tolerable threshold (θ^*). This probability represented the likelihood that LBM harvested from the harvesting area still posed an unacceptable consumer risk at the time of re-opening.

Across simulated datasets, three distinct decision profiles emerged:

- low residual risk scenarios: when monitoring results showed sustained compliance and prior information supported cessation of contamination sources, the posterior probability $P(\theta>\theta^*|x)$ declined rapidly. In these cases, values fell well below precautionary tolerance levels (τ), indicating that residual risk was compatible with re-opening. Posterior CIs were narrow and largely contained below the threshold, demonstrating robust evidence of recovery;
- intermediate uncertainty scenarios: where limited exceedances were observed or where sample size remained small, posterior probabilities of exceeding the threshold remained moderate. In these situations, $P(\theta>\theta^*|x)$ often exceeded precautionary tolerance values while not reaching levels clearly indicative of ongoing contamination. CIs frequently spanned the threshold, reflecting unresolved uncertainty. These conditions supported additional sampling and environmental investigation rather than immediate re-opening or continued closure;
- high residual risk scenarios: in the presence of repeated non-compliant results, recent contamination events, or environmental evidence of persistent hazards, posterior probabilities of exceeding θ^* remained high. In these scenarios, posterior distributions were centred well above the threshold and CIs did not overlap with values compatible with acceptable risk. The model therefore supported maintenance of closure.

These results demonstrated that re-opening decisions based solely on compliance with indicator criteria may underestimate residual consumer risk when contextual evidence indicates ongoing hazard persistence.

Incorporation of prior information derived from historical monitoring and environmental health surveys substantially influenced posterior risk estimates, particularly when recent sample sizes were limited. Conservative prior distributions prevented premature conclusions of safety in the presence of uncertainty and ensured alignment with the precautionary principle.

The hierarchical extension of the model enabled pooling information across harvesting areas or time periods. This structure reduced estimation variance for individual areas with limited data while preserving area-specific variability. As a result, posterior estimates for data-poor areas can be stabilized by information from comparable contexts without obscuring local differences.

Implementation of the Bayesian decision rule based on posterior risk probability and a predefined tolerance level τ provided a transparent mechanism for translating probabilistic outputs into regulatory outcomes (Gelman *et al.*, 2014).

When $P(\theta>\theta^*|x)\leq\tau$, re-opening decisions were supported by quantitative evidence indicating that residual consumer risk was sufficiently low. When the posterior probability exceeded τ, closure was maintained. Intermediate cases highlighted situations in which additional investigative samples or environmental investigation was required before a definitive decision could be justified.

This explicit mapping between posterior probabilities and regulatory actions ensured consistency with Article 63 requirements, allowing competent authorities to document re-opening decisions on the basis of structured quantitative risk assessment rather than fixed numerical criteria.

Sensitivity analyses demonstrated that posterior risk estimates were strongly influenced by sample size, observed exceedances, prior parameter specification, and the selected tolerable contamination threshold θ^*. Table 2 summarizes representative sensitivity-analysis scenarios.

Lower tolerable contamination thresholds produced substantially more precautionary posterior risk estimates, whereas larger sample sizes progressively reduced prior influence and stabilized posterior inference.

The analysis also confirmed that prior specification exerted its greatest influence when monitoring data were sparse or uncertainty remained elevated. Under larger sample sizes and sustained compliance, posterior estimates became increasingly dominated by observed monitoring results.

The decision tolerance τ affected the stringency of re-opening criteria but did not alter qualitative decision patterns across scenarios.

Overall, the Bayesian framework provided coherent and reproducible quantitative support for re-opening decisions. By explicitly representing uncertainty and integrating heterogeneous evidence, the model ensured that residual consumer risk was evaluated consistently with EU regulatory principles and the precautionary approach required under Article 63.

Conclusions

The present study demonstrates that the re-opening of LBM harvesting areas under Article 63 of Regulation (EU) 2019/627 can be coherently and transparently framed as a probabilistic risk inference problem. While Regulation (EC) No 853/2004 provides prescriptive microbiological criteria for area classification, Article 63 introduces a broader and precautionary requirement: the competent authority must ensure that molluscs do not present any additional risk to human health. This condition cannot be adequately addressed through deterministic thresholds or isolated analytical results alone and instead requires structured integration of heterogeneous evidence and explicit treatment of uncertainty. By formalizing the re-opening decision within a Bayesian framework, the approach developed in this study enables systematic updating of prior knowledge with new monitoring and environmental data, producing posterior estimates of contamination probability and residual consumer risk. The use of β-Binomial and hierarchical structures allows integration of routine microbiological results, Sanitary Survey findings, historical surveillance data and scientific knowledge on pathogen ecology into a unified analytical model. This framework reflects the operational reality of official control systems and aligns with the risk-based principles underpinning EU food law.

The results show that posterior probability distributions provide a more informative basis for regulatory judgement than simple compliance counts or fixed numerical rules. In particular, the probability that contamination exceeds a tolerable threshold offers a direct quantitative interpretation of the regulatory requirement that molluscs should not present an additional risk to human health. The explicit mapping of posterior risk probabilities to re-opening, continued closure, or additional data collection ensures that decisions remain consistent with the precautionary principle while avoiding unnecessary prolongation of closures where evidence supports recovery.

Importantly, the introduction of an intermediate uncertainty zone allowed the framework to formally incorporate additional investigative sampling into the regulatory process. This feature reflects the operational reality of official controls, in which re-opening decisions are frequently made under incomplete information and may require iterative evidence collection before definitive action can be justified.

The modelling approach also highlights the central role of uncertainty in re-opening decisions. Limited sample size, environmental variability and incomplete knowledge of contamination dynamics can substantially influence risk estimates. By explicitly representing uncertainty through posterior distributions and CIs, the Bayesian framework prevents unwarranted conclusions of safety based solely on limited data and supports proportionate, evidence-based regulatory action.

Sensitivity analyses further demonstrated that posterior estimates remained strongly influenced by prior assumptions under sparse-data conditions, reinforcing the importance of transparent prior specification and conservative precautionary assumptions. The worked examples presented in this study provide a reproducible operational framework for deriving priors from historical monitoring and environmental evidence.

Beyond its immediate regulatory application, the proposed framework is not intended to replace expert judgement or existing official-control procedures, but rather to provide a transparent quantitative structure supporting harmonized interpretation of heterogeneous evidence during the re-opening phase. The use of explicit probabilistic metrics and documented decision rules facilitates reproducibility, auditability and scientific justification of regulatory actions.

Moreover, the hierarchical extension of the model allows pooling information across harvesting areas and time periods, improving inference in data-limited contexts without obscuring local variability.

In conclusion, the integration of Bayesian inference into the regulatory evaluation of LBM harvesting areas provides a scientifically robust and operationally feasible method for assessing residual consumer risk under Article 63. By combining microbiological data, environmental evidence, historical knowledge and precautionary assumptions within a coherent quantitative framework, the approach supports consistent and transparent re-opening decisions while remaining adaptable to different epidemiological and environmental contexts encountered in official control practice.

Adoption of this framework within official-control systems could improve harmonization across jurisdictions, strengthen evidence-based risk management, and enhance transparency in re-opening decisions for LBM harvesting areas.

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Online supplementary material:
Supplementary Table 1. Mathematical foundations of Bayesian framework.
Supplementary Table 2. Monte Carlo simulation framework and reproducible R code.

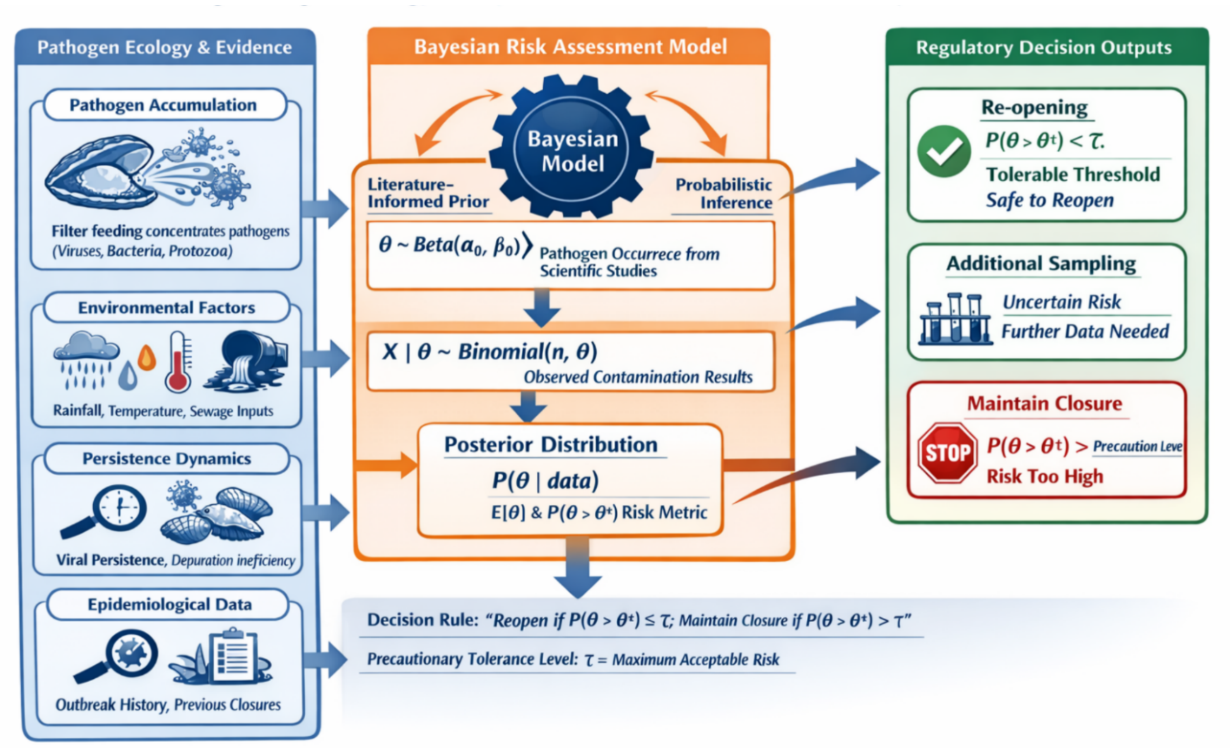

Figure 1. Bayesian decision model for the risk-based decision support (Figure generated by Chat GPT).

Table 1. Basic peer-reviewed literature on microbial pathogen occurrence, accumulation and persistence in live bivalve mollusks.

Pathogen group	**Key references (peer-reviewed)**	**Occurrence in live bivalve mollusks**	**Accumulation dynamics**	**Persistence/depuration behavior**	**Regulatory and risk relevance**
Norovirus (NoV GI/GII)	(Lees, 2000); (EFSA BIOHAZ, 2012, 2015); (Le Guyader *et al.* 2012); (Campos *et al.,* 2014); (Maalouf *et al.*, 2011); (Savini *et al.*, 2021)	Most frequently reported viral hazard in oysters, mussels and clams; detected in both classified and approved harvesting areas	Rapid bioaccumulation through filter feeding; selective binding to digestive tissues and carbohydrate ligands enhances retention	Very persistent; depuration inefficient; may persist for weeks in digestive gland; seasonality (winter peaks) common	Principal cause of shellfish-borne outbreaks in EU; central to risk-based classification and monitoring
Hepatitis A virus (HAV)	(Feherenbach *et al.*, 2024); (Nemes *et al.*, 2023); (EFSA BIOHAZ, 2011)	Less frequent than norovirus but associated with severe outbreaks; detected in oysters and clams	Accumulates similarly to NoV via fecal contamination; high stability in marine environment	Highly resistant to environmental degradation and depuration; prolonged persistence in tissues	Severe public-health impact despite low prevalence → precautionary monitoring and closure criteria
Hepatitis E virus (HEV)	(Okamoto, 2026); (Pavlova *et al.,* 2025); (Tene *et al.*, 2025); (Nemes *et al.*, 2023)	Less frequent than HAV and rarely associated with outbreaks; detected in oysters mussels and clams	Accumulates similarly to HAV via faecal contamination; stable in marine environment	Persist in shellfish and marine environments for weeks to months	No high public-health impact despite sometimes high prevalence
Other enteric viruses (sapovirus, Aichi virus, astrovirus)	(Desdouits et al., 2023); (Feherenbach *et al.*, 2024) (Ekundayo & Ijabadeniyi, 2024)	Frequently detected by molecular methods; often co-occurring with norovirus	Accumulated through filtration of contaminated waters; indicator of sewage contamination	Persistence similar to NoV; depuration generally ineffective	Support use of viral monitoring and environmental indicators in risk-based classification
***Vibrio* spp. (*V. parahaemolyticus, V. vulnificus*)**	EFSA BIOHAZ (2024); (Baker-Austin *et al.,* 2018)	Naturally occurring marine bacteria; prevalence increases with temperature and salinity changes	Active multiplication possible within shellfish tissues; uptake from surrounding water and sediments	Can persist and multiply post-harvest if temperature abused; not removed by depuration effectively	Climate-sensitive hazard; important in warm seasons; risk-based monitoring recommended
***Salmonella* spp.**	(Desdouits et al., 2023; (Simental & Martinez-Urtaza, 2008)	Occasional detection linked to faecal contamination and runoff events	Accumulation proportional to environmental contamination; associated with sewage and river inputs	Can persist for days–weeks; partially removed by depuration but not always eliminated	Indicator of faecal contamination; used in EU microbiological criteria
***E. coli* (indicator organism)**	(FAO, 2021); (Malham *et al.*, 2025)	Widely used indicator of faecal contamination in classification systems	Rapid uptake during filtration; concentration reflects environmental levels	Depuration effective but variable; does not correlate reliably with viral presence	Basis of EU harvesting area classification but limited predictive value for viral risk
Protozoa (*Cryptosporidium, Giardia*)	(Schets *et al.*, 2007); (Kim *et al.*, 2024)	Detected in oysters, mussels and clams in contaminated waters	Oocysts and cysts accumulate via filtration; association with particulate matter	Can persist in shellfish tissues; depuration partially effective	Emerging hazard; supports inclusion in comprehensive risk assessments

Table 2. Summary of representative sensitivity-analysis scenarios.

Prior distribution	Threshold (θ^*)	Observed data (x/n)	Posterior risk $P(\theta>\theta^*\|x)$	Regulatory interpretation
$\beta(2, 58)$	0.10	0/40	0.008	Re-opening supported
$\beta(4, 72)$	0.10	1/30	0.067	Additional sampling
$\beta(10, 60)$	0.10	2/30	0.24	Maintain closure
$\beta(12, 56)$	0.10	1/25	0.31	Maintain closure
$\beta(4, 72)$	0.05	1/30	0.41	Maintain closure
$\beta(4, 72)$	0.15	1/30	0.02	Re-opening supported